AVANIR PHARMACEUTICALS
Form 10-Q
February 08, 2008

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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, 2007

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 periods 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 þ Smaller Reporting Comapny o
(Do not check if a smaller reporting company)

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

As of February 1, 2008, the registrant had 43,198,487 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, 2007 (unaudited)	September 30, 2007
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 28,315,460	$ 30,487,962
Short-term investments in marketable securities	249,832	1,747,761
Receivables, net	1,838,270	988,450
Inventories	17,000	17,000
Prepaid expenses	787,839	1,479,992
Current portion of restricted investments in marketable securities	388,122	688,122
Total current assets	31,596,523	35,409,287
Investments in marketable securities		249,078
Restricted investments in marketable securities, net of current portion	468,475	468,475
Property and equipment, net	1,115,582	1,215,666
Intangible assets, net	21,005	41,048
Long-term inventories	1,331,787	1,337,991
Other assets	372,937	374,348
TOTAL ASSETS	$ 34,906,309	$ 39,095,893
LIABILITIES AND SHAREHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 1,136,260	$ 307,700
Accrued expenses and other liabilities	2,630,570	2,050,864
Accrued compensation and payroll taxes	659,972	1,191,677
Current portion of deferred revenues	2,357,615	2,267,594
Current portion of notes payable	183,278	254,676
Current liabilities of discontinued operations	1,073,695	
Total current liabilities	8,041,390	6,072,511
Accrued expenses and other liabilities, net of current portion	1,092,736	1,170,396
Deferred revenues, net of current portion	12,046,536	13,052,836
Notes payable, net of current portion	11,783,395	11,769,916
Total liabilities	32,964,057	32,065,659
COMMITMENTS AND CONTINGENCIES (NOTE 12)		
SHAREHOLDERS EQUITY:		

Preferred stock no par value, 10,000,000 shares authorized, no shares issued or outstanding as of December 31, 2007 and September 30, 2007		
Common stock no par value, 200,000,000 shares authorized; 43,164,402 and 43,117,358 shares issued and outstanding as of December 31, 2007 and September 30, 2007, respectively	245,958,529	245,531,712
Accumulated deficit	(244,017,367)	(238,498,733)
Accumulated other comprehensive income (loss)	1,090	(2,745)
Total shareholders equity	1,942,252	7,030,234
TOTAL LIABILITIES AND SHAREHOLDERS EQUITY	$ 34,906,309	$ 39,095,893

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,	
	2007	**2006**
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		
Revenues from research and development services		1,270,244
Revenues from government research grant services	167,647	86,348
Revenues from license agreements	57,265	57,265
Revenue from royalties and royalty rights	1,837,853	723,040
Revenues from research services and other	2,062,765	2,136,897
Cost of research and development services	(49,991)	(1,164,075)
Cost of government research grant services	(125,587)	(95,727)
Research services and other gross margin	1,887,187	877,095
Total gross margin	1,916,983	877,095
OPERATING EXPENSES		
Research and development	3,426,259	5,197,253
Selling, general and administrative	3,128,120	9,369,862
Total operating expenses	6,554,379	14,567,115
Loss from operations	(4,637,396)	(13,690,020)
OTHER INCOME (EXPENSES)		
Interest income	427,162	191,476
Interest expense	(234,001)	(418,095)
Other (expense) income	(704)	145,345
Loss from continuing operations before provision for income taxes	(4,444,939)	(13,771,294)
Provision for income taxes		
Loss before discontinued operations	(4,444,939)	(13,771,294)

(Loss) income from discontinued operations	(1,073,695)	153,767
Net Loss	$ (5,518,634)	$ (13,617,527)
BASIC AND DILUTED NET (LOSS) INCOME PER SHARE:		
Loss from continuing operations	$ (0.10)	$ (0.40)
(Loss) income from discontinued operations	(0.03)	0.01
Net Loss per share	$ (0.13)	$ (0.39)
Basic and diluted weighted average number of common shares outstanding	43,106,369	34,626,117

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,	
	2007	2006
PERATING ACTIVITIES:		
t Loss	$ (5,518,634)	$ (13,617,52
ss (income) from discontinued operations	1,073,695	(153,76
justments to reconcile loss before discontinued operations to net cash used in operating activities:		
preciation and amortization	137,480	658,37
are-based compensation expense	443,909	844,51
ortization of debt discount	34,917	61,00
ss on disposal of assets	3,464	
anges in operating assets and liabilities (net of effects of acquisition/disposition of FazaClo):		
ceivables	(849,820)	664,70
ventories	6,204	(1,071,25
epaid and other assets	686,552	63,40
counts payable	828,560	(7,813,24
crued expenses and other liabilities	502,047	(265,66
crued compensation and payroll taxes	(531,705)	(1,015,23
ferred revenue	(916,279)	(821,82
t cash used in operating activities of continuing operations	(4,099,610)	(22,466,51
t cash provided by operating activities of discontinued operations		3,364,62
t cash used in operating activities	(4,099,610)	(19,101,88
VESTING ACTIVITIES:		
vestments in securities		(50,44
oceeds from sales and maturities of investments in securities	2,050,841	16,900,00
rchase of property and equipment	(13,804)	(86,19
t cash provided by investing activities of continuing operations	2,037,037	16,763,36
t cash provided by investing activities	2,037,037	16,763,36
NANCING ACTIVITIES:		
oceeds from issuances of common stock and warrants, net of commissions and offering costs		14,992,97
x withholding payments reimbursed by restricted stock	(17,092)	
yments on notes and capital lease obligations	(92,837)	(3,039,22
t cash (used in) provided by financing activities of continuing operations	(109,929)	11,953,75
t cash used in financing activities of discontinued operations		(56,17
t cash (used in) provided by financing activities	(109,929)	11,897,57

t (decrease) increase in cash and cash equivalents	(2,172,502)	9,559,06
sh and cash equivalents at beginning of period	30,487,962	4,898,21
sh and cash equivalents at ending of period	$ 28,315,460	$ 14,457,27
PPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
erest paid	$ 199,084	$ 542,02
come taxes paid	$ 15,050	$
PPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
ck subscription receivable	$	$ 238,36
rchase price adjustment of assumed liabilities	$	$ 3,067,88
crued 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 10-01 of Regulation S-X. These condensed statements do not include all disclosures required by accounting principles generally accepted in the United States of America (U.S. GAAP) for annual audited financial statements 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, 2007. We believe 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.

On August 3, 2007, the Company sold its rights to the FazaClo® product and the related assets and operations. The sale was made pursuant to an agreement entered into with Azur Pharma, Inc. (Azur) in July 2007. In connection with the sale, the Company transferred certain assets and liabilities related to FazaClo to Azur. The accompanying unaudited condensed consolidated financial statements of Avanir Pharmaceuticals include adjustments to reflect the classification of our FazaClo business as discontinued operations. See Note 3 in the Notes to our Condensed Consolidated Financial Statements for information on discontinued operations.

2. NATURE OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Nature of Business

Avanir Pharmaceuticals is a pharmaceutical company focused on acquiring, developing and commercializing novel therapeutic products for the treatment of chronic diseases. Our product candidates address therapeutic markets that include the central nervous system, inflammatory diseases and infectious diseases. Our 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). 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 and our infectious disease program, which is focused primarily on anthrax antibodies, is currently being funded by grants from the National Institute of Health/National Institute of Allergy and Infectious Disease (NIH/NIAID).

Our 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. Our ability to generate revenues in the future will depend on 1) license arrangements, 2) the timing and success of reaching development milestones, 3) obtaining regulatory approvals and 4) ultimately attaining market acceptance of Zenvia (formerly referred to as Neurodex) for the treatment of PBA, assuming the FDA approves our new drug application. Our operating expenses depend substantially on the level of expenditures for clinical development activities for Zenvia for the treatment of PBA and DPN pain, and program funding authorized by our research grant and the rate of progress being made on such programs.

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Income Taxes

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 SFAS 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 position will not be recognized if it has less than a 50% likelihood of being sustained. Additionally, FIN No. 48 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. FIN No. 48 is effective for fiscal years beginning after December 15, 2006.

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. As a result of the implementation of FIN No. 48, the Company recognized a $2.6 million decrease in deferred tax assets and a corresponding decrease in the valuation allowance. There are no unrecognized tax benefits included in the balance sheet that would, if recognized, affect the effective tax rate.

The Company s practice 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 Balance Sheets at September 30, 2007 and at December 31, 2007, and has recognized $0 in interest and/or penalties in the Statement of Operations for the three months ended December 31, 2007.

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.

Revenue Recognition

The Company generates revenues from product sales, collaborative research and development arrangements, and other activities 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.

We recognize revenue in accordance with the SEC s Staff Accounting Bulletin 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) collectibility 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), we recognize such product revenues at the time of sale only if we have 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. We recognize such product revenues when either we have met all the criteria of FAS 48, including that ability to reasonably estimate future returns, when we can reasonably estimate that the return privilege has substantially expired, or when the return privilege has substantially expired, whichever occurs first.

We allocate 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 our control. We use the relative fair values of the separate deliverables to allocate revenue. For arrangements with multiple elements that are separated, we recognize revenues in accordance with Topic 13. 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) collectibility is reasonably assured. Certain sales transactions include multiple deliverables.

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Product Sales

Active Pharmaceutical Ingredient Docosanol (API Docosanol). Revenue from sales of our 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. We sell the API Docosanol to various licensees upon receipt of a written order for the materials. Shipments generally occur fewer than five times a year. Our contracts for sales of the API Docosanol include buyer acceptance provisions that give our buyers the right of replacement if the delivered product does not meet specified criteria. That right requires that they give us notice within 30 days after receipt of the product. We have the option to refund or replace any such defective materials; however, we have 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 our shipments from the same pre-inspected lot to date. Therefore, we recognize revenue at the time of delivery without providing any returns reserve.

FazaClo. (Sales from Discontinued Operations). In August 2007, we sold FazaClo to Azur and as a result, all revenues, cost of revenues, and operating expenses related to FazaClo for fiscal 2007 have been classified as discontinued operations in the accompanying condensed consolidated financial statements (See Note 3 Acquisition of Alamo Pharmaceuticals, Inc. / Sale of FazaClo).

As discussed in Note 3, Acquisition of Alamo Pharmaceuticals, Inc. / Sale of FazaClo , we acquired Alamo Pharmaceuticals LLC (Alamo) on May 24, 2006, with one marketed product, FazaClo (clozapine, USP), that began shipping to wholesale customers in July 2004 in 48-pill boxes. At that time, FazaClo had a two-year shelf life. In June 2005, Alamo received FDA approval to extend the product expiration date to three years. In October 2005, Alamo began shipping 96-pill boxes and accepted returns of unsold or undispensed 48-pill boxes.

During fiscal 2007, we sold FazaClo to pharmaceutical wholesalers. They resold our product to outlets such as pharmacies, hospitals and other dispensing organizations. We had agreements with our wholesale customers, various states, hospitals, certain other medical institutions and third-party payers throughout the U.S. These agreements frequently contained commercial incentives, which may have included pricing allowances and discounts payable at the time the product was sold to the dispensing outlet or upon dispensing the product to patients. Consistent with pharmaceutical industry practice, wholesale customers can return purchased product during an 18-month period that begins six months prior to the product s expiration date and ends 12 months after the expiration date. Additionally, several of our dispensing outlets have the right to return expired product at any time. Once products have been dispensed to patients the right of return expires. However, upon the sale of the FazaClo assets, Azur assumed all future liabilities for returns and allowances related to the FazaClo sales that were made by the Company. Therefore, as of the date of the sale of the FazaClo assets, we no longer had responsibility for returns and allowances related to our sales of FazaClo.

Beginning in the first quarter of fiscal 2007, we obtained third-party information regarding certain wholesaler inventory levels, a sample of outlet inventory levels and third-party market research data regarding FazaClo sales. The third-party data included, (i) IMS Health Audit - National Sales Perspective reports (NSP), which is a projection of near-census data of wholesaler shipments of product to all outlet types, including retail and non-retail and; (ii) IMS Health National Prescription Audit (NPA) Syndicated data, which captures end-user consumption from retail dispensed prescriptions based upon projected data from pharmacies estimated to represent approximately 60% to 70% of the U.S. prescription universe. Further, we analyzed historical rebates and chargebacks earned by State Medicaid, Medicare Part D and managed care customers. Based upon this additional information and analysis obtained, we estimated the amount of product that was shipped that was no longer in the wholesale or outlet channels, and hence no longer subject to a right of return. Therefore, we began recognizing revenues, net of returns, chargebacks, rebates, and discounts, in the first quarter of fiscal 2007, for product that we estimated had been sold to patients and that was no longer subject to a right of return.

FazaClo product revenues were recorded net of provisions for estimated product pricing allowances including: State Medicaid base and supplemental rebates, Medicare Part D discounts, managed care contract discounts and prompt payment discounts were at an aggregate rate of approximately 25.8% of gross revenues for the fiscal year ended September 30, 2007. Provisions for these allowances were estimated based upon contractual terms and require management to make estimates regarding customer mix to reach. We considered our current contractual rates with

States related to Medicaid base and supplemental rebates, with private organizations for Medicare Part D discounts and contracts with managed care organizations.

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Multiple Element Arrangements.
We have arrangements whereby we deliver 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, we analyze our multiple element arrangements to determine whether the elements can be separated. We perform our 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, we allocate amounts based upon the relative fair values of each element. We determine the fair value of a separate deliverable using the price we charge other customers when we sell that product or service separately; however if we do not sell the product or service separately, we use third-party evidence of fair value. We consider licensed rights or technology to have standalone value to our customers if we or others have sold such rights or technology separately or our customers can sell such rights or technology separately without the need for our 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 and future product royalty payments. These arrangements are often multiple element arrangements.
Non-refundable, up-front fees that are not contingent on any future performance by us, and require no consequential continuing involvement on our 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. We defer recognition of non-refundable upfront fees if we have 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 our performance under the other elements of the arrangement. In addition, if we have required continuing involvement through research and development services that are related to our proprietary know-how and expertise of the delivered technology, or can only be performed by us, then such up-front fees are deferred and recognized over the period of continuing involvement.
Payments related to substantive, performance-based milestones in a research and development arrangement are recognized as revenues upon the achievement of the milestones as specified in the underlying agreements when they represent the culmination of the earnings process.
Research Services Arrangements. Revenues from research services are recognized during the period in which the services are performed and are based upon the number of full-time-equivalent personnel working on the specific project at the agreed-upon rate. Reimbursements from collaborative partners for agreed upon direct costs including direct materials and outsourced services, or subcontracted, pre-clinical studies are classified as revenues 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. We recognize 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.
When we sell our rights to future royalties under license agreements and also maintain continuing involvement in earning such royalties, we defer recognition of any upfront payments and recognize them as revenues over the life of the license agreement. We recognize revenues for the sale of an undivided interest of our 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

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royalties that is expected GlaxoSmithKline will pay Drug Royalty USA over the remaining term of the agreement by the unamortized deferred revenues.

Government Research Grant Revenues. We recognize 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. Amortization of acquired FazaClo product rights is classified within cost of revenues under discontinued operations.

Recognition of Expenses in Outsourced Contracts

Pursuant to management s assessment of the services that have been performed on clinical trials and other contracts, we recognize 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 our contracts extend across multiple reporting periods, including our 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 our estimate of the work completed in our largest contract could increase or decrease our quarterly operating expenses by approximately $213,000.

Capitalization and Valuation of Long-Lived and Intangible Assets

In accordance with Statement of Financial Accounting Standards No. 141, *Business Combinations* (FAS 141) and Statement of Financial Accounting Standards No. 142, *Goodwill and Other Intangible Assets* (FAS 142), goodwill and intangible assets acquired in a purchase business combination and determined to have an indefinite useful life are not amortized, but instead are tested for impairment on an annual basis or more frequently if certain indicators arise. Goodwill represents the excess of purchase price of an acquired business over the fair value of the underlying net tangible and intangible assets. The Company had no goodwill as of December 31, 2007 as a result of the sale of FazaClo. (See Note 3 Acquisition of Alamo Pharmaceuticals, Inc. / Sale of FazaClo) There was no impairment of goodwill for the three month period ended December 31, 2006.

Intangible assets with finite useful lives are amortized over their respective useful lives and reviewed for impairment in accordance with Statement of Financial Accounting Standards No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* (FAS 144 .) The method of amortization shall reflect the pattern in which the economic benefits of the intangible asset are consumed or otherwise used up. If that pattern cannot be reliably determined, a straight-line amortization method will be used. Identifiable intangible assets acquired with the May 2006 purchase of Alamo represent expected benefits of the FazaClo product rights, customer relationships, trade name and non-compete agreement. These acquired intangible assets were disposed of in fiscal 2007 with the sale of FazaClo to Azur. As of December 31, 2007, intangible assets with finite useful lives are comprised of trade names which are not amortized.

In accordance with FAS 144, intangible assets and other long-lived assets, except for goodwill, are evaluated for impairment whenever events or changes in circumstances indicate that their carrying value may not be recoverable. If the review indicates that intangible assets or long-lived assets are not recoverable (i.e. the carrying amount is less than the future projected undiscounted cash flows), their carrying amount would be reduced to fair value. Factors we consider important that could trigger an impairment review include the following:

A significant underperformance relative to expected historical or projected future operating results;

A significant change in the manner of our use of the acquired asset or the strategy for our overall business; and/or

A significant negative industry or economic trend.

Legal expenses for patent related costs are expensed as incurred and classified as research and development expenses in our condensed consolidated statements of operations.

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Share-Based Compensation

The Company accounts for awards of share-based compensation to employees under the fair value method required by Statement of Financial Accounting Standards No. 123 (revised 2004), Share-Based Payment (FAS 123R). The fair value of each award of share-based compensation is measured at the date of grant. Share-based compensation awards generally vest over time, subject to continued service to the Company and/or the satisfaction of certain performance conditions. The Company recognizes the estimated fair value of employee stock options over the service period using the straight-line method.

Share-based compensation expense recognized in the condensed consolidated statements of operations is based on awards ultimately expected to vest, 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 forfeiture rates differ from those estimates. The estimation of the number of stock awards that will ultimately be forfeited requires judgment, and to the extent actual results or updated estimates differ from the Company s current estimates, such amounts will be recorded as a cumulative adjustment in the period in which estimates are revised. The Company considers many factors when estimating expected forfeitures, including types of awards, employee class and historical experience. During the second quarter of fiscal 2007, the Company updated its projected forfeiture rates as it applies to stock-based compensation considering recent actual data following the implementation of various restructuring initiatives earlier that year. Pre-vesting forfeiture rates for the three month periods ended December 31, 2007 and 2006 were estimated to be 30% and 4%, respectively, for all employees, officers and directors. Such estimates have been based on our historical experience. Future estimates, may differ substantially from the Company s current estimates.

Total compensation expense related to all of our share-based awards, recognized under FAS 123R, for the three month periods ended December 31, 2007 and 2006 was classified as cost of research, selling general and administrative expenses and research and development expenses and was comprised of the following:

	For the three months ended December 31,	
	2007	**2006**
From Continuing Operations:		
Selling, general and administrative expense	$ 289,364	$ 708,605
Research and development expense	146,289	122,807
Share-based compensation expense related to continuing operations	435,653	831,412
From Discontinued Operations:	8,256	13,105
Total	$ 443,909	$ 844,517

	For the three months ended December 31,	
	2007	**2006**
Share-based compensation expense from:		
Stock options	$ 214,124	$ 414,847
Restricted stock units	217,670	13,265
Restricted stock awards	12,115	416,405
Total	$ 443,909	$ 844,517

Since we have a net operating loss carryforward as of December 31, 2007, 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, 2007 and 2006 that would have resulted in a reclassification to reduce net cash provided by operating activities with an offsetting increase in net cash provided by financing activities. (See Note 11 Employee Equity Incentive Plans.)

Recently Issued Accounting Pronouncements

Financial Accounting Standards No. 157 (FAS 157). In September 2006, the FASB issued FAS 157, *Fair Value Measurements*. FAS 157 defines fair value, established a framework for measuring fair value in generally accepted accounting principles (GAAP) and expands disclosures about fair value measurements. FAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007. In December 2007, the FASB released a proposed FASB Staff Position (FSP FAS 157-b- Effective Date of FASB Statement No. 157) which, if adopted as proposed, would delay the effective date of SFAS No. 157 for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis

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(at least annually). We do not expect the adoption of FAS 157 to significantly affect 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 date. FAS 159 is effective for fiscal years beginning after November 15, 2007. The Company is evaluating the options provided under FAS 159 and their potential impact on its financial condition and results of operations if implemented. We do not expect the adoption of FAS 159 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. The Company is evaluating the options provided under FAS 141R and their potential impact on its financial condition and results of operations if implemented. We do not expect the adoption of FAS 141R to significantly affect our consolidated financial condition or 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. The Company is evaluating the options provided under FAS 160 and their potential impact on its financial condition and results of operations if implemented. We do not expect the adoption of FAS 160 to significantly affect our consolidated financial condition or results of operations.

3. ACQUISITION OF ALAMO PHARMACEUTICALS, INC. / 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) for approximately $29.2 million in consideration, consisting of approximately $4.0 million in cash, promissory notes with an aggregate face value of $25.1 million and an estimated fair value of $24.3 million, and $912,000 in acquisition-related transaction costs. The purchase price exceeded the net assets acquired resulting in the recognition of $22.1 million of goodwill. The results of operations of Alamo were included in our consolidated financial statements from the date of acquisition until our sale of the Alamo assets in fiscal 2007, at which time the Alamo-related results of operations have been reflected as discontinued operations. 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 FDA approvable letter and resulting delay in the planned launch of Zenvia, we entered into an agreement to sell FazaClo in July 2007. Details of the sale of FazaClo are described below.

In connection with the Alamo acquisition, we also agreed to pay the Selling Holders up to an additional $39,450,000 in revenue-based earn-out payments, based on future sales of FazaClo (clozapine USP), an orally disintegrating drug for the treatment of refractory schizophrenia. On May 15, 2007, we issued an additional $2,000,000 promissory note based on FazaClo sales rates through that quarter and on August 15, 2007, we issued a second promissory note, also in the principal amount of $2,000,000. The remaining earn-out payments of $35,450,000 are based on the achievement of certain target levels of FazaClo sales in the U.S. from the closing date of the acquisition through December 31, 2018. In connection with the FazaClo sale, Azur assumed these remaining contingent payment obligations, however, we are still contingently liable in the event of default by Azur.

We also previously agreed to pay the Selling Holders one-half of all net licensing revenues that we may receive through December 31, 2018 from licenses of FazaClo outside of the U.S., if any (Non-US Licensing Revenues). There were no Non-US Licensing Revenues through August 3, 2007, the date of sale of FazaClo, and these future obligations have been assumed by Azur as described below. We also agreed to apply 20% of any future net equity

offering proceeds to repay the promissory notes and through December 31, 2007, we have paid approximately $6.1 million of the principal amounts due under the notes. In August 2007, we paid an additional $11.0 million of outstanding principal and interest under these notes and amended our agreement with the Selling Holders to partially suspend the early payment obligations remaining under the promissory notes.

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In the first quarter of fiscal 2007, we recognized a reduction of $3.1 million to the purchase price of Alamo as a result of a reduction in the estimated amount of certain assumed liabilities acquired, and thereby reduced the carrying value of goodwill. Additionally, cumulatively, through the sale of FazaClo in August 2007, the purchase price of Alamo was increased by a net of approximately $20,000, as a result of the issuance of additional notes payable issued in fiscal 2007 totaling $4.0 as additional consideration (see above), less cumulative reductions of $3.98 million to the assumed liabilities.

Sale of FazaClo, Presentation of Discontinued Operations, and Contingency for Working Capital Adjustment

In August 2007, we sold FazaClo and our related assets and operations to Azur. In connection with the sale, we received approximately $43.9 million in upfront consideration and have the right to receive up to an additional $10.0 million in contingent payments in 2009, subject to the satisfaction of certain regulatory conditions. In addition, we could receive up to $2.0 million in royalties, based on 3% of annualized net product revenues in excess of $17.0 million. Our 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.

The Asset Purchase Agreement (the Agreement) with Azur provides for an adjustment to the sale price of FazaClo in connection with the final determination of the amount of working capital (as defined in the agreement) included as part of the sale (Working Capital Adjustment). The Agreement also stipulates that an adjustment to working capital shall only exist if the final Working Capital Adjustment is greater than $250,000. As of September 30, 2007, based on the knowledge and information that we had at the time, we estimated that the Working Capital Adjustment was less than the $250,000 threshold. However, based upon current information, we have estimated the Working Capital Adjustment to result in a $868,000 reduction in the sale price. In accordance with FAS 154 Accounting for Changes and Error Corrections the Working Capital Adjustment is considered a change in estimate and represents new information that was not available as of September 30, 2007. As a result, we have accrued a liability for the adjustment and it is reflected in current liabilities of discontinued operations and loss from discontinued operations in the quarter ended December 31, 2007. The current period effect on net loss per share for the Working Capital Adjustment is $.02.

We have not yet reached agreement with Azur on the amount of the Working Capital Adjustment, and further, Azur has made claims that the Working Capital Adjustment should reduce the sale price by $2.0 million, which is approximately $1.1 million more than the amount that we have accrued. Under the terms of the Agreement, Azur has until February 14, 2008 to accept our estimate. If Azur does not accept our estimate, a US accounting firm of national reputation will be retained to resolve the dispute. We believe we have adequately provided for the loss related to the Working Capital Adjustment in accordance with Statement of Financial Accounting Standards No. 5, *Accounting for Contingencies* ; however, there can be assurance as to ultimate settlement of the amount. If the final determination of the Working Capital Adjustment exceeds our accrual of $868,000, the amount in excess of $868,000 will be recognized as a loss on discontinued operations in that period.

In addition to the accrued loss on the Working Capital Adjustment of $868,000, we recognized an additional $206,000 of other costs related to the operations of FazaClo during the quarter ended December 31, 2007, which, we initially believed were assumed by Azur.

A summarized statement of operations for the discontinued operations for the three months ended December 31, 2006 is as follows:

	For the three months ended December 31, 2006
REVENUES FROM PRODUCT SALES	

Net revenues	$	6,270,704
Cost of revenues		1,347,184
Product gross margin		4,923,520
OPERATING EXPENSES		
Research and development		708,748
Selling, general and administrative		3,876,072
Income from operations		338,700
OTHER INCOME (EXPENSE)		
Interest expense		(184,933)
Income before provision for income taxes		153,767
Provision for income taxes		
NET INCOME	$	153,767

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4. RELOCATION OF COMMERCIAL AND GENERAL AND ADMINISTRATIVE OPERATIONS

In fiscal 2006, we relocated all operations other than research from San Diego, California to Aliso Viejo, California. In fiscal 2007, following the Company s receipt of a non-renewal and termination notice from AstraZeneca and the successful completion of our research agreement with Novartis, the Board of Directors approved a plan of disposition to exit the Company s facilities in San Diego. Pursuant to this plan, the Company subleased a total of approximately 48,000 square feet of laboratory and office space in San Diego and relocated remaining personnel and clinical trial support functions to the Company s offices in Orange County, California. In the first quarter of fiscal 2007, we recorded restructuring and other related expenses of $772,000, for employee severance and relocation benefits.

The following table presents the restructuring activities for the three months ended December 31, 2007:

	September 30, 2007	Payments Adjustments	December 31, 2007
Accrued Restructuring:			
Employee severance and relocation benefits	$ 75,790	$ (44,243)	$ 31,547
Lease restructuring liabilities	2,223,802	(370,334)	1,853,468
Subtotal	2,299,592	$ (414,577)	1,885,015
Less: current portion	(1,163,627)		(830,956)
Total	$ 1,135,965		$ 1,054,059

The current portion of the lease restructuring liability of $799,000 is included in Accrued Expenses and Other Liabilities and the non-current portion of lease restructuring liability of $1,054,000 is included in Accrued Expenses and Other Liabilities, net of Current Portion in the accompanying condensed consolidated balance sheet at December 31, 2007.

5. INVENTORIES

The composition of inventories as of December 31, 2007 and September 30, 2007 is as follows:

	December 31, 2007	September 30, 2007
Raw materials	$ 1,348,787	$ 1,354,991
Less: current portion	(17,000)	(17,000)
Long-term portion	$ 1,331,787	$ 1,337,991

Inventories relate to the active pharmaceutical ingredients docosanol and Zenvia ™. The amount classified as long-term 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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6. ACCRUED EXPENSES AND OTHER LIABILITIES

Accrued expenses and other liabilities at December 31, 2007 and September 30, 2007 are as follows:

	December 31, 2007	September 30, 2007
Accrued research and development expenses	$ 872,520	$ 419,989
Accrued general and administrative expenses	619,489	287,517
Deferred rent	38,677	34,432
Lease restructuring liabilities	1,853,468	2,223,802
Other	339,152	255,520
Total accrued expenses and other liabilities	3,723,306	3,221,260
Less: current portion	(2,630,570)	(2,050,864)
Non-current total accrued expenses and other liabilities	$ 1,092,736	$ 1,170,396

See Note 3 for a description of current liabilities of discontinued operations.

7. DEFERRED REVENUES

The following table sets forth as of December 31, 2007 the deferred revenue balances for our sale of future Abreva® royalty rights to Drug Royalty USA and other agreements.

	Drug Royalty USA Agreement	Other Agreements	Total
Deferred revenues as of October 1, 2007	$ 14,738,509	$ 581,921	$ 15,320,430
Changes during the period:			
Additions		50,000	50,000
Recognized as revenues during period	(838,740)	(127,539)	(966,279)
Deferred revenues as of December 31, 2007	$ 13,899,769	$ 504,382	$ 14,404,151
Classified and reported as:			
Current portion of deferred revenues	$ 2,079,801	$ 277,814	$ 2,357,615
Deferred revenues, net of current portion	11,819,968	226,568	12,046,536
Total deferred revenues	$ 13,899,769	$ 504,382	$ 14,404,151

8. COMPUTATION OF NET LOSS PER COMMON SHARE

Basic net loss per common share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period, excluding restricted stock that has been issued but is not yet vested. Diluted net loss per common share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period plus additional weighted average common equivalent shares outstanding during the period. Common equivalent shares result from the assumed exercise of outstanding stock options and warrants (the proceeds of which are then presumed to have been used to repurchase outstanding stock using the treasury stock method) and the vesting of restricted shares of common stock. In the loss periods, certain of the common equivalent shares have been excluded from the computation of diluted net loss per share, because their effect would have been anti-dilutive. For the three

month period ended December 31, 2007, a total of 867,790 stock options, 269,305 stock warrants, 20,500 restricted stock awards and 2,350,483 restricted stock units were excluded from the computation of diluted net loss per share. For the three month period ended December 31, 2006 a total 1,155,537 of stock options, 1,322,305 of stock warrants, 211,082 restricted stock awards and 647,510 restricted stock units were excluded from the computation of diluted net loss per share.

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9. COMPREHENSIVE LOSS

Comprehensive loss consists of the following:

	For the three months ended December 31,	
	2007	**2006**
Net loss	$ (5,518,634)	$ (13,617,527)
Other comprehensive gain, net of tax:		
Unrealized gain on available-for-sale securities	3,835	68,001
Total comprehensive loss	$ (5,514,799)	$ (13,549,526)

10. SHAREHOLDERS EQUITY

During the three month period ended December 31, 2007, we issued 57,340 shares of common stock in connection with the vesting of restricted stock units. In connection with the vesting, two officers exercised their option to pay for minimum required withholding taxes associated with the vesting of restricted stock by surrendering 10,296 shares of common stock at an average market price of $1.66 per share.

In November 2007, warrants to purchase 1,053,000 shares of our common stock at an exercise price of $3.30 per share expired unexercised. As of December 31, 2007, warrants to purchase 269,305 shares of common stock at a weighted-average price per share of $8.92 remained outstanding, all of which are exercisable.

11. EMPLOYEE EQUITY INCENTIVE PLANS

We currently have five equity incentive plans (the Plans): 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 our Annual Report on Form 10-K for the year ended September 30, 2007. 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. Stock-based awards are subject to terms and conditions established by the Compensation Committee of our Board of Directors. Our 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 periods ended December 31, 2007 and 2006, we 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 our employees and consultants. Under the Plans, as of December 31, 2007, we had an aggregate of 5,981,603 shares of our common stock reserved for future issuance. Of those shares, 3,238,773 were subject to outstanding options and other awards and 2,437,830 shares were available for future grants of share-based awards. As of December 31, 2007, no options were outstanding to consultants. We 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, 2007, options to purchase 20,000 shares of our common stock that were issued outside of the Plans (inducement option grants) were outstanding. None of the share-based awards is classified as a liability as of December 31, 2007.

Stock Options. Stock options are granted with an exercise price equal to the current market price of our 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 fully vest and become 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).

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Summaries of stock options outstanding and changes during the three month period ended December 31, 2007 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, 2007	1,040,581	$ 7.69	6.9	$130,000
Forfeited	(172,791)	$ 8.76		
Outstanding, December 31, 2007	867,790	$ 7.47	7.2	$ 1,200
Vested and expected to vest in the future, December 31, 2007	590,528	$ 8.76	6.6	$ 580
Exercisable, December 31, 2007	430,630	$10.26	5.9	$

There were no options granted during the three month period ended December 31, 2007. The weighted average grant-date fair values of options granted during the three month period ended December 31, 2006 was $3.00 per share. There were no options exercised in the three month period ended December 31, 2007. The total intrinsic value of options exercised during the three month period ended December 31, 2006 was $270,000 based on the differences in market prices on the dates of exercise and the option exercise prices. As of December 31, 2007, the total unrecognized compensation cost related to unvested options was $1,350,000 which is expected to be recognized over the weighted-average period of 2.3 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 our 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, 2006 were as follows:

	2006
Expected volatility	75%
Weighted-average volatility	75%
Average expected term in years	6.0
Risk-fee interest rate (zero coupon U.S. Treasury Note)	4.6%
Expected dividend yield	0%

There were no options granted during the three month period ended December 31, 2007.

The following table summarizes information concerning outstanding and exercisable stock options as of December 31, 2007:

	Options Outstanding			Options Exercisable	
		Weighted Average Remaining	Weighted Average		Weighted Average

Range of Exercise Prices	Number Outstanding	Contractual Life in Years	Exercise Price	Number Exercisable	Exercise Price
$1.20 - $1.29	150,960	9.2	$ 1.28		$
$2.30 - $2.28	149,685	7.9	$ 2.42	8,904	$ 2.88
$4.20 - $6.80	128,804	5.4	$ 5.55	106,304	$ 5.45
$6.92 - $9.92	105,190	7.4	$ 8.17	74,148	$ 8.65
$10.24 - $11.76	171,396	6.9	$11.66	110,610	$11.63
$12.12 - $16.60	148,480	6.8	$14.14	117,389	$13.86
$19.38 - $19.38	13,275	3.5	$19.38	13,275	$19.38
	867,790	7.2	$ 7.47	430,630	$10.26

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Restricted stock units. RSUs generally vest based on three years of continuous service and may not be sold or transferred until the awardee s termination of service. The following table summarizes the RSU activities for the three months ended December 31, 2007:

	Number of shares	Weighted average grant date fair value
Unvested, October 1, 2007	1,914,988	$ 2.17
Granted	525,285	$ 1.65
Vested	(57,340)	$ 2.79
Forfeited	(32,450)	$ 2.15
Unvested, December 31, 2007	2,350,483	$ 2.04

During the three month period ended December 31, 2007, we awarded 525,285 shares of restricted stock units to employees with a grant date fair value of $1.65 and were exercisable at a purchase price of $0.00 per share.
The grant-date fair value of RSUs granted during the three month periods ended December 31, 2007 and 2006 was $867,500 and $1,714,000, respectively. As of December 31, 2007, the total unrecognized compensation cost related to unvested shares was $3,343,794 which is expected to be recognized over a weighted-average period of 2.4 years, based on the vesting schedules.
Restricted stock awards. Restricted stock awards are grants that entitle the holder to acquire shares of restricted common stock at a fixed price, which is typically nominal. The shares of restricted stock cannot be sold, pledged or otherwise disposed of until the award vests, and any unvested shares may be reacquired by us for the original purchase price following the awardee s termination of service. The restricted stock awards typically vest on the second or third anniversary of the grant date or on a graded vesting schedule over three years of employment. A summary of our unvested restricted stock awards as of December 31, 2007 and changes during the three month period ended December 31, 2007 are presented below.

	Number of shares	Weighted average grant date fair value
Unvested, October 1, 2007	22,500	$ 11.87
Forfeited	(2,000)	$ 6.91
Unvested, December 31, 2007	20,500	$ 12.35

There were no restricted stock awards granted in the three month period ended December 31, 2007. The grant-date fair value of restricted stock awards granted in the three month period ended December 31, 2006 was $110,025. As of December 31, 2007, the total unrecognized compensation cost related to unvested shares was $138,000 which is expected to be recognized over a weighted-average period of 0.2 years.
We received no cash from exercised options and restricted stock awards under all share-based payment arrangements during the three- month period ended December 31, 2007. During the three month period ended December 31, 2006, we received a total of $289,000 in cash from exercised options and restricted stock awards under all share-based payment arrangements. No tax benefit was realized for the tax deductions from option exercise of the share-base payment arrangements in the three month period ended December 31, 2007 and 2006.

12. COMMITMENTS AND CONTINGENCIES

See Note 3 Acquisition of Alamo Pharmaceuticals, Inc. / Sale of FazaClo regarding a contingency on the Working Capital Adjustment on the sale of FazaClo to Azur.

Center for Neurologic Study (CNS) We hold the exclusive worldwide marketing rights to Zenvia for certain indications pursuant to an exclusive license agreement with the CNS. We will be obligated to pay CNS up to $400,000 in the aggregate in milestones to continue to develop for both PBA and DPN pain, assuming they are both approved for marketing by the FDA. We are not currently developing, nor do we have an obligation to develop, any other indications under the CNS license agreement. In fiscal 2005, we paid $75,000 to CNS under the CNS license agreement, and will need to pay a $75,000 milestone if the FDA approves Zenvia for the treatment of PBA. In addition, we are obligated to pay CNS a royalty on commercial sales of Zenvia with respect to each indication, if and when the drug is approved by the FDA for commercialization. Under certain circumstances, we may have the obligation to pay

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CNS a portion of net revenues received if we sublicense Zenvia to a third party. Under our agreement with CNS, we are 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 we pursued the development of Zenvia for all of the licensed indications. Of the clinical indications that we currently plan to pursue, expected milestone payments could total $800,000. In general, individual milestones range from $150,000 to $250,000 for each accepted new drug application (NDA) and a similar amount for each approved NDA. In addition we are obligated to pay CNS a royalty ranging from approximately 5% to 8% of net revenues.

Eurand, Inc. In August 2006, we entered into a development and license agreement (Eurand Agreement) with Eurand, Inc. (Eurand), under which Eurand will provide research and development services using Eurand s certain proprietary technology to develop a once-a-day controlled release capsule, a new formulation of Zenvia for the treatment of PBA (Controlled-Release Zenvia™). Under the terms of the Eurand Agreement, we will pay Eurand for development services on a time and material basis. We will be required to make payments up to $7.6 million contingent upon achievement of certain development milestones and up to $14.0 million contingent upon achievement of certain sales targets. In addition, we will be required to make royalty payments based on sales of Controlled-Release Zenvia ™. No such payments were made in the first quarter of fiscal 2008.

Contingencies. In the ordinary course of business, we may face various claims brought by third parties and we may, from time to time, make claims or take legal actions to assert our rights, including intellectual property rights as well as claims relating to employment and the safety or efficacy of our products. Any of these claims could subject us to costly litigation and, while we generally believe that we have adequate insurance to cover many different types of liabilities, our insurance carriers may deny coverage or our 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 our operations, cash flows and financial position. Additionally, any such claims, whether or not successful, could damage our reputation and business. Management believes the outcome of currently pending claims and lawsuits will not likely have a material effect on our operations or financial position.

In September 2007, a court awarded us reimbursement of attorneys fees spent over a four-year period in connection with the enforcement of a settlement agreement entered into with a former employee. In January 2008 the California Supreme Court denied a request for appeal and the total funds due to Avanir are approximately $1.3 million. We cannot currently estimate the timing for collection or the probability of collecting these fees.

In addition, we could terminate contracts with certain vendors, including Clinical Research Organizations, where such terminations could result in substantial termination fees.

Guarantees and Indemnities. We indemnify our 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 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. We have not incurred significant amounts 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, 2007.

13. SEGMENT INFORMATION

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

We categorize revenues by geographic area based on selling location. All our operations are currently located in the U.S.; therefore, total revenues for the three month periods ended December 31, 2007 and 2006 are attributed to the U.S. All long-lived assets at December 31, 2007 and September 30, 2007, are located in the U.S.

For the three month periods ended December 31, 2007 and 2006, the sale of rights to royalties under the GlaxoSmithKline (GSK) license agreement were 84% and 34% of our total net revenues, respectively. The increase in

GSK royalties as a percentage of our

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total revenue is attributed to royalty revenue of $934,000 recorded in the first fiscal quarter of 2008 pursuant to the GSK license agreement in which we are entitled to receive 50% of all royalties for annual net sales of Abreva in North America in excess of $62 million during each calendar year. For the three month period ended December 31, 2006, 9% of our total net revenues were derived from our license agreement with AstraZeneca. No revenue was derived from AstraZeneca in the three month period ended December 31, 2007.

Net receivables from AstraZeneca and Novartis accounted for approximately 6% and 6%, respectively, of our net receivables at December 31, 2007 and 10% and 19%, respectively, of our net receivables at September 30, 2007. Net receivables from Bausch and Lomb for docosanol product sales accounted for 7% of net receivables as of December 31, 2007. Net receivables from GlaxoSmithKline for royalties accounted for 61% of net receivables as of December 31, 2007.

14. SUBSEQUENT EVENTS

Subsequent to December 31, 2007, we sold and issued a total of 34,568 shares of our Class A common stock for aggregate gross offering proceeds of $44,200 ($42,600 after offering expenses, including underwriting discounts and commissions).

In January 2008, we received notice from Kobayashi Pharmaceutical Co., Ltd. stating that they may not be able to get approval of docosanol in Japan without a large, controlled clinical study in Japanese patients. If Kobayashi can not use the existing clinical data as a basis for approval in Japan, they may terminate the license agreement with Avanir Pharmaceuticals.

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 expect and 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 Securities and Exchange Commission (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, 2007 may also be referred to as the first quarter of fiscal 2008.

EXECUTIVE OVERVIEW

We are a pharmaceutical company focused on developing, acquiring and commercializing novel therapeutic products for the treatment of chronic diseases. Our product candidates address therapeutic markets that include the central nervous system, inflammatory diseases and infectious diseases. Our lead product candidate, Zenvia(dextromethorphan hydrobromide/quinidine sulfate), is currently in Phase III clinical development for the treatment of pseudobulbar affect (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 and our infectious disease program, which is focused primarily on anthrax antibodies, is currently being funded by grants from the National Institute of Health/National Institute of Allergy and Infectious Disease (NIH/NIAID).

Zenvia Status

Zenvia is currently in Phase III clinical development for the treatment of two conditions: (1) pseudobulbar affect (PBA), which is an involuntary emotional expression disorder 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 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. However, in order to address safety concerns, we

agreed to re-formulate Zenvia and conduct one additional confirmatory Phase III clinical trial using lower dose formulations. The goal of the study is to demonstrate improved safety while maintaining significant

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efficacy. 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 expect this study to be completed (as defined as top-line safety and efficacy data becomes available) during the second half of calendar 2009.

In April 2007, we announced positive top-line data results from our first Phase III clinical trial of Zenvia for DPN pain. We are currently conducting 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 before discussing a further Phase III trial with the FDA. While we have received no formal direction from the FDA to 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.

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. (GlaxoSmithKline) the exclusive rights to market docosanol 10% cream in North America. GlaxoSmithKline markets the product under the name Abreva® in the United States and Canada. In fiscal 2003, we sold an undivided interest in our GlaxoSmithKline 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 under the GlaxoSmithKline license agreement for annual net sales of Abreva in North America in excess of $62 million. Starting in fiscal 2007, annual Abreva sales exceeded this threshold and we began participating in the excess royalties at that time.

Inflammation Program

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

Our patented Xenerex antibody technology can be used to develop human monoclonal antibodies for use as prophylactic and therapeutic drugs, which may be used to prevent or treat anthrax and other infectious diseases. This proprietary technology provides a platform for accessing human monoclonal antibodies against disease antigens. The Xenerex technology is capable of generating fully human antibodies to target antigens and draws on the natural diversity of the human donor population. Using Xenerex technology, we have discovered a human monoclonal antibody, AVP-21D9, that provides immediate post-exposure neutralization and immediate immunity to animals exposed to a lethal dose of recombinant anthrax toxins.

Our anthrax antibody is in preclinical development and is currently being funded by grants from the NIH/NIAID. In May 2007, we were notified that we had been awarded a one-year extension of our $2.0 million research grant from the NIH/NIAID for ongoing research and development related to our anthrax antibody. Under the terms of the grant, the NIH/NIAID will reimburse us for up to $2.0 million in certain expenses related to the establishment of a current Good Manufacturing Practices (cGMP) manufacturing process and the preclinical testing of the anthrax antibody. Subject to certain conditions, we, as the awardee organization, retain the principal worldwide patent rights to any invention developed with the U.S. government support. Our progress on this program will substantially depend on future grants, as well as our business priorities. Currently, we expect that we will continue with the development of this program only to the extent that its development is funded by research grants. Because all of our monoclonal antibody research is at an early preclinical stage of development and is unpredictable in terms of the outcome, we are

unable to predict the cost and timing for development of this antibody.

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Restructuring Activities

In May 2006, we acquired FazaClo® (clozapine, USP), a product marketed for the management of treatment-resistant schizophrenia and the reduction in the risk of recurrent suicidal behavior in schizophrenia or schizoaffective disorders. We had intended to leverage the FazaClo sales force to assist with the commercial launch of Zenvia for PBA, a launch that was planned for early 2007. However, due to the receipt of the approvable letter and the resulting delay in the planned launch of Zenvia ™, the strategic rationale for continued marketing of FazaClo by Avanir no longer existed. Therefore, we entered into an agreement in July 2007 to sell FazaClo to Azur Pharma. The sale, which closed August 3, 2007, provided approximately $43.9 million in an up-front cash payment and may provide up to an additional $10.0 million in contingent payments to be paid in calendar year 2009, subject to certain regulatory conditions. In addition, the Company is eligible to receive up to $2.0 million in royalties, based on 3% of annualized net product revenues in excess of $17.0 million. Azur acquired the FazaClo sales force and support operations, representing approximately 80 employees in total. As a result, we became a substantially smaller organization following the sale of FazaClo, as well as the divestiture of our drug discovery operations in San Diego, and will be principally focused over the next two to three years on seeking regulatory approval of Zenvia for the treatment of patients with PBA and patients with DPN pain.

Based on our current capital resources and focus on obtaining approval for Zenvia, we have also structured the ongoing development of our anthrax human monoclonal antibody program so that direct development costs do not materially exceed funding levels from National Institutes of Health/National Institute of Allergy and Infectious Disease (NIH/NIAID) research grants or potential development partners. In May 2007, we received a one-year extension of our grant from the NIH/NIAID to fund further pre-clinical development of our anti-anthrax human monoclonal antibody and we are continuing development under this grant. We have suspended all funding activities associated with our selective cytokine inhibitor program and have also ended all further prosecution and maintenance of associated patents.

As a result of these initiatives, we have undergone significant organizational changes in fiscal 2007. Our principal focus is currently on gaining regulatory approval for Zenvia ™, first for the treatment of patients with PBA and then for patients with DPN pain. We believe that the proceeds from the sale of FazaClo will be sufficient to fund our operations, including our ongoing confirmatory Phase III trial for Zenvia in patients with PBA, through at least the next twelve months. We are currently considering additional means of raising capital to fund ongoing Zenvia development and operations, including borrowing funds, selling common stock or other securities, and the monetization of remaining non-core assets. If we are unable to raise sufficient additional capital when needed in the future to fund our development programs, we may need to slow the development rate of some programs or sell additional rights to one or more drug candidates. For additional information about the risks and uncertainties that may affect our business and prospects, please see Risk Factors.

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 Securities and Exchange Commission (SEC). No portion of our website is incorporated by reference into this Annual Report on Form 10-K. 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.

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 sales deductions for estimated chargebacks, rebates, sales incentives and

allowances, certain royalties and returns and losses. Significant estimates and assumptions are also required in the appropriateness of capitalization and amortization periods for identifiable intangible assets, inventories, the potential impairment of goodwill and other intangible assets, income taxes, contingencies, estimate on working capital adjustment 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

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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, 2007 in the Critical Accounting Policies and Estimates section and in Note 2 of the Notes to our condensed consolidated financial statements included herein.

RESULTS OF OPERATIONS

COMPARISON OF THREE MONTHS ENDED DECEMBER 31, 2007 AND 2006

	Three months ended December 31			
	2007	**2006**	**$ Change**	**% Change**
PRODUCT SALES				
Net revenues	$ 36,000	$	$ 36,000	100%
Cost of revenues	6,204		6,204	100%
Gross margin	$ 29,796	$	$ 29,796	100%
LICENSES, RESEARCH SERVICES AND GRANTS				
Revenues:				
License agreements	$ 57,265	$ 57,265	$	0%
Research services		1,270,244	(1,270,244)	-100%
Government research grant	167,647	86,348	81,299	94%
Royalty and sale of royalty rights	1,837,853	723,040	1,114,813	154%
Revenues from licenses, research services and grants	2,062,765	2,136,897	(74,132)	-3%
Costs:				
Research services	49,991	1,164,075	(1,114,084)	-96%
Government research grant	125,587	95,727	29,860	31%
Costs from licenses, research services and grants	175,578	1,259,802	(1,084,224)	-86%
Total revenues	$ 2,098,765	$ 2,136,897	$ (38,132)	-2%
Total gross margin	$ 1,916,983	$ 877,095	$ 1,039,888	119%

Revenues

Net product revenues for the three months ended December 31, 2007 include sales of docosanol 10% cream of $36,000. Revenues from licenses, royalties, research services and grants remained constant at $2.1 million for the first quarter of fiscal 2008 compared to the first quarter of fiscal 2007. A decline in revenue of $1.3 million from research services from our agreements with AstraZeneca and Novartis was largely offset by an increase in revenue from

royalties of $1.1 million. The decline in revenue from research services is partially due to a decline in direct reimbursable costs from period to period and AstraZeneca having elected to rely less upon our resources when the research agreement was still active. The increase in revenue from royalties is due to GSK royalty revenue of $934,000 recorded in the first fiscal quarter of 2008 pursuant to the GSK license agreement in which we are entitled to receive 50% of all royalties for annual net sales of Abreva in North America in excess of $62 million.

As discussed above in the Executive Overview, we received notice from Novartis of the non-renewal of the research collaboration portion of our agreement with them. However, we remain eligible to receive up to more than $200 million in milestone payments, contingent upon Novartis performance and achievement of certain development and regulatory milestones, including achievement of certain sales targets, if a licensed compound is approved by the FDA.

Potential revenue-generating contracts that remained active as of December 31, 2007 include several docosanol 10% cream license agreements and our license agreement with Novartis for the Company s MIF technology. Partnering, licensing and research collaborations have been, and may continue to be, an important part of our business development strategy. We may continue to seek partnerships with pharmaceutical companies that can help fund our operations in exchange for sharing in the success of any licensed compounds or technologies.

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Cost of Revenues

Cost of product revenues for the three months ended December 31, 2007 include the cost of docosanol 10% cream. Cost of licenses, research services and grants declined to $176,000 or 15% of revenues for the first quarter of fiscal 2008 compared with $1.3 million or 59% of revenues for the first quarter of fiscal 2007. The cost of licenses, research services and grants includes primarily direct and indirect payroll costs and the costs of outside vendors.

	Three Months ended December 31			
	2007	2006	$ Change	% Change
OPERATING EXPENSES				
Research and development	$ 3,426,259	$ 5,197,253	$ (1,770,994)	-34%
Selling, general and administrative	3,128,120	9,369,862	(6,241,742)	-67%
Total Operating Expenses	$ 6,554,379	$ 14,567,115	$ (8,012,736)	-55%

Research and Development Expenses

Research and development expenses decreased by $1.8 million from $5.2 million in the first quarter of fiscal 2007 to $3.4 million for the first quarter of fiscal 2008. The decrease is primarily due to decreased costs incurred for Zenvia as the Company was conducting a study in the first quarter of fiscal 2007 for the DPN pain indication of Zenvia.

Over the next two years, we expect that our research and development costs will consist mainly of expenses related to the confirmatory Phase III trial for Zenvia for PBA.

Selling, General and Administrative Expenses

Selling, general and administrative expenses decreased by $6.2 million from $9.4 million for the first quarter of fiscal 2007 compared to $3.1 million for the first quarter of fiscal 2008. The decrease resulted primarily from expenses incurred in the first fiscal quarter of 2007 in preparation for commercial readiness for the launch of Zenvia which were not repeated in the first fiscal quarter of 2008.

In September 2007, a court awarded us reimbursement of attorneys fees spent over a four-year period in connection with the enforcement of a settlement agreement entered into with a former employee. In January 2008 the California Supreme Court denied a request for appeal and the total funds due to Avanir are approximately $1.3 million. We cannot currently estimate the timing for collection or the probability of collecting those fees.

Share-Based Compensation

During the second quarter of fiscal 2007, the Company updated its projected forfeiture rates as it applies to stock-based compensation considering recent actual data. Forfeiture rates for the three month periods ended December 31, 2007 and 2006 were estimated to be approximately 30% and 4%, respectively, based on our historical experience. Future estimates may differ substantially from the Company s current estimates.

Total compensation expense for our share-based payments in the three month period ended December 31, 2007 and the same period in 2006 was $444,000 and $845,000, respectively. Selling, general and administrative expense in the three month periods ended December 31, 2007 and 2006 include share-based compensation expense of $297,000 and $722,000, respectively. Research and development expense in the three month periods ended December 31, 2007 and 2006 include share-based compensation expense of $147,000 and $123,000, respectively. As of December 31, 2007, $4.8 million of total unrecognized compensation costs related to nonvested options and awards is expected to be recognized over a weighted average period of 2.4 years. See Note 11, Employee Equity Incentive Plans in the Notes to Condensed Consolidated Financial Statements (Unaudited) for further discussion.

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Interest Expense and Interest Income

For the three month period ended December 31, 2007, interest expense decreased to $234,000, compared to $418,000 for the same period in the prior year. The decrease in interest expense is primarily due to a decrease in the balance of Seller Notes due to payments made on the Notes totaling $17.1 million. The Seller Notes were issued in May 2006 in connection with the purchase of Alamo.

For the three month period ended December 31, 2007, interest income increased to $427,000, compared to $191,000 for the same period in the prior year. The increase is due to approximately a 49% increase in the average balance of cash, cash equivalents and investments in securities for the quarter ended December 31, 2007, compared to the same period in the prior year.

(Loss) income from Discontinued Operations

Loss from discontinued operations was $1.1 million in the three month period ended December 31, 2007, compared to income from discontinued operations of $154,000 for the three month period ended December 31, 2006. The loss recognized in the three month period ended December 31, 2007 is attributed to the accrued loss related to the Working Capital Adjustment of $868,000 as well as additional costs of $206,000 related to the operations of FazaClo during the quarter ended December 31, 2007, which we initially believed were assumed by Azur.

Net Loss

Net loss was $5.5 million, or $0.13 per share, in the three month period ended December 31, 2007, compared to a net loss of $13.6 million, or $0.39 per share for the three month period ended December 31, 2006.

LIQUIDITY AND CAPITAL RESOURCES

We assess our liquidity by our ability to generate 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; funds required for acquisitions; funds required to repay notes payable and capital lease obligations as they become due; adequate credit facilities; and financial flexibility to attract long-term equity capital on favorable terms. Historically, cash required to fund on-going business operations has been provided by financing activities and used to fund operations and working capital requirements and investing activities. Cash, cash equivalents and investments, as well as, net cash provided by or used for operating, investing and financing activities are summarized in the table below.

	December 31, 2007	Increase (Decrease) During Period	September 30, 2007
Cash, cash equivalents and investment in securities	$29,421,889	$(4,219,509)	$33,641,398
Cash and cash equivalents	$28,315,460	$(2,172,502)	$30,487,962
Net working capital	$23,555,133	$(5,781,643)	$29,336,776

	Three Months Ended December 31, 2007	Change Between Periods	Three Months Ended December 31, 2006
Net cash used in operating activities	$ (4,099,610)	$(15,002,274)	$ (19,101,884)
Net cash provided by investing activities	2,037,037	14,726,330	16,763,367
Net cash (used in) provided by financing activities	(109,929)	12,007,506	11,897,577
Net (decrease) increase in cash and cash equivalents	$ (2,172,502)	$ 11,731,562	$ 9,559,060

Operating activities. Net cash used in operating activities amounted to $4.1 million in the first quarter of fiscal 2008 compared to $19.1 million in the first quarter of fiscal 2007. The decrease in cash used for operating activities is

primarily related to the decrease in overall operating costs as seen in the $8.2 million decrease in operating loss coupled with an $8.6 million decrease in cash used for accounts payable.

Investing activities. Net cash provided by investing activities was $2.0 million in the first quarter of fiscal 2008, compared to $16.8 million used in the first quarter of fiscal 2007. The decrease in cash provided by investing activities is primarily related to the decrease in proceeds from the sale of securities which provided $16.9 million in the first quarter of fiscal 2007.

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Financing activities. Net cash used in financing activities was $110,000 in the first quarter of fiscal 2008 compared to net cash provided by financing activities of $11.9 million in the first quarter of fiscal 2007. The decrease in net cash provided by financing activities is primarily related to approximately $15.0 million received from the sale of our common stock through private placements received in the first quarter of fiscal 2007.

In June 2005, we filed a shelf registration statement on Form S-3 with the SEC to sell an aggregate of up to $100 million in Class A common stock and preferred stock, depositary shares, debt securities and warrants. This shelf registration statement was declared effective on August 3, 2005 and through December 31, 2007, we had sold a total of 14,406,755 shares of Class A common stock under this registration statement, raising gross offering proceeds of approximately $71.5 million and net offering proceeds of approximately $69.5 million. We have also issued under this registration statement common stock warrants to purchase a total of 1,053,000 shares of our Class A common stock at an exercise price of $3.30 per share. The warrants expired in November 2007 unexercised.

In December 2006 we entered into a financing facility with Brinson Patrick Securities Corporation. Under this facility, through January 31, 2008, we have offered and sold an aggregate of 6,160,200 shares of Class A common stock, which resulted in net proceeds of $16.2 million. As of January 31, 2008, 5.5 million shares remained available for sale under this facility.

As of December 31, 2007, we have contractual obligations for long-term debt, capital (finance) lease obligations and operating lease obligations, as summarized in the table that follows.

	Payments Due by Period				
	Total	**Less than 1 Year**	**1-3 Years**	**3-5 Years**	**More than 5 Years**
Long-term debt (principal and interest)	$ 13,062,958	$ 965,342	$ 12,097,616	$	$
Operating lease obligations	7,708,467	2,012,862	3,033,334	2,616,249	46,022
Purchase obligations (1)	14,012,788	6,625,532	7,387,256		
Total	$ 34,784,213	$ 9,603,736	$ 22,518,206	$ 2616,249	$ 46,022

(1) Purchase obligations consist of the total of trade accounts payable and trade related accrued expenses at December 31, 2007 which approximates our contractual commitments for goods and services in the normal course of our business.

As part of the purchase consideration of the Alamo acquisition, we initially issued three promissory notes in the principal amounts of $14,400,000, $6,675,000 and $4,000,000 (the First Note, Second Note and Third Note , respectively) (collectively, the Notes). The Notes bear interest at an average rate equal to the London Inter-Bank Offered Rate, or LIBOR, plus 1.33%. Interest accruing on the Notes is payable monthly and the principal amount of the Notes matures on May 24, 2009, provided that (i) the Selling Holders may demand early repayment of the First Note if the closing price of our common stock, as reported on the NASDAQ Global Market, equals or exceeds $15.00 per share for a total of 20 trading days in any 30 consecutive trading-day period (the Stock Contingency), and (ii) we must apply 20% of any future net offering proceeds from equity offerings and other financing transactions to repay the Notes (starting with the First Note), and must repay the Notes in full if we have raised in an offering more than $100,000,000 in future aggregate net proceeds. In connection with the equity offering we completed in the first nine months of fiscal year 2007, and in accordance with the terms of the Notes, we used approximately $6.1 million or 20% of the net proceeds received to pay down the First Note. In connection with our sale of FazaClo in August 2007, we agreed to prepay $11 million of outstanding principal due under the Notes, and the Note holder agreed to suspend the Company s obligation to use a portion of future equity offering proceeds to repay the Notes, up to $55 million in future net offering proceeds. Twenty percent of any offering proceeds above this amount will need to be paid to the Note holders, as per the original agreement.

We have the right to prepay, in cash or in common stock, the amounts due under the Notes at any time, provided that we may only pay the Notes in common stock if the Stock Contingency has occurred prior to the maturity date and if we have registered the shares on an effective registration statement filed with the SEC. If we elect to prepay the Notes with common stock, the shares will be valued at 95% of the average closing price of the common stock, as reported on the NASDAQ Global Market, for the five trading days prior to repayment, subject to a price floor.

Contingency on Working Capital Adjustment. The Asset Purchase Agreement (the Agreement) with Azur provides for an adjustment to the sale price of FazaClo in connection with the final determination of the amount of working capital (as defined in the agreement) included as part of the sale (Working Capital Adjustment). The Agreement also stipulates that an adjustment to working capital shall only exist if the final Working Capital Adjustment is greater $250,000. As of September 30, 2007, we estimated that there

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would not be a Working Capital Adjustment. However, based upon current information, we have estimated the Working Capital Adjustment to result in an $868,000 reduction in the sale price which would be an additional use of working capital.

We have not yet reached agreement with Azur on the amount of the Working Capital Adjustment, and further, Azur has made claims that the Working Capital Adjustment should reduce the sale price by $2.0 million, which is $1.1 million more than the amount that we have accrued. Under the terms of the Agreement, Azur has until February 14, 2007 to accept our estimate. If Azur does not accept our estimate, a US National Accounting Firm will be selected to resolve the dispute. We believe we have adequately provided for the loss related to the Working Capital Adjustment in accordance with Statement of Financial Accounting Standards No. 5, *Accounting for Contingencies*; however, there can be no assurance as to the ultimate settlement of the amount. If the final determination of the Working Capital Adjustment exceeds our accrual of $868,000, the amount in excess of $868,000 will be recognized as a loss on discontinued operations in that period.

Alamo Earn-Out Payments. In connection with the Alamo acquisition, we agreed to pay up to an additional $39,450,000 in revenue-based earn-out payments, based on future sales of FazaClo. These earn-out payments are based on FazaClo sales in the U.S. from the closing date of the acquisition through December 31, 2018 (the Contingent Payment Period). Based on the results of the quarters ended March 31, 2007 and June 30, 2007, we issued the first and second of these revenue-based payments through the issuance of additional promissory notes in the principal amount of $2,000,000 per note. As previously discussed in this filing, we sold the FazaClo product line to Azur Pharma. Our future earn-out obligations that would have been payable to the prior owner of Alamo Pharmaceuticals upon the achievement of certain milestones were assumed by Azur Pharma.

Eurand Milestone and Royalty Payments. In August 2006, we entered into a development and license agreement (Eurand Agreement) with Eurand, Inc. (Eurand), under which Eurand will provide R&D services using Eurand s certain proprietary technology to develop a once-a-day controlled release capsule, a new formulation, of Zenvia for the treatment of PBA (Controlled-Release Zenvia). Under the terms of the Eurand Agreement, we will pay Eurand for development services on time and material basis. We will be required to make payments up to $7.6 million contingent upon achievement of certain development milestones and up to $14.0 million contingent upon achievement of certain sales targets. In addition, we will be required to make royalty payments based on sales of Controlled-Release Zenvia, if it is approved for commercialization. Development milestone events include program initiation, delivery of prototypes, delivery of clinical trial material for phase 1, achieving target PK Profile in the pilot clinical study, delivery of clinical trial material for phase 3, filing of the first NDA for the Product with the FDA, completion of manufacturing validation and approval of the NDA with the FDA. Sales target milestones are $2.0 million upon achieving $100 million of U.S. net revenues, $4.0 million upon achieving $200 million of U.S. net revenues and $8.0 million upon achieving $400 million of U.S. net revenues. The agreement remains in effect on a country by country basis for the longer of 10 years after first commercial sale or the life of any Eurand patent, unless earlier terminated in accordance with the agreement. In November 2006, we provided Eurand with notification to suspend activity on this project until further notice. The Company may terminate the agreement upon 30 days notice in the event the company receives a response from the FDA that is something other than an unconditional approval of the original formulation of Zenvia. Upon expiration of the agreement the Company shall own a fully-paid irrevocable license. Effective December 2006, we suspended further work under this agreement until resolution of further development plans for Zenvia resulting from our meeting with the FDA in late February 2007. All material remaining obligations would only be due in the event we initiate the agreement in future.

Zenvia License Milestone Payments. We hold the exclusive worldwide marketing rights to Zenvia for certain indications pursuant to an exclusive license agreement with the Center for Neurologic Study (CNS). We will be obligated to pay CNS up to $400,000 in the aggregate in milestones to continue to develop both indications, assuming they are both approved for marketing by the FDA. We are not currently developing, nor do we have an obligation to develop, any other indications under the CNS license agreement. In fiscal 2005, we paid $75,000 to CNS under the CNS license agreement, and will 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 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, we

may have the obligation to pay CNS a portion of net revenues received if we sublicense Zenvia to a third party. Under our agreement with CNS, we are 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 we pursued the development of Zenvia for all of the licensed indications. Of the clinical indications that we currently plan to pursue, expected milestone payments could total $800,000. In general, individual milestones range from $150,000 to $250,000 for each accepted NDA and a similar amount for each approved NDA. In addition, we are obligated to pay CNS a royalty ranging from approximately 5% to 8% of net revenues.

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Management Outlook

The minimum balance of securities available for sale under our existing shelf registration was approximately $28.5 million as of December 31, 2007. We believe that cash and investments in securities of approximately $29.4 million at December 31, 2007 will be sufficient to sustain our planned level of operations for at least the next twelve months. However, the Company cannot provide assurances that our plans will not change, or that changed circumstances will not result in the depletion of capital resources more rapidly than anticipated. If we are unable to generate sufficient cash flows from licensed technologies or are unable to raise sufficient capital, management believes that expenditures could be curtailed in order to continue operations for the next 12 months.

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 while achieving attractive yields, without significantly increasing risk. We classify our investments in securities as of December 31, 2007 as available-for-sale and our restricted investments in securities as held-to-maturity. These available-for-sale securities are subject to interest rate risk. In general, we would expect that the volatility of this portfolio would decrease as its duration decreases. Based on the average duration of our investments as of December 31, 2007 and 2006, an increase of one percentage point in the interest rates would have resulted in increases in interest income of approximately $238,000 and $27,000, respectively.

Item 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our Chief Executive Officer and Corporate Controller, after evaluating the effectiveness of our disclosure controls and procedures (as defined in the Securities Exchange Act of 1934, Rules 13a-15(e) and 15d-15(e), as of the end of the period covered by this report, have concluded that, based on such evaluation, as of December 31, 2007 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. 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 the Company s internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) during the Company s fiscal quarter ended December 31, 2007, that has materially affected, or is reasonably likely to materially affect the Company s internal control over financial reporting.

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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

Below are the risk factors that have been revised since the filing of our annual report on Form 10-K for the year ended September 30, 2007 (the 2007 Form 10-K). We face significant additional risks, which are set forth in the other risk factors contained in our 2007 Form 10-K under the caption Risk Factors. You are urged to read these risk factors in the 2007 Form 10-K, in addition to the following revised risk factors set forth below, before making an investment decision with regard to our securities.

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 or that an approval, if granted, will be on terms we may seek.

In October 2006, we received an approvable letter from the FDA for our new drug application (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 concerns of the original dose formulation that was tested in earlier trials. However, in order to address remaining safety concerns, we agreed to re-formulate Zenvia and conduct one additional confirmatory Phase III clinical trial using lower dose formulations. The goal of the study is to demonstrate improved safety while maintaining a significant degree of the efficacy seen in our earlier trials testing higher doses. The study is expected to be completed (as defined as top-line safety and efficacy data becomes available) during the second half of calendar 2009. It is possible that the efficacy will be so reduced that we will not be able to satisfy the FDA s efficacy requirements and 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 (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, it is possible that Zenvia may not be approved with the labeling claims or for the patient population that we consider most desirable for the promotion of the product. Less desirable labeling claims could adversely affect the commercial potential for the product and could also affect our long-term prospects.

Additionally, although we have a Special Protocol Assessment (SPA) from the FDA for our recently completed Phase III trial for DPN pain and for our planned 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. However, even where an SPA has been granted, 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. As a result, even with an SPA, we cannot be certain that the trial results will be found to be adequate to support an efficacy claim and 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

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such as DPN pain, we believe that it is possible that the FDA will raise similar concerns for this indication. Accordingly, we are investigating the potential use of alternative formulations with lower doses of quinidine and various DM levels in the next Phase III trial for Zenvia for this indication. Although we achieved positive results in our initial Phase III trial, an alternative lower dose may not yield the same levels of efficacy as seen in the earlier trials and any drop in efficacy may be so great that the drug does not demonstrate a statistically significant improvement over placebo. Additionally, any alternative dose 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 two additional Phase III trials for regulatory approval, which would be costly and delay the potential commercial launch of this drug.

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 operating losses totaling $244 million as of December 31, 2007, and we expect to continue to incur substantial operating losses for the foreseeable future. As of December 31, 2007, we had approximately $29.4 million in cash, cash equivalents, investments in marketable securities and restricted cash. 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 need to raise significant amounts of additional capital in the future to complete the development of Zenvia and to finance our long-term operations. 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 next twelve months. Although we expect to be able to raise additional capital and/or curtail current levels of operations to be able to continue to fund our operations beyond that time, 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 and DPN pain. This may result in significant delays in our planned clinical trial of Zenvia for PBA 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.

We will seek to raise additional capital and may do so at any time through various financing alternatives, including licensing or sales of our technologies, drugs and/or drug candidates, selling shares of common or preferred stock, 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. If we instead seek to raise capital through licensing transactions or sales of one or more of our technologies, drugs or drug candidates, as we have stated we are actively considering with certain investigational compounds, 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 many of our non-core drug development programs and related assets and these dispositions carry certain risks.

Since 2005, we have entered into three large agreements for the licensing out or sale of certain of our drug development programs, including the following drugs and drug candidates: FazaClo, MIF, and RCT. Additionally, we are seeking to monetize our remaining non-core assets to help fund the development of Zenvia. 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.

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Transactions such as these may result in disputes regarding representations and warranties, indemnities, earn-outs, and other provisions in the transaction agreements. For example, we are currently in discussions with Azur to resolve a dispute over a working capital adjustment whereby Azur seeks to be repaid approximately $1.1 million that we have disputed. If this or other 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.

Additionally, 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 that could come from our technologies such as anti-inflammatory compounds and antibodies. 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; or
- 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.

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 for Zenvia in the U.S., which could result in the introduction of generic competition within in 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 patents for Zenvia expire in 2016. These expirations do not account for any potential patent term restoration nor does this account for the issuance of any patents pending. If Zenvia is approved, we can apply for an up to five-year extension to one patent covering Zenvia; however, as Zenvia is not a new chemical entity, it is unknown whether or not Zenvia will qualify for patent term restoration under the U.S. Patent and Trademark Office guidelines. Once the patents covering Zenvia expire or the three-year Hatch Waxman exclusivity period has passed, 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. If we are unsuccessful in strengthening our patent portfolio, 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 process 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 have recently experienced significant turnover in senior management.

In the past twelve months, we have experienced significant turnover in our senior management team, including the departures of our President and Chief Executive Officer, Chief Financial Officer, Interim Chief Financial Officer, Vice President of Human Resources, and Vice President of Drug Discovery. As a result of these changes, we essentially have a new management team. It is not yet possible to assess how effective this management team will be and whether they will be able to work together to accomplish the Company s business objectives. Additionally, changes in management are disruptive to the organization and any further changes may slow the Company s progress toward its goals. Further, the Board of Directors is planning to reduce its size to streamline operations and to reflect the fact that the Company is significantly smaller than it was previously. Changes in Board composition may also be disruptive and the loss of the experience and capabilities of any of our Board members may reduce the effectiveness of the Board.

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, sales and marketing and 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 extensive employee turnover recently, as discussed above, and the loss of any additional 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 for 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 recent 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 a New Drug Application (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; or
- the rejection of an application.

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;
- 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 compete against antidepressants, atypical anti-psychotic agents and other agents.

Our competitors may have specific expertise and development technologies that are better than ours and many of these 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, 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.

Developing and marketing pharmaceutical products for human use involves product liability risks, for which we currently have limited insurance coverage.

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 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.

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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. 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 API for docosanol 10% cream and supplies for 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. 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. Any delays or difficulties in obtaining APIs or in manufacturing, packaging or distributing our products and product candidates could delay Zenvia clinical trials for PBA and/or DPN pain. Additionally, the third parties we rely on for manufacturing and packaging are subject to regulatory review, and any regulatory compliance problems with these third parties could significantly delay or disrupt our commercialization activities.

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 license and collaboration agreement for our reverse cholesterol transport (RCT) mechanism technology. We similarly rely on licensing partners to obtain regulatory approval for Docosanol in foreign jurisdictions. Because much of the potential value of these license arrangements is contingent upon the successful development and commercialization of the licensed technology, the ultimate value of these licenses will depend on the efforts of licensing partners. If our licensing partners do not succeed in developing the licensed technology for whatever reason, or elect to discontinue the development of these programs, we may be unable to realize the potential value of these arrangements.

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 revenue from international product sales will suffer.

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Risks Relating to Our Stock

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

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

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

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

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

Sales of our Class A common stock by our directors, officers, or significant shareholders;

Announcements by our competitors of clinical trial results or product approvals; 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.

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 listed on The NASDAQ Global Market. The listing standards of The NASDAQ Global Market provide 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. Additionally, we must satisfy at least one of the following conditions: (A) stockholders equity of at least $10 million, (B) total market value of listed securities of at least $50 million or (C) at least $50 million of total assets and $50 million of total revenue.

Recently our stock has traded near $1.00 and our total market value of listed securities has, at times, dropped below $50 million. We currently do not satisfy other alterative listing standards and thus our stock is at risk for delisting if our stock price declines for a sustained period of time. 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 and liquidity of our common stock. In addition, the delisting of our common stock could 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.

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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 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 8, 2008
/s/ *Christine G. Ocampo* Christine G. Ocampo	Corporate Controller (Principal Financial and Accounting Officer)	February 8, 2008