AVANIR PHARMACEUTICALS
Form 10-Q
August 14, 2003

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SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

[X] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.

For the quarterly period ended June 30, 2003

OR

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

For the transition period from _____ to _____ .

Commission File No. 0-18734

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.)

11388 Sorrento Valley Road, Suite 200, San Diego, California	**92121**
(Address of principal executive offices)	(Zip Code)

(858) 622-5200
(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 [X] NO [ ]

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). YES [X] NO [ ]

The number of shares of Common Stock of the registrant issued and outstanding as of August 4, 2003:

Class A Common stock, no par value	65,816,434
Class B Common stock, no par value	13,500

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PART I. FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

INDEPENDENT ACCOUNTANTS REPORT

Board of Directors and Shareholders
AVANIR Pharmaceuticals

We have reviewed the accompanying consolidated balance sheet of AVANIR Pharmaceuticals (the Company) and subsidiary as of June 30, 2003 and the related consolidated statements of operations and cash flows for the three-month and nine-month periods ended June 30, 2003 and 2002. These interim financial statements are the responsibility of the Company s management.

We conducted our review in accordance with standards established by the American Institute of Certified Public Accountants. A review of interim financial information consists principally of applying analytical procedures to financial data and of making inquiries of persons responsible for financial and accounting matters. It is substantially less in scope than an audit conducted in accordance with auditing standards generally accepted in the United States of America, the objective of which is the expression of an opinion regarding the financial statements taken as a whole. Accordingly, we do not express such an opinion.

Based on our review, we are not aware of any material modifications that should be made to such consolidated interim financial statements for them to be in conformity with accounting principles generally accepted in the United States of America.

We have previously audited, in accordance with auditing standards generally accepted in the United States of America, the consolidated balance sheet of the Company as of September 30, 2002 and the related consolidated statements of operations, shareholders equity and cash flows for the year then ended (not presented herein); and in our report dated December 24, 2002, we expressed an unqualified opinion on those financial statements. In our opinion, the information set forth in the accompanying consolidated balance sheet as of September 30, 2002 is fairly stated, in all material respects, in relation to the consolidated balance sheet from which it has been derived.

DELOITTE & TOUCHE LLP

San Diego, California
August 6, 2003

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AVANIR PHARMACEUTICALS

CONSOLIDATED BALANCE SHEETS (UNAUDITED)

	June 30, 2003	September 30, 2002
ASSETS		
Current assets:		
Cash and cash equivalents	$ 12,291,647	$ 8,630,547
Short-term investments in securities	1,203,954	695,840
Receivables, net	126,919	1,098,954
Inventory	210,854	238,126
Prepaid expenses	838,086	683,111
Total current assets	14,671,460	11,346,578
Investments in securities	704,695	2,986,023
Restricted investments	856,597	856,597
Property and equipment, net	7,798,651	3,180,966
Intangible assets, net	1,925,681	1,659,418
Other assets	342,762	303,347
TOTAL ASSETS	$ 26,299,846	$ 20,332,929
LIABILITIES AND SHAREHOLDERS EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 2,067,406	$ 2,705,606
Accrued expenses and other liabilities	1,642,557	1,598,625
Accrued compensation and payroll taxes	439,146	462,118
Loan payable		299,980
Current portion of deferred revenue	1,794,745	233,333
Current portion of capital lease obligations	138,492	128,833
Total current liabilities	6,082,346	5,428,495
Deferred revenue, net of current portion	21,350,232	
Capital lease obligations, net of current portion	229,438	323,764
Total liabilities	27,662,016	5,752,259
CONTINGENCIES (Note 13)		
REDEEMABLE CONVERTIBLE PREFERRED STOCK		
Series D no par value, 500 shares authorized; no and 50 shares issued and outstanding as of June 30, 2003 and September 30, 2002, respectively		521,189
SHAREHOLDERS EQUITY (DEFICIT)		
Preferred stock no par value, 9,999,500 shares authorized:		
Series C Junior Participating - 1,000,000 shares authorized; no shares issued or outstanding		
Common stock no par value:		
Class A - 99,288,000 shares authorized; 59,088,038 and 58,270,533 shares issued and outstanding as of June 30, 2003 and September 30, 2002, respectively	87,872,865	87,053,257
Class B - 712,000 shares authorized; 13,500 shares issued and outstanding as of June 30, 2003 and September 30, 2002 (convertible into Class A common stock)	8,395	8,395

Accumulated deficit	(89,260,062)	(73,002,878)
Accumulated other comprehensive income	16,632	707
Total shareholders equity (deficit)	(1,362,170)	14,059,481
TOTAL LIABILITIES AND SHAREHOLDERS EQUITY (DEFICIT)	$ 26,299,846	$ 20,332,929

See notes to consolidated financial statements.

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AVANIR PHARMACEUTICALS

CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

	Three months ended June 30,		Nine months ended June 30,	
	2003	2002	2003	2002
REVENUES:				
Research contracts and licenses	$	$ 5,000	$ 50,000	$ 5,089,167
Royalties and sale of royalty rights	302,741	763,851	1,377,486	2,547,151
Government research grants	95,481	27,129	394,085	28,255
Product sales		23,360	17,400	23,360
Total revenues	398,222	819,340	1,838,971	7,687,933
OPERATING EXPENSES:				
Research and development	4,523,860	4,119,526	12,995,762	9,631,293
General and administrative	1,185,881	1,343,075	3,477,765	3,376,114
Sales and marketing	727,465	392,881	1,758,933	1,073,678
Cost of product sales		4,731	3,102	4,731
Total operating expenses	6,437,206	5,860,213	18,235,562	14,085,816
LOSS FROM OPERATIONS	(6,038,984)	(5,040,873)	(16,396,591)	(6,397,883)
Interest income	49,375	150,833	202,525	519,659
Other income	8,060	8,649	19,919	95,597
Interest expense	(11,113)	(13,874)	(34,448)	(46,717)
LOSS BEFORE INCOME TAXES	(5,992,662)	(4,895,265)	(16,208,595)	(5,829,344)
Provision for income taxes	(36,766)		(36,766)	
NET LOSS	$ (6,029,428)	$ (4,895,265)	$ (16,245,361)	$ (5,829,344)
NET LOSS ATTRIBUTABLE TO COMMON SHAREHOLDERS:				
Net loss	$ (6,029,428)	$ (4,895,265)	$ (16,245,361)	$ (5,829,344)
Dividends on redeemable convertible preferred stock	(3,622)	(6,250)	(16,122)	(18,750)
Accretion of discount related to redeemable convertible preferred stock	(2,705)	(4,559)	(11,823)	(13,677)
NET LOSS ATTRIBUTABLE TO COMMON SHAREHOLDERS	$ (6,035,755)	$ (4,906,074)	$ (16,273,306)	$ (5,861,771)
NET LOSS PER SHARE:				
BASIC AND DILUTED	$ (0.10)	$ (0.08)	$ (0.28)	$ (0.10)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:				
BASIC AND DILUTED	58,741,635	58,275,445	58,463,328	58,180,998

See notes to consolidated financial statements.

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AVANIR PHARMACEUTICALS

CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

	Nine Months Ended June 30,	
	2003	**2002**
OPERATING ACTIVITIES:		
Net loss	$ (16,245,361)	$ (5,829,344)
Adjustments to reconcile net loss to net cash provided by (used for) operating activities:		
Depreciation and amortization	672,980	424,142
Compensation paid with common stock and stock options	213,749	133,947
Loss on disposal of assets	1,896	485
Intangible assets abandoned	74,432	
Changes in assets and liabilities:		
Receivables, net	972,035	1,743
Inventory	27,272	8,629
Prepaid expenses and other assets	(194,390)	63,933
Accounts payable	(638,200)	1,276,317
Accrued expenses and other liabilities	43,928	783,771
Accrued compensation and payroll taxes	(22,972)	1,734
Deferred revenue	22,911,644	
Net cash provided by (used for) operating activities	7,817,013	(3,134,643)
INVESTING ACTIVITIES:		
Investments in securities	(710,861)	(8,577,566)
Proceeds from sales and maturities of investments in securities	2,500,000	3,875,000
Patent costs	(392,741)	(455,929)
Purchases of property and equipment	(5,240,514)	(693,739)
Net cash used for investing activities	(3,844,116)	(5,852,234)
FINANCING ACTIVITIES:		
Proceeds from issuance of common stock	85,350	260,574
Dividends paid on preferred stock	(12,500)	(18,750)
Payments on loans and capital lease obligations	(384,647)	(271,039)
Net cash used for financing activities	(311,797)	(29,215)
Net increase (decrease) in cash and cash equivalents	3,661,100	(9,016,092)
Cash and cash equivalents at beginning of period	8,630,547	16,542,545
Cash and cash equivalents at end of period	$ 12,291,647	$ 7,526,453
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Interest paid	$ 34,448	$ 46,717
Income taxes paid	$ 91,600	$ 1,600
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Acquisition of equipment under capital leases	$	$ 122,662

Conversion of Series D redeemable convertible preferred stock to Class A common stock	$ 536,630	$

See notes to consolidated financial statements.

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AVANIR PHARMACEUTICALS

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

1. BASIS OF PRESENTATION

AVANIR Pharmaceuticals (AVANIR, we or the Company) has prepared the unaudited consolidated financial statements in this quarterly report in accordance with the instructions to Form 10-Q adopted under the Securities Exchange Act of 1934. Certain information and footnote disclosures normally included in consolidated financial statements prepared in accordance with accounting principles generally accepted in the United States have been condensed or omitted pursuant to such rules and regulations. These unaudited consolidated financial statements should be read with our audited consolidated financial statements and the accompanying notes included in our Annual Report on Form 10-K for the fiscal year ended September 30, 2002. In our opinion, all adjustments (consisting only of normal recurring adjustments) necessary to present a fair statement of our financial position as of June 30, 2003 and September 30, 2002, and the results of operations for the three-month and nine-month periods ended June 30, 2003 and 2002, have been made. The results of operations for the three-month and nine-month periods ended June 30, 2003 are not necessarily indicative of the results for the fiscal year ending September 30, 2003 or any future periods.

2. STOCK-BASED COMPENSATION

In December 2002, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 148 (SFAS No. 148), Accounting for Stock-based Compensation Transition and Disclosure, an Amendment of FASB Statement No. 123. SFAS No. 148 amends the disclosure requirements of SFAS No. 123 to require prominent disclosures in both annual and interim financial reports about the method of accounting for stock-based compensation and the effect of the method used on reported results. SFAS No. 123, as amended, encourages, but does not require, companies to record compensation cost for stock-based employee compensation at fair value. The Company has chosen to continue to account for stock-based compensation using the intrinsic value method prescribed in Accounting Principles Board (APB) Opinion No. 25, Accounting for Stock Issued to Employees, and related interpretations for all periods presented. Accordingly, compensation costs for stock options is measured as the excess, if any, of the fair value of the Company s stock at the date of the grant over the amount an employee must pay to acquire the stock.

The following table summarizes the impact on the Company s net loss had compensation costs been determined based upon the fair value at the grant date for awards under the stock option plans consistent with the methodology prescribed under SFAS No. 123.

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2003	2002	2003	2002
Net loss attributable to common shareholders, as reported	$(6,035,755)	$(4,906,074)	$(16,273,306)	$(5,861,771)
Add: Stock-based employee compensation included in reported net loss attributable to common shareholders	29,343	42,966	205,086	128,898
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(386,189)	(529,975)	(1,444,397)	(1,850,384)
Pro forma net loss attributable to common shareholders	$(6,392,601)	$(5,393,083)	$(17,512,617)	$(7,583,257)
Net loss per share:				
Basic and diluted as reported	$ (0.10)	$ (0.08)	$ (0.28)	$ (0.10)
Basic and diluted pro forma	$ (0.11)	$ (0.09)	$ (0.30)	$ (0.13)

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The Company accounts for stock options granted to non-employees using the fair value method. Compensation expense for options granted to non-employees has been determined in accordance with Emerging Issues Task Force (EITF) No. 96-18, Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services, as the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measurable.

3. RECLASSIFICATIONS

Certain amounts from the prior period have been reclassified to conform to the current period presentation.

4. BALANCE SHEET DETAILS

The following tables provide details of selected balance sheet items.

Receivables. Receivables consist of the following:

	June 30, 2003			September 30, 2002		
	Gross Carrying Value	Allowance for Doubtful Accounts	Net	Gross Carrying Value	Allowance for Doubtful Accounts	Net
Receivables	$132,291	$(5,372)	$126,919	$1,098,954	$	$1,098,954

Property and Equipment. During the three months ended June 30, 2003, the Company completed construction on approximately 31,700 square feet of laboratory and office space, located at 11388 and 11750 Sorrento Valley Road, San Diego, CA. At the time of completion of construction, $3.9 million that was classified as construction in progress was reclassified as leasehold improvements. Property and equipment as of June 30, 2003 and September 30, 2002 consist of the following:

	June 30, 2003			September 30, 2002		
	Gross Carrying Value	Accumulated Depreciation	Net	Gross Carrying Value	Accumulated Depreciation	Net
Research and development equipment	$3,267,262	$(1,176,212)	$2,091,050	$2,420,028	$ (867,991)	$1,552,037
Computer equipment and related software	1,090,533	(348,436)	742,097	851,952	(238,199)	613,753
Leasehold improvements	4,771,523	(325,987)	4,445,536	866,318	(175,410)	690,908
Office equipment, furniture, and fixtures	456,108	(166,227)	289,881	254,731	(128,557)	126,174
Construction in progress	230,087		230,087	198,094		198,094
Total property and equipment	$9,815,513	$(2,016,862)	$7,798,651	$4,591,123	$(1,410,157)	$3,180,966

Intangible Assets. Effective October 1, 2002, the Company adopted SFAS No. 142, Goodwill and Other Intangible Assets, which requires goodwill and other intangible assets that have indefinite useful lives to no longer be amortized; however, these assets must be reviewed at least

annually for impairment. Intangible assets with indefinite useful lives consist of costs of trademarks for AVANIR and Xenerex and similar names intended for use or potential use in the United States and the rest-of-the-world. Intangible assets with finite lives continue to be amortized over their useful lives for the three and nine-month periods ended June 30, and are evaluated for impairment whenever events or changes in circumstances indicate that their carrying value may not be recoverable under SFAS No. 144, Accounting for

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Impairment or Disposal of Long-lived Assets. AVANIR s amortizable intangible assets consist of the costs of patents, patent applications, and licenses.

Intangible assets, consisting of both intangible assets with finite and indefinite useful lives, are as follows:

	June 30, 2003			September 30, 2002		
	Gross Carrying Value	Accumulated Amortization	Net	Gross Carrying Value	Accumulated Amortization	Net
Intangible assets with finite lives:						
Patent applications pending	$1,259,232	$	$1,259,232	$ 966,781	$	$ 966,781
Patents	840,002	(237,863)	602,139	741,175	(192,190)	548,985
Licenses	41,215	(12,818)	28,397	41,215	(6,445)	34,770
Licenses pending				22,101		22,101
Total intangible assets with finite lives	2,140,449	(250,681)	1,889,768	1,771,272	(198,635)	1,572,637
Intangible assets with indefinite useful lives	35,912		35,912	86,781		86,781
Total intangible assets	$2,176,361	$(250,681)	$1,925,680	$1,858,053	$(198,635)	$1,659,418

Amortization expense related to amortizable intangible assets was $17,000 and $52,000 for the three-month and nine-month periods ended June 30, 2003, and $16,000 and $39,000 for the same periods, respectively, in the prior year. Based solely on the amortizable intangible assets as of June 30, 2003, the estimated annual amortization expense of intangible assets for the fiscal years ending September 30 is as shown in the following table. Actual amortization expense to be reported in future periods could differ from these estimates as a result of acquisitions, divestitures, and other relevant factors.

Amortization Expense

Quarter ending September 30, 2003	$ 13,693
Fiscal year ending September 30:	
2004	61,059
2005	60,574
2006	60,109
2007	58,842
Thereafter	376,259
Subtotal	630,536
Patent applications pending	1,259,232
Total	$ 1,889,768

5. USE OF ESTIMATES

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results

could differ from those estimates.

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6. INVENTORY

Inventory is stated at the lower of cost (first-in, first-out) or market. Inventory consists primarily of the raw material docosanol, which is the active ingredient in docosanol 10% cream. Docosanol in its present form as stored by the Company has a substantial shelf life, a relatively stable value and long-term use, and carries a low risk of becoming excess inventory or obsolete. AVANIR does not own or store any docosanol 10% cream in its finished product form. The Company and one of its licensees receive raw materials from a single supplier. AVANIR also supplies several other licensees with raw materials from the same supplier. The inability of a sole supplier to fulfill supply requirements of the Company or its licensees could materially impact future operating results.

7. ASSET SALE

On December 24, 2002, AVANIR sold an undivided interest in its Abreva® license agreement with SB Pharmco Puerto Rico, Inc. (SB or GlaxoSmithKline) to Drug Royalty USA, Inc. (Drug Royalty USA). Under the terms of the Drug Royalty USA agreement, Drug Royalty USA acquired the rights to all royalties accruing after September 30, 2002 from the sale of Abreva for cold sores in the United States and Canada payable under the Abreva license agreement, subject to AVANIR s right to receive 50% of all such royalties payable on sales of Abreva over $62 million per year. Drug Royalty USA paid AVANIR $20.5 million at the closing and an additional $3.6 million in April 2003 upon AVANIR s receipt from the United States Patent and Trademark Office of a grant of patent term extension for U.S. Patent Number 4,874,794. In connection with the sale, AVANIR and Drug Royalty USA entered into a security agreement pursuant to which AVANIR granted Drug Royalty USA a security interest in AVANIR s United States and Canadian patents related to the treatment of cold sores.

AVANIR retains all rights to develop and license docosanol 10% cream (or Abreva, as marketed by SB s parent, GlaxoSmithKline) outside the United States and Canada for the treatment of cold sores. AVANIR also retains all rights to develop and license docosanol 10% cream worldwide for all other indications, subject to certain rights of SB in the United States and Canada.

In recording the sale transaction in December 2002, AVANIR increased cash by $20.4 million (net of transaction costs), reduced accrued expenses by $301,000 in connection with the forgiveness of a related advance, and recorded deferred revenue in the amount of $20.7 million. We recorded the initial net proceeds of the transaction as deferred revenue because of our ongoing involvement in earning future revenues under our license agreement with SB. We also classified the additional $3.6 million received in April 2003 as deferred revenue, to be recognized ratably over the life of the license agreement.

The expiration date for U.S. Patent Number 4,874,794 has been extended from April 2009 to April 2014. The effect of extending the expiration of the patent from 2009 to 2014 has extended the term of the patent royalty and the accounting period over which the deferred revenue that relates to the patent royalty will be recognized as revenue. Thus, less deferred revenue is being recognized as revenue during the fiscal quarter ended June 30, 2003 than the fiscal quarter ended March 31, 2003. Deferred revenues recognized as revenue for the three-month and nine-month periods ended June 30, 2003 were $298,000 and $1.4 million, respectively. Abreva royalties earned for the three-month and nine-month periods ended June 30, 2002 were $764,000 and $2.5 million, respectively.

AVANIR is recognizing the deferred revenue amount as revenue over the life of the Drug Royalty USA agreement. Revenue recognition is being determined under the units-of-revenue method. Under this method, the amount of deferred revenue to be recognized as revenue in each period is calculated by multiplying (i) the ratio of the royalty payments due to Drug Royalty USA for the period to the total remaining royalties that we expect SB will pay Drug Royalty USA over the term of the agreement, by (ii) the unamortized deferred revenue amount. The portion of deferred revenue classified as part of current liabilities represents the amount AVANIR expects to realize as revenue within the next 12 months.

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The following table sets forth the deferred revenue recorded from the sale to Drug Royalty USA of rights to future Abreva royalties and other deferred revenue balances as of June 30, 2003 and September 30, 2002.

	Drug Royalty USA Agreement	Other Agreements	Total
Deferred revenue as of September 30, 2002	$	$233,333	$ 233,333
Changes during the period:			
Initial proceeds from sale of future Abreva royalties	20,500,000		20,500,000
Less cost of transaction	(143,982)		(143,982)
Net proceeds	20,356,018		20,356,018
Forgiveness of a related advance	300,912		300,912
Subtotal	20,656,930		20,656,930
Additions to deferred revenue	3,620,748		3,620,748
Recognized as revenues during the period	(1,366,034)		(1,366,034)
Deferred revenue as of June 30, 2003	$22,911,644	$233,333	$23,144,977
Classified as:			
Current portion of deferred revenue	$ 1,561,412	$233,333	$ 1,794,745
Deferred revenue, net of current portion	21,350,232		21,350,232
Total deferred revenue	$22,911,644	$233,333	$23,144,977

8. REVENUE RECOGNITION

Performance-based license fees. We recognize revenues from license fees when the performance requirements have been met, the fee is fixed or determinable, and collection of fees is probable. We defer revenues and recognize them ratably over the life of the agreement when we have continuing obligations to perform under the agreement.

Royalty revenues. We recognize royalty revenues from our licensed products when earned. Net sales figures used for calculating royalties due to the Company can often include deductions for costs of unsaleable returns, managed care chargebacks, cash discounts, freight and warehousing, and miscellaneous write-offs, which may vary over the course of the license agreement. Sales of Abreva, if publicly reported by the licensee s parent, GlaxoSmithKline, could differ from net sales used in calculating royalties and in determining the royalties earned in accordance with the license agreement. In agreements where we have sold our rights to future royalties under license agreements and we maintain continuing involvement in earning such royalties, we defer revenues and recognize them ratably over the life of the license agreement.

Revenue arrangements with multiple deliverables. In certain circumstances, we may enter into revenue arrangements whereby we are obligated to deliver to the customer multiple products and/or services (multiple deliverables). Such arrangements could include antibody generation services agreements and other forms of research collaborations. In these transactions, we allocate the total revenue to be earned under the arrangement among the various elements based on their relative fair value. In the case of antibody generation services, the allocation is based on customer-specific objective evidence of fair value. In the case of other forms of research collaborations, milestone payments are deferred and recognized ratably over the period of the obligation. We recognize revenue related to the delivered products or services only if: (i) the performance or service criteria are met; (ii) any undelivered products or services are not essential to the functionality of the delivered products or services; (iii) payment for the delivered products or services is not contingent upon delivery of the remaining products or services; (iv) we have an enforceable claim to receive the amount due in the event we do not deliver the undelivered

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products or services; and (v) as discussed above, there is evidence of the fair value for each of the undelivered products or services.

Federal research grant revenue. We recognize revenues from federal research grants during the period in which the related expenditures are incurred.

9. INVESTMENTS

The following tables summarize the Company s investments in securities:

	Amortized Cost	Gross Unrealized Gains (2)	Gross Unrealized Losses (2)	Fair Value
As of June 30, 2003:				
Certificates of deposit	$2,056,597	$21,387	$	$2,077,984
Government securities	692,017		(4,755)	687,262
Total	$2,748,614	$21,387	$(4,755)	$2,765,246
Reported as:				
Short-term investments:				
Classified as available-for-sale	$1,203,954			
Long-term investments:				
Classified as available-for-sale	704,695			
Restricted investments (1)	856,597			
Long-term investments	1,561,292			
Total	$2,765,246			

	Amortized Cost	Gross Unrealized Gains (3)	Gross Unrealized Losses (3)	Fair Value
As of September 30, 2002:				
Certificates of deposit	$2,056,597	$10,434	$	$2,067,031
Government securities	2,281,156	3,173	(12,900)	2,271,429
Commercial paper	200,000	5,542		205,542
Total	$4,537,753	$19,149	$(12,900)	$4,544,002
Reported as:				
Short-term investments:				
Classified as available-for-sale	$ 495,840			
Classified as held-to-maturity	200,000			
Short-term investments	695,840			
Long-term investments:				
Classified as available-for-sale	2,986,023			
Restricted investments (1)	856,597			

Long-term investments	3,842,620
Total	$4,538,460

(1) Restricted investments amounting to $856,597 as of June 30, 2003 and September 30, 2002 represent amounts that we pledged to our bank as collateral for letters of credit that our bank issued in connection with our leases of office and laboratory space.

(2) Gross unrealized gains of $21,387 and gross unrealized losses of $4,755 on government securities and certificates of deposit represent an accumulated net unrealized gain of $16,632, which is reported as Accumulated other comprehensive income on the consolidated balance sheet as of June 30, 2003.

(3) Gross unrealized gains of $13,607 and gross unrealized losses of $12,900 on government securities and certificates of deposit represent an accumulated net unrealized gain of $707, which is reported as Accumulated other comprehensive income on the consolidated balance sheet as of September 30, 2002.

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10. COMPUTATION OF NET LOSS PER COMMON SHARE

We compute basic net loss per common share by dividing the net loss attributable to common shareholders by the weighted-average number of common shares outstanding during the period (Basic EPS Method). We compute diluted net loss per common share by dividing the net loss attributable to common shareholders by the weighted-average number of common and dilutive common equivalent shares outstanding during the period (Diluted EPS Method). Dilutive common equivalent shares consist of shares issuable upon exercise of stock options and warrants and conversion of preferred stock. In the accompanying consolidated statements of operations, we have presented our net loss per share for the three-month and nine-month periods ended June 30, 2003 and 2002 using the Basic EPS Method and the Diluted EPS Method. The shares of common stock issuable upon exercise of stock options and warrants and conversion of preferred stock under the Diluted EPS method were excluded from the three-month and nine-month periods ended June 30, 2003 and 2002, as the inclusion of such shares would have been anti-dilutive.

The following table provides a reconciliation from the basic to the diluted EPS computations for the three and nine-month periods ended June 30, 2003 and 2002:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2003	2002	2003	2002
Numerator:				
Net loss	$ (6,029,428)	$ (4,895,265)	$ (16,245,361)	$ (5,829,344)
Less:				
Dividends on redeemable convertible preferred stock	(3,622)	(6,250)	(16,122)	(18,750)
Accretion of discount related to redeemable convertible preferred stock	(2,705)	(4,559)	(11,823)	(13,677)
Net loss attributable to common shareholders for basic earnings per share computation	(6,035,755)	(4,906,074)	(16,273,306)	(5,861,711)
Effect of dilutive securities:				
Stock options, warrants and convertible preferred stock				
Net loss attributable to common shareholders for diluted earnings per share computation	$ (6,035,755)	$ (4,906,074)	$ (16,273,306)	$ (5,861,711)
Denominator:				
Shares for basic and diluted net loss per share weighted average shares outstanding	58,741,635	58,275,445	58,463,328	58,180,998
Basic and diluted net loss per share	$ (0.10)	$ (0.08)	$ (0.28)	$ (0.10)

For the three months and nine months ended June 30, 2003 and 2002, options to purchase 6,388,238 and 5,602,842 shares of common stock, respectively, were excluded from the computation of diluted net loss per share, as the inclusion of such shares would be antidilutive.

For the three months and nine months ended June 30, 2003 and 2002, warrants to purchase 944,227 and 1,184,550 shares of common stock were excluded from the computation of diluted net loss per share, as the inclusion of such shares would be antidilutive.

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For the three months and nine months ended June 30, 2002, preferred stock convertible into 347,211 shares of common stock was excluded from the computation of diluted net loss per share, as the inclusion of such shares would be antidilutive.

11. SHAREHOLDERS EQUITY

Preferred Stock

Preferred stock consists of Series C Junior Participating Preferred Stock and Series D Redeemable Convertible Preferred Stock.

Series C Junior Participating Preferred Stock.

None of the Series C Junior Participating Preferred Stock is outstanding.

Series D Redeemable Convertible Preferred Stock.

During May 2003, the holders of Series D redeemable convertible preferred stock (Series D Shares) exercised their rights to convert 50 Series D Shares, representing $500,000 in redeemable convertible preferred stock and $36,630 in accrued and unpaid dividends, into 660,305 shares of Class A common stock, for an average stock price of $0.81 per share. None of the Series D Shares remained outstanding on June 30, 2003.

12. RECENT ACCOUNTING PRONOUNCEMENTS

In July 2002, the FASB issued SFAS No. 146, Accounting for Costs Associated with Exit or Disposal Activities, which addresses financial accounting and reporting for costs associated with exit or disposal activities and supersedes EITF Issue 94-3, Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring). SFAS No. 146 requires that a liability for a cost associated with an exit or disposal activity be recognized when the liability is incurred. Under Issue 94-3, a liability for an exit cost as defined in EITF 94-3 was recognized at the date of an entity s commitment to an exit plan. SFAS No. 146 also establishes that the liability should initially be measured and recorded at fair value. SFAS No. 146 became effective for the Company on January 1, 2003. The application of SFAS No. 146 did not have a material impact on the Company s financial statements.

In November 2002, the FASB issued FASB Interpretation No. 45, Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others, which elaborates on the disclosures to be made by a guarantor about its obligation under certain guarantees issued. It also clarifies that a guarantor is required to recognize, at the inception of a guarantee, a liability for the fair value of the obligation undertaken in issuing the guarantee. The Interpretation expands on the accounting guidance of SFAS No. 5, Accounting for Contingencies, SFAS No. 57, Related Party Disclosures, and SFAS No. 107, Disclosures about Fair Value of Financial Instruments. It also incorporates without change the provisions of FASB Interpretation No. 34, Disclosure of Indirect Guarantees of Indebtedness of Others. FASB Interpretation No. 45 became effective for the Company on January 1, 2003. The application of FASB Interpretation No. 45 did not have a material impact on the Company s financial statements.

In December 2002, the FASB issued SFAS No. 148, Accounting for Stock-Based Compensation -Transition and Disclosure, an Amendment of FASB Statement No. 123. SFAS No. 148 provides alternative methods of transition for a voluntary change to the fair value-based method of accounting for

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stock-based employee compensation. In addition, SFAS No. 148 amends the disclosure requirements of SFAS No. 123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based compensation and the effect of the method used on reported results. The voluntary transition and amended disclosure requirements are effective for the Company for the fiscal year ending September 30, 2003. The interim reporting requirements became effective for the Company s interim periods beginning January 1, 2003. The Company currently accounts for stock-based employee compensation under the intrinsic value method in accordance with APB No. 25. The Company does not plan to voluntarily change its method of accounting, but has implemented the amended disclosure requirements for the quarter ended June 30, 2003.

In January 2003, the FASB issued FASB Interpretation No. 46, Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51. Interpretation No. 46 provides guidance for identifying a controlling financial interest established by means other than voting interests. It requires consolidation of a variable interest entity by an enterprise that holds such a controlling financial interest. The Interpretation is effective for all newly formed variable interest entities after January 31, 2003. The Interpretation is effective for fiscal years or interim periods beginning after June 15, 2003 for variable interest entities in which a company holds a variable interest that it acquired before February 1, 2003. The adoption of FASB Interpretation No. 46 did not have a material impact on the Company s financial statements.

In May 2003, the FASB issued SFAS No. 150, Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity. SFAS No. 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). SFAS No. 150 is effective for financial instruments entered into or modified after May 15, 2003, and otherwise is effective for public entities at the beginning of the first interim period beginning after June 15, 2003. The effect, if any, of SFAS No. 150 on the Company s financial statements has not yet been determined.

13. CONTINGENCIES

In the ordinary course of business, we may face various claims brought by third parties, including claims relating to 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 and financial position. Additionally, any such claims, whether or not successful, could damage our reputation and business. Management believes the outcome of currently identified claims and lawsuits will not have a material adverse effect on the Company s operations or financial position.

14. SUBSEQUENT EVENT

On July 23, 2003, AVANIR sold and issued 6,728,396 shares of Class A common stock and warrants to purchase an aggregate of up to 1,345,673 shares of the Company s Class A common stock to several accredited investors and received gross proceeds totaling $10,025,320. The warrant exercise price is $2.23 per share. The financing transaction was made pursuant to the terms of a securities purchase agreement that provided each investor with a warrant to purchase one share of Class A common stock for every five shares of Class A common stock purchased under the agreement. The effect of the financing transaction was an increase in cash and shareholders equity in the amount of $10,025,320 before taking into effect the costs of the transaction.

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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 our company. You should not rely excessively on these forward-looking statements, because they are only predictions based on our current expectations and assumptions. When used in this report, the words intend, estimate, anticipate, believe, plan or expect and similar expressions are included identify forward-looking statements. 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 as set forth below and under Risk Factors that Might Affect Future Results and in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC). We disclaim any obligation or intent to update or announce revisions to any forward-looking statements to reflect actual events or developments.

Overview

AVANIR Pharmaceuticals, based in San Diego and incorporated in California in 1988, is a drug discovery and development company with a commercialized FDA-approved product (Abreva®) and products in clinical development for the treatment of pseudobulbar affect (Phase III), neuropathic pain (Phase II), and allergy and asthma (Phase I). AVANIR is engaged in small-molecule research to development treatments for central nervous system disorders and inflammatory diseases. Through the use of its Xenerex technology, AVANIR also develops human monoclonal antibodies for infectious diseases and other therapeutic applications.

AVANIR s first commercialized product, docosanol 10% cream, is a topical treatment for cold sores. The product is also known as Abreva in the United States and Canada, Herepair in South Korea and Abrax in Israel and is being marketed in those countries. A regulatory decision on marketing approval of the product in Sweden is pending. AVANIR has out-licensed docosanol 10% cream in the United States and in several foreign countries. AVANIR is continuing to expand its commercialization efforts for docosanol 10% cream while pursuing a broader effort to discover new drugs and develop others that are already in our development pipeline.

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AVANIR s offices and research facilities are located at 11388 Sorrento Valley Road, Suite 200, San Diego, California 92121. Our telephone number is (858) 622-5200 and our e-mail address is *info@AVANIR.com*. Additional information about AVANIR can be found on our website, at *www.AVANIR.com*, and in our periodic and current reports filed with the SEC. Copies of our current and periodic reports filed with the SEC are available at the SEC Public Reference Room at 450 Fifth Street, N.W., Washington, D.C. 20549, and online at *www.sec.gov* and our website at *www. AVANIR.com*.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

The preparation of financial statements in accordance with accounting principles generally accepted in the United States requires that management make a number of assumptions and estimates that affect the reported amounts of assets, liabilities, revenues and expenses in our consolidated financial statements and accompanying notes. Management bases its estimates on historical information and assumptions believed to be reasonable. Although these estimates are based on management s best knowledge of current events and actions that may impact the Company in the future, actual results may differ from these estimates and assumptions.

Our critical accounting policies are those that affect our financial statements materially and involve a significant level of judgment by management. Our critical accounting policies regarding revenue recognition are in the following areas: milestone payments in license agreements, royalties on licensed products, sale of rights to future royalties, and recognition of revenues in research contracts. Our critical accounting policies regarding expense recognition are principally related to research contracts. Our critical accounting policies also involve the valuation of long-lived and intangible assets.

Milestone Payments in License Agreements

We recognize revenues from license fees when the performance requirements have been met, the fee is fixed or determinable, and collection of fees is probable. We defer revenues and recognize them ratably over the life of the agreement when we have continuing obligations to perform under the agreement.

Our largest and most significant license agreement is with SB Pharmco Puerto Rico, Inc., a subsidiary of GlaxoSmithKline (GlaxoSmithKline). On March 31, 2000, we transferred the rights to manufacture, use, and sell Abreva in the United States and Canada to GlaxoSmithKline and gave them full control, authority and responsibility over research, development, registration including actions required to obtain appropriate government approvals, and commercialization of the product in those territories. GlaxoSmithKline has achieved and paid all of the performance milestones under the agreement. With regard to the milestones, we have no further performance obligations. Future revenues, if any, to be earned under the GlaxoSmithKline agreement will come solely from royalty revenues.

We expect to enter into additional license agreements in the future. We expect that each license agreement will have its own set of circumstances and terms of performance. We will consider the specific facts and circumstances of each license agreement to determine the appropriate revenue recognition for such items, including nonrefundable up-front fees and milestone payments and taking into consideration when the earnings process is complete and collection is reasonably assured.

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Royalties on Licensed Products

We recognize royalty revenues from our licensed products based on the reported sales by our licensees and computed in accordance with the specific terms of the license agreements. Since the launch of Abreva in October 2000 through June 30, 2003, substantially all of our royalties have come from GlaxoSmithKline. We have entered into additional license agreements that contain royalties as a source of revenues, and we expect to enter into additional similar license agreements with foreign-based companies.

Sale of Rights to Future Abreva Royalties

In December 2002, we sold an undivided interest in our license agreement with SB Pharmco Puerto Rico, Inc. (SB or GlaxoSmithKline) to Drug Royalty USA, Inc. (Drug Royalty USA) and received a payment of $20.5 million at closing and an additional $3.6 million in April 2003. Because of our ongoing involvement with GlaxoSmithKline in earning future royalty revenues, we have recorded the amounts received from Drug Royalty USA, net of costs of the transaction and after the forgiveness of certain advances, as deferred revenue. (See Note 7, Asset Sale, in the accompanying financial statements.) The amount recorded as deferred revenue is being recognized as revenue under the units-of-revenue method. Under this method, the amount of deferred revenue being recognized as revenue in each period is calculated by multiplying (i) the ratio of the royalty payments due to Drug Royalty USA for the period to the total remaining royalties that we expect SB will pay Drug Royalty USA over the term of the agreement, by (ii) the unamortized deferred revenue amount. The portion of deferred revenue classified as part of current liabilities represents the amount AVANIR expects to realize as revenue within the next 12 months.

Recognition of Revenues in Research Contracts

In certain circumstances, we may enter into research contracts or collaborations having obligations to deliver to the customer multiple products and/or services (multiple deliverables) in exchange for fees or milestone payments. Such contracts could include antibody generation services agreements and other forms of research collaborations.

Antibody generation services. As of June 30, 2003, Xenerex Biosciences, our subsidiary, was engaged in work on two research collaboration agreements, both of which have research initiation fees. In these agreements, the customer provides antigens to Xenerex. Xenerex then performs research services to develop potential antibodies for those antigens. If we are able to estimate the period of service in the contract in advance of beginning the work, then we recognize such research initiation fees ratably as revenue over the estimated period of service. If we are unable to identify the period of service in the contract in advance of beginning the work, we defer research initiation fees and recognize such fees as revenue once Xenerex has completed its efforts to create the antibodies. In the research phases of the research collaboration agreement, Xenerex may receive payment either to start a research phase or to complete a research phase (including receipt by the customer of the deliverable). We recognize revenue once the product has been delivered, because the earning process would be complete and an exchange has been made. Factors taken into consideration in recognizing revenues include the following:

The performance criteria have been met;

Any undelivered products or services are not essential to the functionality of the delivered products or services;

Payment for the delivered products or services is not contingent on delivery of the remaining products or services; and

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We have an enforceable claim to receive the amount due in the event we do not deliver the remaining undelivered products or services. *Other research contracts.* As with all our research contracts, including the up-front initiation fee, we defer revenue recognition until services have been rendered or products (e.g. developed antibodies) are delivered. The milestones established within the contract are set to approximate the effort associated with the completion of each phase.

Recognition of Expenses in Research Contracts

The Company recognizes expenses related to its clinical trials and other research contracts as the services are provided.

Valuation of Long-Lived and Intangible Assets

We assess the impairment of identifiable intangible assets and long-lived assets whenever events or changes in circumstances indicate that the carrying value may not be recoverable. 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.

When we determine that the carrying value of intangible assets or long-lived assets are not recoverable based upon the existence of one or more of the above indicators of impairment, we may be required to record impairment charges for these assets that have not been previously recorded.

RESULTS OF OPERATIONS

Comparison of Three Months Ended June 30, 2003 and 2002

Revenues

Revenues in the third quarter of fiscal 2003 amounted to $398,000, compared to $819,000 for the same period last year. Revenues in the third quarter of fiscal 2003 included $298,000 in revenues that the Company recognized from the sale of Abreva® royalty rights to Drug Royalty USA and $95,000 from government research grants. In December 2002, AVANIR sold rights to a portion of Abreva royalties to Drug Royalty USA and received $20.5 million at the closing and an additional $3.6 million in April 2003. AVANIR is recognizing the payments as revenue over the term of the agreement with Drug Royalty USA, or until April 2014. (See Note 7, Asset Sale.) Revenues in the third quarter of fiscal 2002 included $764,000 in royalties on Abreva product sales.

During fiscal 2003, we expect to recognize approximately $1.7 million in revenues from the sale transaction to Drug Royalty USA, with a corresponding reduction in deferred revenue. Also during the fiscal year, we expect to earn approximately $500,000 in revenues from research being performed under government research grants. Potential revenues from license fees, milestone payments, and royalties on foreign sales of docosanol 10% cream will depend substantially on the timing of approval decisions by foreign regulatory agencies and our ability to enter into additional license arrangements and achieve milestones under those arrangements. Potential revenues from licensing and/or selling products in

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clinical and preclinical development, including Neurodex and treatments for inflammatory diseases and high cholesterol, are less predictable.

Revenue-generating Contracts

Partnering, licensing and research collaborations have been, and will continue to be, an important part of AVANIR s business development strategy. We intend to partner with pharmaceutical companies that can help fund AVANIR s research in exchange for sharing in the rights to commercialize new drugs coming from this research. We have licensed and continue to seek licensees in other countries for docosanol 10% cream and other potential products in our development pipeline. Research collaborations also represent an important way to achieve our development goals, while sharing in the risks and the opportunities that come from such development efforts.

As of August 4, 2003, we had several contracts and grants that are generating or could generate revenues in the future to help fund our research and development programs. Five contracts are in the form of docosanol 10% cream (Abreva) license agreements, one contract is for a Neurodex license, and two contracts are in the form of antibody research service agreements. For the last three years, GlaxoSmithKline has been our most significant revenue source, representing over 95% of the Company s revenues in fiscal 2002. A list of our revenue-generating contracts is set forth in the following table.

Revenue-generating Contracts

Company or Research Grant	Description	Product License, Sale, Service or Research
GlaxoSmithKline	Undivided interest in the license agreement for Abreva® (U.S. and Canada)	Cold sore product license
Drug Royalty USA	License Purchase Agreement with Drug Royalty USA represents an undivided interest in the Abreva license agreement (U.S. and Canada)	Sale of undivided interest in Abreva license agreement and royalties
Miscellaneous docosanol licenses outside North America	- Israel - CTS Chemical Industries, Ltd. - South Korea - Boryung Pharmaceuticals Co., Ltd. - Egypt - BioPharm Group - Italy - Bruno Farmaceutici S.p.A	Cold sore product licenses
Medison Pharma, Ltd.	Neurodex license (Israel)	Research and commercialization agreement related to pseudobulbar affect
DNAX Research, Inc. and Peregrine Pharmaceuticals	Pre-funded antibody research currently totaling $233,000	Antibody generation services
Miscellaneous Federal and State Government grant awards	Represents five grant awards totaling approximately $1.4 million	Pre-clinical research related to genital herpes, anthrax, and cytomegalovirus

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Expenses

Operating Expenses. Total operating expenses were $6.4 million in the third fiscal quarter 2003, compared to $5.9 million in the same period in fiscal 2002. Contributing to the $577,000 increase in operating expenses were increases of $404,000 in research and development and $335,000 in sales and marketing, partially offset by a $157,000 reduction in general and administrative expenses. Research and development programs accounted for 70% of total operating expenses for the fiscal quarters ended June 30, 2003 and 2002. General and administrative expenses accounted for 19% and 23% of total operating expenses for the fiscal quarters ended June 30, 2003 and 2002, respectively. Sales and marketing expenses accounted for 11% and 7% of total operating expenses for the fiscal quarters ended June 30, 2003 and 2002, respectively. These and other costs are more fully described below.

Research and Development Expenses. Research and development (R&D) expenses were $4.5 million in the third fiscal quarter 2003, compared to $4.1 million in the same period a year ago. We had four clinical trials under way in the third fiscal quarter 2003, compared to one clinical trial during the same period a year ago. Increases in our clinical development programs for Neurodex in the treatment of pseudobulbar affect (PBA) in patients with multiple sclerosis and in the treatment of neuropathic pain, and increases in our research related to regulating MIF in the treatment of inflammatory diseases, were partially offset by decreases in spending on allergy and asthma research following completion of preclinical toxicology in 2002. (See the table on R&D spending on the page that follows.)

During the third fiscal quarter 2003, the Phase III clinical trials for Neurodex in the treatment of PBA in patients with multiple sclerosis and the open-label study of Neurodex accounted for 28% of all R&D spending. The recently completed Phase II open-label study of Neurodex for the treatment of neuropathic pain accounted for 14% of total R&D spending. Costs associated with AVANIR s allergy and asthma research program, including the Phase I clinical trials underway on our lead compound, accounted for 21% of total R&D spending. The balance of R&D spending was primarily for drug discovery and pre-clinical research related to development of treatments for various inflammatory diseases, cholesterol, cancer, and antibody research programs, including pre-clinical research on antibodies to the anthrax toxin and cytomegalovirus.

In the third fiscal quarter 2002, we were engaged in extensive toxicology and other pre-clinical work related to development of an orally-bioavailable compound for the treatment of allergy and asthma. Other spending in the third fiscal quarter 2002 related to the Phase II/III clinical trial for Neurodex in treating pseudobulbar affect and preparing for a Phase II open label study of Neurodex in the treatment of neuropathic pain.

We expect to continue efforts on current clinical development programs in fiscal 2003 treatments for PBA (Phase III trial and open-label study), neuropathic pain (Phase II) and allergy and asthma (Phase I) and earlier-stage research in the areas of inflammation, cholesterol reduction, cancer and infectious diseases.

We caution that many of our R&D efforts could experience delays, setbacks and failures, with no assurance that any of our clinical research or research conducted by our licensees or partners will ever reach the stage of a new drug application (NDA) with the FDA or that the NDA will be approved. The following table sets forth the status of, and costs attributable to, our proprietary research and clinical development programs.

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Research and Development Projects and Other Research Programs Expense

Company-Funded Projects (1):	Three Months Ended June 30, 2003 (2)	Three Months Ended June 30, 2002 (2)	Nine Months Ended June 30, 2003 (2)	Nine Months Ended June 30, 2002 (2)	Inception Through June 30, 2003(2) (3)	Estimated Cost To Complete Project (2)
Development of Neurodex for FDA marketing approval in treating PBA. Estimated timing to complete remaining phases of project necessary to file an NDA with the FDA is mid- 2004	$1,260,026	$ 969,804	$ 3,355,826	$2,256,716	$ 8,094,637	$ 7M
Development of Neurodex for neuropathic pain. Phase II open-label study completed	618,340	568,724	1,315,872	1,152,932	4,606,936	(4)
Develop AVP-13358 as a treatment for allergy and asthma. Estimated timing to complete Phase I and bioanalytical work: third quarter of 2004. Estimated timing to license the product: second quarter of 2005	965,104	1,564,295	3,468,760	2,989,563	13,281,892	9M
Develop compound for regulating the target, MIF, as a potential treatment for inflammatory diseases Estimated timing to complete Phase I and license the product: fourth quarter of 2005	591,435	206,714	1,606,606	1,022,799	4,437,303	12M
Government-Funded Projects:						
Pre-clinical research for potential treatments for genital herpes and anthrax and development of a blood donor program for infectious diseases Estimated timing to complete the various projects is up to one year	220,454	35,056	564,505	37,531	866,328	0.7M(5)
Other Pre-clinical Research Projects:						
Use of proprietary technologies (CCM and antibody generation	868,501	774,933	2,684,193	2,171,752	12,300,609	

technology) to pursue potential treatments for lowering cholesterol and treating infectious diseases. Costs and timing to complete pre-clinical research are unpredictable because of the uncertainty of outcomes of the research					
Total	$4,523,860	$4,119,526	$12,995,762	$9,631,293	$43,587,705

1. At June 30, 2003, we held the worldwide rights to manufacture, market and sell all of the products in clinical development and any of the products that might come from our own internal R&D programs. All dates in the schedule refer to calendar year.

2. Each project includes allocation of laboratory occupancy costs. M refers to millions.

3. Inception dates are on or after October 1, 1998, at which time we began identifying and tracking costs for these research programs.

4. Clinical development and licensing strategy are being evaluated.

5. State and Federal research grants totaling $1.4 million are related to genital herpes, antibodies to anthrax and cytomegalovirus, and a blood donor program.

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Research and Development Program Strategy

We are pursuing an R&D program strategy that is intended to provide a stream of potential products in various stages of development as well as in several therapeutic areas and technology platforms. Our approach is not to rely on any one therapeutic area or technology platform, but to extend our development expertise across several therapeutic areas, technology platforms and research targets that could lead to a product. To help conserve cash resources as we continue these R&D programs, we intend to use our own funds for clinical trials that are relatively small and license our products and technologies to others when we expect the development costs will exceed available cash resources. We are pursuing this strategy because the costs of pursuing all of our development programs through all clinical phases are beyond our current available cash resources. There can be no assurances that we will be successful in licensing any of our products or technologies.

Neurodex for the treatment of PBA. We completed the initial Phase II/III clinical trial in May 2002. We intend to use the trial to qualify as one of two required pivotal clinical trials necessary to obtain FDA approval for marketing the product in the United States. A second Phase III clinical trial and an open label study are currently underway. Our goal is to complete the enrollments in those trials before the end of calendar year 2003. If the trials are successful, we intend to file an NDA with the FDA by mid-2004 calendar year. If we are successful in filing an NDA, then we expect to develop our own sales force in preparation for selling the product if it is approved by the FDA. We also intend to find a licensee and/or co-promotion partner for Neurodex for both indications of PBA and neuropathic pain, as more fully described below.

Neurodex for the treatment of neuropathic pain. In June 2003, we announced the results of a four-week open-label dose escalation study of Neurodex in patients with painful diabetic neuropathy. Results of the Phase II study indicated that Neurodex was well tolerated up to the highest target dose, and patients reported decreased pain intensity that was significantly different from baseline ($p < 0.0001$). Out of 36 adult patients with diabetic neuropathy who experience pain on a daily basis in the lower extremities, three did not complete the study. Of those patients not completing the study, two were due to adverse events (one serious and not related, one serious and possibly related) and one due to inability to comply with the protocol. Commonly reported adverse events (reported by three or more individuals) included nausea, constipation, diarrhea, dry mouth, fatigue, dizziness, insomnia, headache, upper respiratory tract infection, and somnolence. Most adverse events were either mild or moderate in intensity, and 92% of participants completed the study.

We are currently evaluating the Phase II study results for Neurodex for the treatment of neuropathic pain and are developing plans for next steps in clinical development. As part of our strategy, we intend to seek a licensee of Neurodex for all markets outside the United States and a co-promotion partner to share in the distribution of the product in the United States. Thereafter, we expect to begin recognizing revenues from the license or co-promotion arrangement. There can be no assurances as to the timing of such a license or co-promotion arrangement.

Development program for allergy and asthma (IgE regulator). In March 2003, we initiated Phase Ia clinical trials of our lead oral compound for the treatment of allergy and asthma. Our compound appears capable of selectively inhibiting the production of immunoglobulin epsilon (IgE) antibodies, a target that has been identified in the pathophysiology of allergy and asthma. Phase 1a trials are intended to establish safety of the drug in single rising doses in healthy patients and to assess the compound s affect on certain disease biomarkers. These trials will be followed by Phase Ib clinical trials using rising multi-doses in healthy patients. We estimate that Phase Ib clinical trials for this compound will be completed by mid-2004 calendar year. Assuming the results are favorable, we expect to license the drug to another pharmaceutical company and begin recognizing revenues from our partner by mid-2005 calendar year.

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Anti-inflammatory research program (MIF inhibitor). We are currently conducting toxicology studies and other preclinical research on several potential drug candidates capable of inhibiting or blocking the activity of macrophage migration inhibitory factor (MIF). Our research indicates that MIF may serve as a potential drug target in a variety of diseases, including rheumatoid arthritis, Crohn s disease, colitis and asthma. Assuming we are successful in finding a lead compound and filing with the FDA for an investigational new drug (IND), we intend to license the compound to another pharmaceutical company by December 2005 and begin recognizing positive cash flows thereafter from our partner.

Government research contracts. AVANIR also is engaged in research funded by $1.4 million in government research grants. The government research grants are to be used for investigating the market potential for a topical genital herpes treatment, conducting research on various docosanol-based formulations for a potential genital herpes product, development of antibodies to anthrax toxins and cytomegalovirus, and development of a blood donor program intended to find high-affinity antibodies to infectious diseases. We expect the current government-funded research programs will continue through fiscal years 2003 and part of fiscal 2004.

Other Operating Expenses

General and Administrative Expenses. During the third fiscal quarter 2003, general and administrative expenses amounted to $1.2 million, compared to $1.3 million in the same period a year ago. The Company continues to concentrate its efforts on R&D programs and market research for Neurodex and expects that near-term increases in general and administrative expenses will be moderate.

Sales and Marketing Expenses. During the third fiscal quarter 2003, sales and marketing expenses were $727,000, compared to $393,000 in the same period a year ago. Higher expenses in the third fiscal quarter 2003 were related to market research and planning and preparation for product launch of Neurodex for the treatment of pseudobulbar affect.

Loss from Operations

For the third fiscal quarter 2003, the loss from operations was $6.0 million, compared to $5.0 million for the same period a year ago. Contributing to the higher losses were the higher R&D expenses associated with additional clinical development programs and costs related to product planning for Neurodex. Revenues decreased by $421,000, reflecting the sale of rights to a portion of future Abreva royalties. Higher operating expenses reflected the greater number and extent of R&D programs and increases in sales and marketing activities, including market research and planning for the product launch of Neurodex in the treatment of PBA.

Other Income and Expenses

Interest Income. In the third fiscal quarter 2003, interest income amounted to $49,000, compared to $151,000 for the same period a year ago. The decrease in interest income during the second fiscal quarter 2003 was primarily due to lower average interest rates on investments and lower average invested amounts compared with the same period a year ago.

Other Income. Other income, consisting of rental income, was $8,000 in the third quarter of fiscal 2003, compared to $9,000 in the same period a year ago.

Interest Expense. In the third fiscal quarter 2003, interest expense amounted to $11,000, compared to $14,000 for the same period a year ago. Lower interest expense for the second fiscal quarter 2003 was due to lower interest rates on extended payment plans for our insurance policies.

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Net Loss

For the third fiscal quarter 2003, the net loss attributable to common shareholders was $6.0 million, compared to $4.9 million for the same period a year ago. The basic and diluted net loss per share was $0.10 for the third fiscal quarter 2003, compared to $0.08 for the same period a year ago.

For the remainder of the 2003 fiscal year, we expect to continue developing our current products, with particular emphasis on products engaged in clinical trials. We intend to continue to develop Neurodex for the treatment of both pseudobulbar affect (Phase III status) and neuropathic pain (Phase II status) and our lead compound for the treatment of allergy and asthma (Phase I status). We expect that our spending on clinical trials and earlier stage R&D programs, combined with other operating costs, will exceed our revenues for at least the next two quarters. We anticipate that we will file a New Drug Application with the FDA by mid-2004 calendar year for Neurodex for the treatment of pseudobulbar affect.

RESULTS OF OPERATIONS

Comparison of Nine Months Ended June 30, 2003 and 2002

Revenues

Revenues for the first nine months of fiscal 2003 amounted to $1.8 million, compared to $7.7 million for the same period last year. Revenues for the first nine months of fiscal year 2003 included $1.4 million in revenues that the Company recognized from the sale of certain rights to future Abreva royalties to Drug Royalty USA, $394,000 from government research grants and $17,000 in sales of the raw material docosanol. Revenues for the first nine months of fiscal 2003 included a $5 million milestone payment from GlaxoSmithKline and $2.5 million in royalties on Abreva® product sales.

Expenses

Operating Expenses. Total operating expenses were $18.2 million in the first nine months of fiscal 2003, compared to $14.1 million in the same period in fiscal 2002. The 29% increase in operating expenses was primarily caused by a 35% increase in spending on research and development programs. Research and development programs accounted for 71% and 68% of total operating expenses for the first nine months of fiscal 2003 and 2002, respectively. General and administrative expenses accounted for 19% and 24% of total operating expenses for the first nine months of fiscal 2003 and 2002, respectively. Sales and marketing expenses accounted for 10% and 8% of total operating expenses for first nine months of fiscal 2003 and 2002, respectively. These and other costs are more fully described below.

Research and Development Expenses. Research and development (R&D) expenses were $13.0 million in the first nine months of fiscal 2003, compared to $9.6 million in the same period a year ago. Costs associated with completion of toxicology, filing an IND and initiating Phase I clinical trials of AVANIR s lead compound for the treatment of allergies and asthma accounted for 27% of total R&D spending in the first nine months of fiscal 2003. The clinical trials of Neurodex in the treatment of pseudobulbar affect in patients with multiple sclerosis and in the treatment of neuropathic pain accounted for 36% of all R&D spending in the first nine months of fiscal 2003. The balance of R&D spending was for other programs, including pre-clinical research related to inflammation and cholesterol-lowering compounds and antibody research programs.

In the first nine months of fiscal 2002, R&D expenses were primarily related to costs associated with pre-clinical development of an orally-bioavailable compound for the treatment of allergy and asthma, a Phase II/III clinical trial for Neurodex in treating pseudobulbar affect, and development of the antibody generation technology.

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General and Administrative Expenses. General and administrative expenses amounted to $3.5 million in the first nine months of fiscal 2003, representing a 3% increase over expenses of $3.4 million in the same period in the prior year. Higher expenses were attributable to modest increases in staff size to support growing Company operations. General and administrative expenses continued the trend established in fiscal 2002 of growing at a slower rate than R&D and sales and marketing expenses.

Sales and Marketing Expenses. During the first nine months of fiscal 2003, sales and marketing expenses were $1.8 million, compared to $1.1 million in the same period a year ago. Higher expenses in the first nine months of fiscal 2003 were related to market research and planning and preparation for product launch of Neurodex for the treatment of pseudobulbar affect.

Loss from Operations

For the first nine months of fiscal 2003, the loss from operations was $16.4 million, compared to $6.4 million for the same period a year ago. Contributing to the higher losses were $5.8 million lower revenues, $3.4 million higher R&D expenses, $685,000 higher sales and marketing expenses and $102,000 higher general and administrative expenses. During the first nine months of fiscal 2003, AVANIR did not receive any milestone payments from its licensees and incurred higher R&D expenses associated with three clinical development programs and costs related to product planning for Neurodex. During the first nine months of fiscal 2002, AVANIR received a $5.0 million milestone from GlaxoSmithKline and had only one clinical development program underway.

Other Income and Expenses

Interest Income. In the first nine months of fiscal 2003, interest income amounted to $203,000 compared to $520,000 for the same period a year ago. The decrease in interest income during the first nine months of fiscal 2003 was primarily due to lower average interest rates on investments and lower average invested amounts compared with the same period a year ago.

Other Income. Other income amounting to $20,000 in the first nine months of fiscal 2003 represents rental income on emergency standby power generating equipment. Other income, amounting to $96,000 in the first nine months of fiscal 2003, represents miscellaneous Xenerex contract services, rental income for use of the Company s conference center and rental income on emergency standby power generating equipment.

Interest Expense. In the first nine months of fiscal 2003, interest expense amounted to $34,000 compared to $47,000 for the same period a year ago. Lower interest expense for the first nine months of fiscal 2003 was due to lower interest rates on extended payment plans for our insurance policies.

Net Loss

For the first nine months of fiscal 2003, the net loss attributable to common shareholders was $16.3 million, compared to $5.9 million for the same period a year ago. The basic and diluted net loss per share was $0.28 for the first nine months of fiscal 2003, compared to $0.10 for the same period a year ago.

LIQUIDITY AND CAPITAL RESOURCES

As of June 30, 2003, we had cash and investments totaling $15.1 million, including cash and cash equivalents of $12.3 million, short and long-term investments of $1.9 million and restricted investments of $857,000. Our net working capital balance as of June 30, 2003 was $8.6 million. As of September 30,

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2002, we had cash and investments totaling $13.2 million, including cash and cash equivalents of $8.6 million, short and long-term investments of $3.7 million and restricted investments of $857,000. Our net working capital balance as of September 30, 2002 was $5.9 million.

Operating Activities. Net cash provided by operating activities amounted to $7.8 million in the first nine months of fiscal 2003, compared to net cash used for operating activities of $3.1 million during the same period a year ago. On December 24, 2002, we sold to Drug Royalty USA an undivided interest in our Abreva license agreement with GlaxoSmithKline and received $20.4 million, net of transaction costs, at closing and an additional $3.6 million in April 2003. The net cash provided by operating activities in the first nine months of fiscal 2003 reflects the $24.1 million in cash received from Drug Royalty USA and an $876,000 royalty payment from GlaxoSmithKline, partially offset by the $16.2 million net loss for the first nine months of the fiscal year. The sale of rights to future Abreva royalties was recorded as deferred revenue and is being recognized as revenue over the life of the license agreement with GlaxoSmithKline. (See Note 7, Asset Sale in the accompanying notes to the financial statements.) For the first nine months of fiscal 2002, net cash used for operations amounting to $3.1 million reflected a loss of $5.8 million, partially offset by a $1.3 million increase in accounts payable, a $784,000 increase in accrued expenses and other liabilities, depreciation and amortization ($424,000) and compensation paid with stock options ($134,000).

Investing Activities. Net cash used for investing activities during the first nine months of 2003 amounted to $3.8 million, including investments in securities totaling $711,000, capital expenditures related to purchases of capital equipment and leasehold improvements totaling $5.2 million, and patent costs of $393,000, partially offset by sales and maturities of investments totaling $2.5 million. Net cash used for investing activities during the first nine months of fiscal 2002 amounted to $5.9 million, including investments in securities totaling $8.6 million, capital expenditures for property and equipment totaling $694,000 and patent costs of $456,000, partially offset by sales and maturities of investments totaling $3.9 million.

In May 2003, the Company completed construction on approximately 31,700 square feet of existing leased laboratory and office space, located at 11388 and 11750 Sorrento Valley Road, San Diego, California. The facilities are subject to a lease between the Company and Sorrento Plaza, a California limited partnership, effective May 20, 2002. Leasehold improvements to the facilities were necessary before taking occupancy. The Company also made leasehold improvements to laboratory and office space at 11388 Sorrento Valley Road to accommodate the relocation of several departments. The expenditures at all three facilities are intended to accommodate current as well as potential future expanded business operations. The Company has 57,065 square feet of usable laboratory and office space and the capacity to accommodate approximately 100 employees. The Company currently has about 65 employees. Total leasehold improvements that the Company has made for the nine months ended June 30, 2003 have amounted to $3.9 million. (See Note 4, Balance Sheet Details Property and Equipment.)

Financing Activities. Net cash used for financing activities amounted to $312,000 during the first nine months of 2003, compared to $29,000 in cash used for financing activities for the same period a year ago. We believe that cash, short and long-term investments in securities and restricted investments totaling $15.1 million as of June 30, 2003, together with the sale of Class A Common Stock that raised an additional $10.0 million in July 2003, plus anticipated future payments and revenues, should be sufficient to sustain our planned level of operations for at least the next twelve months. Additionally, to continue to enhance our capital base and liquidity and to continue to fund the development of our drug candidates and technology platforms, we expect to continue to pursue various alternatives for raising additional funds during the next twelve months. Potential alternatives that we are considering for raising capital include, but are not limited to, partnering arrangements where partners share development costs, issuance

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of debt or equity securities, and licensing or sales of any of our platform technologies or new drug candidates.

RECENT ACCOUNTING PRONOUNCEMENTS

See Note 12, Recent Accounting Pronouncements in the accompanying financial statements for a discussion of recent accounting pronouncements and their effect, if any, on the Company.

RISK FACTORS THAT MIGHT AFFECT FUTURE OPERATIONS

We expect that we will need to raise additional capital to fund ongoing operations. If we cannot raise additional capital, we may be forced to curtail operations. If we succeed in raising additional capital, it may affect our stock price and future revenues.

In order to maintain sufficient cash and investments for future operations, we will need to raise additional capital. We expect to seek to raise additional capital over the next twelve months through various alternatives, including licensing or sales of our technologies and drug candidates and sale of shares of our Class A common stock.

If we raise capital through licensing or sales of one or more of our technologies and drug candidates, then we may lose an opportunity for product sales if a product is successfully developed, approved by the U.S. Food and Drug Administration (FDA) and marketed. If we license any of our technologies or drug candidates, then the development of the product or technology will no longer be in our control. A licensee might not ever reach any of the milestones in a license agreement and we would not earn any additional payments in such an event. Further, if we sell any of our technologies or drug candidates, there can be no assurance that the sales price will cover our investment in such technology or drug candidate.

If we raise capital by issuing additional shares of Class A common stock at a price per share less than the then-current market price per share, then the value of the shares of Class A common stock outstanding will be diluted or reduced. Further, even if we were to sell shares of common stock at prices equal to or higher than the current market price, the issuance of additional shares may depress the market price of our common stock and dilute your voting rights in the Company.

We may not be able raise capital on terms that we find acceptable, if at all. If we are unable to raise additional capital to fund future operations, then we might have to reduce operations or defer or abandon one or more of our clinical research programs. Any of these actions could be expected to have an adverse effect on our stock price.

AVANIR and its licensees may not be successful in obtaining regulatory approval of docosanol 10% cream immediately as an over-the-counter (OTC) product in the rest of the world or in licensing, marketing and selling the product in foreign countries.

AVANIR and its licensees face a wide variety of risks in foreign countries in obtaining regulatory approval and in marketing and selling docosanol 10% cream, including:

Regulatory approval requirements differ by country, and obtaining approvals to market the drug in foreign countries may be difficult to obtain, may require additional costly and time consuming clinical trials, or may require prescription status first before obtaining sufficient experience to warrant approval as an OTC product;

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Building product awareness of a new drug, whether prescription or OTC, among customers or retail store decision makers may require a substantial amount of product promotion, which does not guarantee success;

Consumers may not perceive that docosanol 10% cream is superior to existing and potentially new OTC products for oral herpes;

Acceptance of docosanol 10% cream in the OTC consumer market may not be widespread; and

Potential price erosion could occur due to competitive products and responses to our product s introduction.

Developing and testing a drug candidate is a very expensive and time-consuming process that may not ultimately lead to a marketable product.

We may spend millions of dollars in pre-clinical studies researching the potential safety and efficacy of our drug candidates. If any such drug candidate fails to demonstrate the desired safety and efficacy, we may abandon the development of the compound, in which event we would not recover our expenditures incurred to date for that compound. If a compound appears to be safe and effective in pre-clinical studies, we may decide to proceed with human clinical trials. The full complement of clinical trials required to obtain regulatory approval for a new drug may involve several million dollars. Because of the Company s limited financial resources, we may be required to license the compound to a pharmaceutical company with greater financial resources in order to complete development of the drug. There is no assurance that we will be able to find a large pharmaceutical company interested in licensing the drug or, if we do locate such a licensee, that the proposed license terms will be acceptable to the Company. In the event that we are unable to find a large pharmaceutical partner or licensee on acceptable terms, we may be forced to abandon one or more of our drug candidates.

We expect our quarterly operating results to fluctuate significantly from period-to-period for a number of reasons.

Future operating results will continue to be subject to significant quarterly fluctuations based on a variety of factors, including:

Limited rights to future Abreva royalties In December 2002 we sold to Drug Royalty USA the rights to a substantial portion of our future royalty revenues from sales of Abreva by GlaxoSmithKline. We will not receive any future royalty payments unless and until annual Abreva sales exceed $62 million, at which time we will receive one-half of the stated royalty rate on any excess sales. We expect that any royalty payments on these excess sales, if any, would occur only once a year, after the end of each calendar year.

Concentration of significant customers, suppliers and industries Milestone payments and royalties earned from a single licensee (GlaxoSmithKline) accounted for approximately 95% and 99% of our fiscal 2002 and 2001 revenues, respectively. We have now received all of the milestone payments from GlaxoSmithKline. With the sale of our Abreva royalty rights to Drug Royalty USA, future royalty payments from GlaxoSmithKline will come exclusively from our remaining 50% share of Abreva royalties on contract sales in excess of $62 million a year. Additionally, we purchase our raw materials from a sole foreign supplier that has been approved for manufacture by the FDA. Any disturbances or delays in the manufacture of the raw materials could seriously and adversely affect our business.

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Achievement of milestones under license agreements may be outside our control Recognition of revenue under several of our license agreements may depend solely on the efforts and performance of our licensees in reaching milestones outside of our control. Such milestones may include specific events, such as regulatory approval, product launch, the passage of time, or reaching a sales threshold.

Acquisitions/alliances If, in the future, we acquire technologies, products, or businesses, or we form alliances with companies requiring technology investments or commitments, we will face a number of risks to our business. The risks that we may encounter include those associated with integrating operations, personnel, and technologies acquired or licensed, and the potential for unknown liabilities of the acquired business. Our business and operating results on a quarterly basis could be adversely affected if any of our acquisition or alliance activities are not successful.

Foreign sales of docosanol 10% cream and other potential products are subject to various foreign trade risks.

Our license agreement with GlaxoSmithKline is for the United States and Canada only. We also have exclusive license agreements for docosanol 10% cream for Israel, South Korea, Italy and Egypt. We are holding discussions with other potential licensees for marketing and selling docosanol 10% cream in other countries not already licensed. However, we may not finalize any license or distribution arrangements for other territories on a timely basis or on favorable terms, if at all. Further, our foreign licensees expose us to various foreign trade risks relating to development and marketing of docosanol 10% cream. We may arrange for contracts in the future for the manufacture, marketing and distribution of docosanol 10% cream overseas by foreign licensees, which will be substantially outside our control. Even if we are able to obtain experienced licensees in foreign markets, specific risks that could impact significantly our ability to deliver products abroad include:

difficulties in obtaining regulatory approval of docosanol 10% cream in foreign countries;

changes in the regulatory and competitive environments in foreign countries;

changes in a specific country s or region s political or economic conditions;

difficulty in finding foreign partners with sufficient capital to effectively launch, market and promote the product;

shipping delays;

difficulties in managing operations across disparate geographic areas;

fluctuations in foreign currency exchange rates;

prices of competitive products;

difficulties associated with enforcing agreements through foreign legal systems;

trade protection measures, including customs duties and export quotas; and

foreign tax withholding laws.

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Our Xenerex antibody generation technology faces intense competition and rapid technological change, particularly in the area of product development for infectious diseases. If we fail to develop antibody products that keep pace with competitive products and new technologies, our products and technologies could become obsolete.

The biotechnology industry is highly competitive and subject to significant and rapid technological change. We compete with several companies that develop and market antibody products and technologies. These competitors have specific expertise and technologies related to antibody development. Also, they introduce new or modified technologies from time to time. These companies include Abgenix, Inc., Medarex, GenPharm, Kirin Brewing Co., Genmab, Cambridge Antibody Technology Group, Protein Design Labs, Dyax, and MorphoSys. Many of these companies, either alone or together with their customers, have substantially greater financial resources, larger research and development staffs, and substantially greater experience than we do.

Our failure or inability to comply with government regulations regarding the development, production, testing, manufacturing and marketing of our products may adversely affect our operations.

Governmental authorities in the U.S., including the FDA, and other countries highly regulate the development, production, testing, manufacturing and marketing of pharmaceutical products. The clinical testing and regulatory approval process can take a number of years and requires the expenditure of substantial resources. Failure to obtain, or delays in obtaining, these approvals will adversely affect our business operations, including our ability to commence marketing of any proposed products. We may find it necessary to use a significant portion of our financial resources for research and development and the clinical trials necessary to obtain these approvals for our proposed products. We will continue to incur costs of development without any assurance that we will ever obtain regulatory approvals for any of our products under development. Additionally, we cannot predict the extent to which adverse governmental regulation might arise from future U.S. or foreign legislative or administrative action. Moreover, we cannot predict with accuracy the effects of any future changes in the regulatory approval process and in the domestic health care system for which we develop our products. Future changes could affect adversely the time frame required for regulatory review, our financial resources, and the sale prices of our proposed products, if approved for sale.

Unsuccessful or lengthy research and development programs for proposed new products could negatively affect our business.

The drug development process is lengthy and capital intensive. Our drug development programs are exposed to all of the risks inherent in product development based on innovative technologies, including unanticipated development problems and the possible lack of funding or collaborative partners. Any of a number of problems in the development process could result in the abandonment or substantial change in the development of a specific product. Our Phase III clinical trial of Neurodex for the treatment of pseudobulbar affect in multiple sclerosis patients may experience setbacks or failures for reasons we have not anticipated. We might experience delays in our plans for review with the FDA of the results of our Phase II open-label dose escalation clinical trial of Neurodex for the treatment of neuropathic pain and in gaining timely acceptance by the FDA of our Phase III study plans. Our Phase I clinical trial of our lead compound for treating allergy and asthma may not demonstrate the efficacy of, or have the safety profile necessary for, a proposed product for human use. Unsuccessful clinical trial results for our proposed products could affect materially and adversely our future business operations and financial condition.

Business interruptions could adversely affect our business.

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Our operations are vulnerable to interruption by fire, earthquake, power loss, telecommunications failure, terrorist attacks and other events beyond our control. For example, during 2001 and again in 2003, we have experienced blackouts, where we experienced a period of time lasting several hours in which our utility provider was unable to provide us with electrical power. The loss of electrical power or blackouts for any significant periods of time could adversely affect our ability to conduct experiments and could also harm our vendors. Further, we could lose valuable data made to date in experiments currently underway. We have mitigated the severity of power losses by installing on our premises emergency power equipment, which we have used on several occasions to supply electricity in the areas that we consider to be the most critical to our operations. However, the emergency power unit does not cover all of our electrical needs and, further, it might not operate properly in the event of a power loss.

Our inability to attract and retain key management and scientific personnel could negatively affect our business.

Our success depends on the performance of a small core staff of key management and scientific employees with biotech experience. Given our small staff size and programs currently under development, we depend substantially on our ability to hire, train, retain and motivate high quality personnel, especially our scientists and management team in this field. If we were to lose one or more of our key scientists, then we would likely lose some portion of our institutional knowledge and technical know-how, potentially causing a substantial delay in one or more of our development programs until adequate replacement personnel could be hired and trained.

Our future success also depends on our continuing ability to identify, hire, train and retain highly qualified, technical, sales, marketing and customer service personnel. We presently employ approximately 65 people. Further, we expect to hire additional people over the next twelve months. Other than our chief executive officer, our executives do not have employment agreements. We do not have key person life insurance policies for any of our executives. The industry in which we compete has a high level of employee mobility and aggressive recruiting of skilled personnel. This type of environment creates intense competition for qualified personnel, particularly in product research and development, sales and marketing, and accounting and finance.

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

We rely substantially on the protection of our intellectual property through our ownership or control of issued patents and patent applications. Patents and patent applications owned or controlled by the Company are for docosanol-related products and technologies, Neurodex , compounds capable of regulating the target IgE in controlling symptoms of allergy and asthma, compounds capable of regulating the target MIF in the treatment of several inflammatory diseases, and Xenerex technologies for developing monoclonal 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;
- present and future competitors will not develop similar or superior technologies independently, duplicate our technologies or design around the patented aspects of our technologies;
- our proposed technologies will not infringe 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

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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.

Our inability to obtain or maintain patent protections for our products in foreign markets may negatively affect our financial condition.

The process for the approval of patent applications in foreign countries may differ significantly from the process in the U.S. These differences may delay our plans to market and sell docosanol 10% cream and other products in the international marketplace. Approval in one country does not indicate that approval will be obtained in other countries. The patent authorities in each country administer that country s laws and regulations relating to patents independently of the laws and regulations of any other country and we must seek and obtain the patents separately. Our inability to obtain or maintain patent protections for docosanol 10% cream and other products in foreign markets would severely hamper our ability to generate international sales from our first product and other products still under development.

If we do not protect our technical innovations, then our business may be negatively affected.

We rely substantially on confidentiality agreements to protect our innovations. We cannot assure you that secrecy obligations will be honored, or that others will not independently develop similar or superior technology. Additionally, if our consultants, key employees or other third parties apply technological information independently developed by them or by others to our projects, then disputes may arise as to the ownership rights of these innovations. It is costly to litigate these disputes and an unfavorable result could adversely affect our intellectual property portfolio as well as our business and financial condition.

Developing new 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. We maintain product liability insurance coverage for our clinical trials in the amount of $2 million per incident and $2 million in the aggregate. However, product liability claims can be high in the pharmaceutical industry and our insurance may not sufficiently cover our actual liabilities. If a suit against our business or proposed products 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.

We could incur significant liabilities as a result of material litigation.

In the ordinary course of business, we face various claims brought by third parties, including claims relating to 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 and financial position. Additionally, any such claims, whether or not successful, could damage our reputation and business.

Abreva faces competition from a number of existing and well-established products and the companies that market their products.

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We have the opportunity to earn royalties on Abreva product wholesale sales if sales exceed $62 million a year. Abreva competes with several other products for oral-facial herpes currently on the market in the U.S., as well as other products or potential products that are or may be under development or undergoing FDA review. Most of our competitors, including such companies as Bayer Corp. and Schering Plough, have substantial financial resources, research and development facilities and manufacturing and marketing experience. Even with Abreva being marketed by one of the world s largest consumer healthcare companies, GlaxoSmithKline, not all competitive responses and the impacts of those responses can be foreseen.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risks related to changes in interest rates. Because substantially all of our revenue, expense, 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. 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 exposures as the needs and risks should arise.

Interest rate sensitivity

Our investment portfolio consists primarily of fixed income instruments with an average duration of 1.7 years as of June 30, 2003 (2.3 years as of September 30, 2002). The primary objective of our investments in debt securities is to preserve principal while achieving attractive yields, without significantly increasing risk. We carry some investments that we intend to hold to maturity and others that we classify as available-for-sale. These available-for-sale securities are subject to interest rate risk. In general, we would expect that the volatility of this portfolio would increase as its duration increases.

Item 4. CONTROLS AND PROCEDURES

The Company s Chief Executive Officer and Chief Financial Officer carried out an evaluation of the effectiveness of the Company s disclosure controls and procedures (as defined in the Securities Exchange Act of 1934 Rules 13a-15(e) and 15(d)-15(e)), as of the end of the period covered by this report. Based on that evaluation, these officers have concluded that the Company s disclosure controls and procedures were adequate and designed to ensure that material information relating to the Company and the Company s consolidated subsidiary would be made known to them by others within those entities.

PART II. OTHER INFORMATION

Items 1-5. NOT APPLICABLE

Item 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits

15.0	Letter on unaudited interim financial information
31.1	Certification pursuant to Section 302 of Sarbanes-Oxley Act of 2002

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31.2 Certification pursuant to Section 302 of Sarbanes-Oxley Act of 2002

32.1 Certification pursuant to Section 906 of Sarbanes-Oxley Act of 2002

32.2 Certification pursuant to Section 906 of Sarbanes-Oxley Act of 2002

(b) Current Reports on Form 8-K

On May 8, 2003, we filed a current report on Form 8-K, furnishing under Item 9 a press release that reported the Company s results of operations for the quarter ended March 31, 2003.

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/Gerald J. Yakatan, Ph.D.	President and Chief Executive Officer	August 14, 2003
Gerald J. Yakatan, Ph.D.	(Principal Executive Officer)	
/s/Gregory P. Hanson	Vice President, Finance and Chief Financial Officer	August 14, 2003
Gregory P. Hanson	(Principal Financial and Accounting Officer)	

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15.0	Letter on unaudited interim financial information
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32.2	Certification pursuant to Section 906 of Sarbanes-Oxley Act of 2002