ALFACELL CORP
Form 10-Q
June 09, 2006

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended: April 30, 2006

|_| TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number: 0-11088

ALFACELL CORPORATION
(Exact name of registrant as specified in its charter)

Delaware	22-2369085
(State or other jurisdiction of organization)	(I.R.S. Employer Identification No.)

225 Belleville Avenue, Bloomfield, New Jersey 07003
(Address of principal executive offices) (Zip Code)

(973) 748-8082
(Registrant's telephone number, including area code)

NOT APPLICABLE
(Former name, former address, and former fiscal year, if changed since last report.)

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

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

Large Accelerated Filer |_| Accelerated Filer |X| Non-accelerated Filer |_|

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

The number of shares of common stock, $.001 par value, outstanding as of June 7, 2006 was 37,627,989 shares.

ALFACELL CORPORATION
(A Development Stage Company)

PART I. FINANCIAL INFORMATION
Item 1. Financial Statements

CONDENSED BALANCE SHEETS
April 30, 2006 and July 31, 2005

	April 20 (Unaud
ASSETS	
Current assets:	
Cash and cash equivalents	$ 2,32
Other current assets	4
Total current assets	2,36
Property and equipment, net	7
Loan receivable, related party	16
Total assets	$ 2,61
LIABILITIES AND STOCKHOLDERS' EQUITY	
Current liabilities:	
Accounts payable	$ 46
Accrued expenses	1,61
Total liabilities	2,08
Commitments and contingencies	
Stockholders' equity:	
Preferred stock, $.001 par value; Authorized and unissued, 1,000,000 shares at April 30, 2006 and July 31, 2005	
Common stock, $.001 par value; Authorized 100,000,000 shares at April 30, 2006 and July 31, 2005; Issued and outstanding, 37,453,062 shares at April 30, 2006 and 36,534,235 shares at July 31, 2005	3
Capital in excess of par value	80,71
Common stock to be issued, 174,927 shares	60
Deficit accumulated during development stage	(80,82
Total stockholders' equity	52
Total liabilities and stockholders' equity	$ 2,61

See accompanying notes to condensed financial statements.

ALFACELL CORPORATION
(A Development Stage Company)

CONDENSED STATEMENTS OF OPERATIONS

Three and nine months ended April 30, 2006 and 2005
and the Period from August 24, 1981
(Date of Inception) to April 30, 2006

(Unaudited)

	Three Months Ended April 30,		Nine Months E April 30,	
	2006	2005	2006	
Revenue:				
Sales	$ --	$ --	$ --	$
Investment income	20,128	41,033	76,176	
Other income	--	9,836	--	
Total revenue	20,128	50,869	76,176	
Costs and expenses:				
Cost of sales	--	--	--	
Research and development	1,101,450	1,385,753	3,690,881	
General and administrative	556,312	331,716	2,026,036	
Interest:				
Related parties, net	--	--	--	
Others	92	7,961	112	
Total costs and expenses	1,657,854	1,725,430	5,717,029	
Loss before state tax benefit	(1,637,726)	(1,674,561)	(5,640,853)	
State tax benefit	--	--	317,382	
Net loss	$ (1,637,726)	$ (1,674,561)	$ (5,323,471)	$
Loss per basic and diluted common share	$ (0.04)	$ (0.05)	$ (0.14)	$
Weighted average number of shares outstanding	37,382,365	35,246,456	36,899,644	

See accompanying notes to condensed financial statements.

ALFACELL CORPORATION
(A Development Stage Company)

CONDENSED STATEMENTS OF CASH FLOWS

Nine months ended April 30, 2006 and 2005
and the Period from August 24, 1981
(Date of Inception) to April 30, 2006

(Unaudited)

	Nine Months Ended April 30,		(D
	2006	2005	
Cash flows from operating activities:			
Net loss	$(5,323,471)	$(4,710,721)	
Adjustments to reconcile net loss to net cash used in operating activities:			
Gain on sale of marketable securities	--	--	
Depreciation and amortization	21,586	22,319	
Loss on disposal of property and equipment	--	--	
Issuance of common stock, stock options and warrants for services rendered	959,707	13,500	
Amortization of debt discount	--	34,120	
Amortization of deferred compensation	--	--	
Amortization of organization costs	--	--	
Changes in assets and liabilities:			
Decrease (increase) in other current assets	150,443	(137,351)	
Increase in loan receivable-related party	(7,146)	(7,179)	
Increase in interest payable-related party	--	--	
Increase (decrease) in accounts payable	70,901	(111,583)	
Increase in accrued payroll and expenses, related parties	--	--	
Increase in accrued expenses	335,871	427,705	
Net cash used in operating activities	(3,792,109)	(4,469,190)	
Cash flows from investing activities:			
Purchase of marketable equity securities	--	--	
Purchase of short-term investments	--	(1,993,644)	
Proceeds from sale of marketable equity securities	--	--	
Purchase of property and equipment	(14,931)	(43,086)	
Patent costs	--	--	
Net cash used in investing activities	(14,931)	(2,036,730)	

(continued)

See accompanying notes to condensed financial statements.

ALFACELL CORPORATION
(A Development Stage Company)

CONDENSED STATEMENTS OF CASH FLOWS, Continued

Nine months ended April 30, 2006 and 2005
and the Period from August 24, 1981
(Date of Inception) to April 30, 2006

(Unaudited)

	Nine Months Ended April 30,	
	2006	200
Cash flows from financing activities:		
Proceeds from short-term borrowings	$ --	$
Payment of short-term borrowings	--	
Increase in loans payable - related party, net	--	
Proceeds from bank debt and other long-term debt, net of costs	--	
Reduction of bank debt and long-term debt	--	(6
Proceeds from issuance of common stock, net	--	
Proceeds from exercise of stock options and warrants, net	1,067,508	261
Proceeds from common stock to be issued	600,000	
Proceeds from issuance of convertible debentures, related party	--	
Proceeds from issuance of convertible debentures, unrelated party	--	
Net cash provided by financing activities	1,667,508	254
Net increase (decrease) in cash and cash equivalents	(2,139,532)	(6,250
Cash and cash equivalents at beginning of period	4,462,951	10,147
Cash and cash equivalents at end of period	$ 2,323,419	$ 3,896
Supplemental disclosure of cash flow information - interest paid	$ 112	$
Noncash financing activities:		
Issuance of convertible subordinated debenture for loan payable to officer	$ --	$
Issuance of common stock upon the conversion of convertible subordinated debentures, related party	$ --	$
Conversion of short-term borrowings to common stock	$ --	$
Conversion of accrued interest, payroll and expenses by related parties to stock options	$ --	$
Repurchase of stock options from related party	$ --	$
Conversion of accrued interest to stock options	$ --	$

Conversion of accounts payable to common stock	$ --	$
Conversion of notes payable, bank and accrued interest to long-term debt	$ --	$
Conversion of loans and interest payable, related party and accrued payroll and expenses, related parties to long-term accrued payroll and other, related party	$ --	$

(continued)

See accompanying notes to condensed financial statements.

ALFACELL CORPORATION
(A Development Stage Company)

CONDENSED STATEMENTS OF CASH FLOWS, Continued

Nine months ended April 30, 2006 and 2005
and the Period from August 24, 1981
(Date of Inception) to April 30, 2006

(Unaudited)

	Nine Months Ended April 30, 2006	2005
Issuance of common stock upon the conversion of convertible subordinated debentures, other	$ --	$ 224,520
Issuance of common stock for services rendered	$ --	$ --
Issuance of warrants with notes payable	$ --	$ --

See accompanying notes to condensed financial statements.

ALFACELL CORPORATION
(A Development Stage Company)

NOTES TO CONDENSED FINANCIAL STATEMENTS

(Unaudited)

1. ORGANIZATION AND BASIS OF PRESENTATION

In the opinion of management, the accompanying unaudited condensed financial statements contain all adjustments (consisting of normal recurring adjustments) necessary to present fairly the Company's financial position as of April 30, 2006 and its results of operations and cash flows for the three and nine month periods ended April 30, 2006 and 2005 and the period from August 24, 1981 (date of inception) to April 30, 2006. The results of operations for the three and nine months ended April 30, 2006 are not necessarily indicative of the results to be expected for the full year. The condensed balance sheet as of July 31, 2005 presented herein has been derived from the audited financial statements included in the Form 10-K for the fiscal year ended July 31, 2005, filed with the Securities and Exchange Commission.

Certain footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been omitted in accordance with the published rules and regulations of the Securities and Exchange Commission. The condensed financial statements in this report should be read in conjunction with the financial statements and notes thereto included in the Form 10-K for the fiscal year ended July 31, 2005.

The Company is a development stage company as defined in Statement of Financial Accounting Standards No. 7. The Company is devoting substantially all of its present efforts to developing new drug products. Its planned principal operations have not commenced and, accordingly, no significant revenue has been derived therefrom.

The Company has reported net losses of approximately $5,323,000 for the nine months ended April 30, 2006 and $6,462,000, $5,070,000 and $2,411,000 for the fiscal years ended July 31, 2005, 2004 and 2003, respectively. The loss from date of inception, August 24, 1981, to April 30, 2006 amounts to approximately $80,830,000.

The Company's long-term continued operations will depend on its ability to raise additional funds through various potential sources such as equity and debt financing, collaborative agreements, strategic alliances, sale of tax benefits, revenues from the commercial sale of ONCONASE(R), licensing of its proprietary RNase technology and its ability to realize revenues from its technology and its drug candidates via out-licensing agreements with other companies. Such additional funds may not become available as the Company may need them or may not be available on acceptable terms. Through April 30, 2006, a significant portion of the Company's financing has been through the sale of its equity securities and convertible debentures in registered offerings and private placements and the exercise of stock options and warrants. Additionally, the Company has raised capital through debt financings, the sale of tax benefits and research products, interest income and financing received from its Chief Executive Officer. Until and unless the Company's operations generate significant revenues, the Company expects to continue to fund operations from the sources of capital previously described. There can be no assurance that the Company will be able to raise the capital it needs on terms which are acceptable, if at all. As of April 30, 2006, management believes that the Company's cash balance is sufficient to fund its operations through July 31, 2006, based on its expected level of expenditures in relation to activities in

(Unaudited)

1. ORGANIZATION AND BASIS OF PRESENTATION, Continued

preparing ONCONASE(R) for marketing registrations in the U.S. and Europe and other ongoing operations of the Company. However, to assure the Company's ability to continue its operations beyond this date, the Company continues to seek additional financing through equity or debt financings and the sale of net operating loss carryforwards, but cannot be sure that it will be able to raise capital on favorable terms or at all. The Company may also obtain additional capital through the exercise of outstanding options and warrants, although it cannot provide any assurance of such exercises or estimate the amount of capital it will receive, if any. If the Company is unable to raise additional funds in the future on acceptable terms, or at all, its operations will be severely curtailed and its business and financial condition will be adversely affected.

The Company will continue to incur costs in conjunction with its U.S. and foreign registrations for marketing approval of ONCONASE(R). The Company is currently in discussions with potential strategic alliance partners to further the development and marketing of ONCONASE(R) and other related products in its pipeline. However, it cannot be sure that any such alliances will materialize.

2. EARNINGS (LOSS) PER COMMON SHARE

"Basic" earnings (loss) per common share equals net income (loss) divided by weighted average common shares outstanding during the period. "Diluted" earnings per common share equals net income divided by the sum of weighted average common shares outstanding during the period, adjusted for the effects of potentially dilutive securities. The Company's basic and diluted per share amounts are the same since the Company had losses in each period presented and the assumed exercise of stock options and warrants outstanding as of April 30, 2006 and 2005 would be anti-dilutive. The number of outstanding options and warrants that could dilute earnings per share in future periods was 15,858,026 and 15,183,029 at April 30, 2006 and 2005, respectively.

3. STOCK-BASED COMPENSATION

Statement of Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation ("SFAS 123"), provides for the use of a fair value-based method of accounting for employee stock compensation. However, SFAS 123 also allowed an entity to continue to measure compensation cost for stock options granted to employees and directors using the intrinsic value method of accounting prescribed by Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees ("APB 25"), which only required charges to compensation expense for the excess, if any, of the fair value of the underlying stock at the date a stock option was granted (or at an appropriate subsequent measurement date) over the amount the employee had to pay to acquire the stock, if such amounts differed materially from the historical amounts. Prior to August 1, 2005, the Company had elected to continue to account for employee stock options using the intrinsic value method under APB 25. As the exercise price of all options granted under the stock option plans was equal to the market value of the underlying common stock on the grant date, no stock-based employee compensation cost had been recognized in the condensed statement of operations for the three and nine months ended April 30, 2005.

NOTES TO CONDENSED FINANCIAL STATEMENTS, Continued

(Unaudited)

3. STOCK-BASED COMPENSATION, Continued

In December 2004, the Financial Accounting Standards Board issued SFAS No. 123(R) (revised 2004), "Share-Based Payment" ("SFAS 123(R)"), which amends SFAS 123. The new standard requires all share-based payments, including stock option grants to employees, to be recognized as an operating expense in the statement of operations. The cost is recognized over the requisite service period based on fair values measured on the date of grant. The Company adopted SFAS 123(R) effective August 1, 2005 using the modified prospective method and, accordingly, prior period amounts have not been restated. Under the modified prospective method, the fair value of all new stock options issued after July 31, 2005 and the unamortized fair value of unvested outstanding stock options at August 1, 2005 will be recognized as expense as services are rendered. The Company recorded $276,362 or $0.01 per basic and diluted common share and $790,388 or $.02 per basic and diluted common share of stock-based compensation expense for employees under SFAS 123R for the three and nine month periods ended April 30, 2006, respectively. Had the Company accounted for its stock-based awards under the fair value method for the three and nine months ended April 30, 2005 the proforma impact to its financial statements would have been as follows:

	Three Months Ended April 30, 2005	Nine Mon Ended April 30,
Net loss applicable to common shares		
As reported	$(1,674,561)	$(4,710,
Less total stock-based employee compensation expense determined under fair value method for all awards, net of related tax effects	(632,419)	(1,856,
Pro forma	$(2,306,980)	$(6,567,
Basic and diluted loss per common share		
As reported	$ (0.05)	$ (0
Pro forma	(0.07)	(0

For options granted to employees during the nine months ended April 30, 2006, the weighted-average fair value at the grant date was $1.27 per option and the weighted average exercise price was $1.69 per option. The fair value of the stock options was estimated using the Black-Scholes options pricing model based on the following weighted-average assumptions:

	Nine Months Ended April 30,	
	2006	2005
Expected dividend yield	0%	0%
Risk-free interest rate	4.47%	4.25%
Expected stock price volatility	84.79%	99.44%
Expected term until exercise (years)	5.86	9.2
Forfeiture rate	36.61%	N/A

ALFACELL CORPORATION
(A Development Stage Company)

NOTES TO CONDENSED FINANCIAL STATEMENTS, Continued

(Unaudited)

3. STOCK-BASED COMPENSATION, Continued

The following table summarizes the stock option activity for the period August 1, 2005 to April 30, 2006:

	Stock Options Outstanding	Weighted Average Exercise Price Per Share
Balance August 1, 2005	3,497,845	$3.35
Granted	745,000	1.76
Exercised	(172,445)	0.92
Expired/Cancelled	(44,000)	4.59
Balance April 30, 2006	4,026,400	3.14
Exercisable as of April 30, 2006	2,337,700	3.10

The total intrinsic value of options exercised by employees during the nine months ended April 30, 2006 was $120,894. As of April 30, 2006, there was approximately $2,041,000 of total unrecognized compensation cost related to unvested share-based compensation arrangements granted under the Company's stock option plans, which is to be recognized over a weighted average period of 1.37 years.

Shares, warrants and options issued to non-employees for services are accounted for in accordance with SFAS 123(R) and Emerging Issues Task Force ("EITF") Issue No. 96-18, Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring or In Conjunction with Selling Goods or Services. The fair value of such securities is recorded in expense and additional paid-in capital in stockholders' equity over the applicable service periods using variable accounting through the vesting date based on the fair value of the securities at the end of each period.

4. LOAN RECEIVABLE, RELATED PARTY

Amounts due from the Company's CEO totaling $168,488 at April 30, 2006 and $161,342 at July 31, 2005, are classified as a long-term asset in loan receivable, related party as the Company does not expect repayment of these amounts within one year. In each of the nine month periods ended April 30, 2006 and 2005, the Company earned 8% interest in the amount of approximately $7,100 on the unpaid principal balance.

5. CAPITAL STOCK

During the quarter ended October 31, 2005, the Company issued an aggregate of 132,082 shares of common stock upon the exercise of warrants and stock options by an unrelated party, an employee and an executive officer at per share exercise prices ranging from $0.54 to $0.85. The Company realized aggregate gross proceeds of $96,738 from these exercises.

ALFACELL CORPORATION
(A Development Stage Company)

NOTES TO CONDENSED FINANCIAL STATEMENTS, Continued

(Unaudited)

5. CAPITAL STOCK, Continued

During the quarter ended January 31, 2006, the Company issued an aggregate of 436,778 shares of common stock upon the exercise of warrants and stock options by unrelated parties, employees and directors at per share exercise prices ranging from $0.26 to $1.50. The Company realized aggregate gross proceeds of $574,747 from these exercises.

During the quarter ended January 31, 2006, the Company issued 25,000 ten-year stock options to a consultant as payment for services rendered. The options vested immediately and have an exercise price of $1.32 per share. The Company recorded a total of $23,166 of non-cash expense for these options.

During the quarter ended January 31, 2006, the Company issued 50,000 five-year stock options to a consultant as payment for services to be rendered. These options vest over a one year period, 50% of which vested immediately and 12.5% will vest equally for the next four quarters following the grant date. The stock options have an exercise price of $2.04 per share. The fair value of these options is being expensed over the service period using the provisions of EITF 96-18. During the nine months ended April 30, 2006, the Company recorded under EITF 96-18, a total of $63,204 of non-cash expense for these options.

During the quarter ended April 30, 2006, the Company issued 25,000 ten-year stock options to a consultant as payment for services to be rendered. The options vested immediately and have an exercise price of $3.37 per share. The Company recorded a total of $58,387 of non-cash expense for these options.

During the quarter ended April 30, 2006, the Company issued an aggregate of 349,967 shares of common stock upon the exercise of warrants and stock options by unrelated parties, consultants and a director at per share exercise prices ranging from $0.75 to $3.46. The Company realized aggregate gross proceeds of $396,023 from these exercises.

During the quarter ended April 30, 2006, the Company received proceeds of $600,000 in anticipation of a subscription to purchase 174,927 shares of common stock at a price of $3.43 per share, which the Company has accounted for as common stock to be issued at April 30, 2006. The Company and the investor reached a definitive agreement on the sale of the common stock on May 1, 2006 and the common stock was subsequently issued in May 2006.

During the nine months ended April 30, 2006, the Company recorded under EITF 96-18, a total of $24,562 of non-cash expense for options issued to consultants during the fiscal year ended July 31, 2005.

ALFACELL CORPORATION
(A Development Stage Company)

NOTES TO CONDENSED FINANCIAL STATEMENTS, Continued

(Unaudited)

6. SALE OF NET OPERATING LOSS CARRYFORWARDS

New Jersey has enacted legislation permitting certain corporations located in New Jersey to sell a portion of its state tax loss carryforwards and state research and development credits in order to obtain tax benefits. For the state fiscal year 2006 (July 1, 2005 to June 30, 2006), the Company had approximately $1,903,000 of total available net operating loss carryforwards that were saleable, of which New Jersey permitted the Company to sell approximately $356,000. In December 2005, the Company received approximately $317,000 from the sale of the $356,000 of net operating loss carryforwards, which was recognized as a tax benefit for the nine months ended April 30, 2006.

For the state fiscal year 2005 (July 1, 2004 to June 30, 2005), the Company had approximately $1,335,000 of total available net operating loss carryforwards that were saleable, of which New Jersey permitted the Company to sell approximately $339,000. In December 2004, the Company received approximately $288,000 from the sale of the $339,000 of net operating loss carryforwards, which was recognized as a tax benefit for the nine months ended April 30, 2005.

If still available under New Jersey law, the Company will attempt to sell the remaining $1,547,000 of its net operating loss carryforwards between July 1, 2006 and June 30, 2007 (state fiscal year 2007). This amount, which is a carryover of the Company's remaining net operating loss carryforwards from state fiscal year 2006, may increase if the Company incurs additional net losses and research and development credits during state fiscal year 2007. The Company cannot estimate, however, what percentage of its saleable net operating loss carryforwards New Jersey will permit it to sell, how much money will be received in connection with the sale, if the Company will be able to find a buyer for its net operating loss carryforwards or if such funds will be available in a timely manner.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Information herein contains, in addition to historical information, forward-looking statements that involve risks and uncertainties. All statements, other than statements of historical fact, regarding our financial position, potential, business strategy, plans and objectives for future operations are "forward-looking statements." These statements are commonly identified by the use of forward-looking terms and phrases as "anticipates," "believes," "estimates," "expects," "intends," "may," "seeks," "should," or "will' or the negative thereof or other variations thereon or comparable terminology, or by discussions of strategy. We cannot assure you that the future results covered by these forward-looking statements will be achieved. The matters set forth in Item 1A. "Risk Factors" in this quarterly report on Form 10-Q constitute cautionary statements identifying important factors with respect to these forward-looking statements, including certain risks and uncertainties, that could cause actual results to vary significantly from the future results indicated in these forward-looking statements. Other factors could also cause actual results to differ significantly from the future results indicated in these forward-looking statements.

Overview

Since our inception, we have devoted the vast majority of our resources to the research and development of ONCONASE(R) and related drug candidates. We have focused our resources towards the completion of the clinical program for unresectable, or inoperable, malignant mesothelioma.

Since ONCONASE(R) has Fast Track Designation from the Food and Drug Administration, or FDA, for the treatment of malignant mesothelioma patients, we continue to have meetings and discussions with the FDA to establish mutually agreed upon parameters for the New Drug Application, or NDA, to obtain marketing approval for ONCONASE(R), assuming the Phase III clinical trial for the treatment of malignant mesothelioma yields favorable results.

We received an Orphan Medicinal Product Designation for ONCONASE(R) from the European Agency for the Evaluation of Medicinal Products, or EMEA. We continue to fulfill the EMEA requirements regarding the Marketing Authorization Application, or MAA, registration requirements for ONCONASE(R) for the treatment of malignant mesothelioma.

We received an Orphan Drug Designation for ONCONASE(R) for malignant mesothelioma in Australia from the Therapeutics Goods Administration, or TGA. This designation in Australia entitles us to five years of marketing exclusivity, a 100% waiver of filing fees and regulatory guidance from the TGA.

Almost all of our research and development expenses since our inception of $53,728,000 have gone toward the development of ONCONASE(R) and related drug candidates. For the fiscal years 2005, 2004 and 2003 our research and development expenses were $5,082,000, $3,353,000 and $1,700,000, respectively, almost all of which were used for the development of ONCONASE(R) and related drug candidates. ONCONASE(R) is currently in an international, centrally randomized Phase III trial. The first part of the trial has been completed and the second confirmatory part of the trial is ongoing for which we have exceeded the full enrollment target of 316 patients. The primary endpoint of the trial is survival, and as such, a sufficient number of deaths must occur in order to perform the required statistical analyses to determine the efficacy of ONCONASE(R) in patients with unresectable (inoperable) malignant mesothelioma. The first interim analysis results based on the 105 events (deaths) showed a two-month survival advantage of ONCONASE(R) + doxorubicin (12 months) vs. doxorubicin (10 months). These results were consistent with the results from the first part of the trial and were the basis for our decision to continue the trial. If the results of the clinical trials are positive, we expect to file for marketing

registrations (NDA in the U.S. and MAA in Europe and Australia) for ONCONASE(R) within six months of completion of the statistical analyses. However, at this time, we cannot predict with certainty when a sufficient number of deaths will occur to achieve statistical significance. The timing of when we will be able to file for marketing registrations in the US, EU and Australia is data driven. Therefore, we cannot predict with certainty what our total cost associated with obtaining marketing approvals will be, or when and if such approvals will be granted, or when actual sales will occur.

We fund the research and development of our products primarily from cash receipts resulting from the sale of our equity securities and convertible debentures in registered offerings and private placements and the exercise of stock options and warrants. Additionally, we have raised capital through debt financings, the sale of our tax benefits and research products, interest income

and financing received from our Chief Executive Officer. As of April 30, 2006, we believe our cash balance is sufficient to fund our operations through July 31, 2006 based on our expected level of expenditures in relation to activities in preparing ONCONASE(R) for marketing registrations and other ongoing operations of the Company. To assure our ability to continue our operations beyond this date, we continue to seek additional financing through equity or debt financings and the sale of net operating loss carryforwards, but we cannot be sure that we will be able to raise capital on favorable terms or at all. We may also obtain additional capital through the exercise of outstanding options and warrants, although we cannot provide any assurance of such exercises or estimate the amount of capital we will receive, if any. If we are unable to raise sufficient capital, our operations will be severely curtailed and our business and financial condition will be adversely affected.

Results of Operations

Three and nine month periods ended April 30, 2006 and 2005

Revenues. We are a development stage company as defined in the Financial Accounting Standards Board's Statement of Financial Accounting Standards No. 7. We are devoting substantially all of our present efforts to establishing a new business and developing new drug products. Our planned principal operations of marketing and/or licensing new drugs have not commenced and, accordingly, we have not derived any significant revenue from these operations. We focus most of our productive and financial resources on the development of ONCONASE(R) and as such we have not had any sales in the three and nine month periods ended April 30, 2006 and 2005. For the three and nine month periods ended April 30, 2006, our investment income was $20,000 and $76,000 compared to $41,000 and $104,000 for the same period last year, a decrease of $21,000 and $28,000, respectively. These decreases were due to lower balances of cash and cash equivalents.

Research and Development. Research and development expense for the three months ended April 30, 2006 was $1,101,000 compared to $1,386,000 for the same period last year, a decrease of $285,000, or 21%. The decrease resulted from the completion of key toxicology requirements and key requirements for chemistry, manufacturing and controls of approximately $348,000; reduction in costs related to clinical trials of approximately $52,000; decrease in patent expenses of approximately $39,000; and decrease in pre-clinical sponsored research and development expenses of approximately $7,000. These decreases were offset by an increase in compensation expense of approximately $99,000 which is primarily related to share-based compensation; and non-cash expense related to stock options issued to consultants of approximately $62,000. The share-based compensation expense is expected to continue as a result of the adoption of SFAS 123(R), which requires us to charge compensation expense for all employee stock options.

Research and development expense for the nine months ended April 30, 2006 was $3,691,000 compared to $3,861,000 for the same period last year, a decrease of $170,000, or 4%. The decrease resulted from the completion of key toxicology requirements and key requirements for chemistry, manufacturing and controls of approximately $367,000; decrease in patent expenses of approximately $148,000; reduction in costs related to clinical trials of approximately $105,000; and decrease in pre-clinical sponsored research and development expenses of approximately $46,000. These decreases were offset by an increase in compensation expense of approximately $390,000 which is primarily related to share-based compensation; and non-cash expense related to stock options issued to consultants of approximately $106,000. The share-based compensation expense is expected to continue as a result of the adoption of SFAS 123(R), which

requires us to charge compensation expense for all employee stock options.

General and Administrative. General and administrative expense for the three months ended April 30, 2006 was $556,000 compared to $332,000 for the same period last year, an increase of $224,000, or 67%. This increase was primarily due to an increase in compensation expense of approximately $135,000 which is primarily related to share-based compensation. The share-based compensation expense is expected to continue as a result of the adoption of SFAS 123(R). The increase in general and administrative expense also resulted from legal fees of approximately $68,000; consultant and board of directors fees of approximately $31,000; and non-cash share-based compensation expense related to stock options issued to a consultant and board members of approximately $11,000; offset by decreases in investor relations activities of approximately $11,000; Sarbanes-Oxley compliance and auditing fees of approximately $5,000; and insurance expense of approximately $5,000.

General and administrative expense for the nine months ended April 30, 2006 was $2,026,000 compared to $1,200,000 for the same period last year, an increase of $826,000, or 69%. This increase was primarily due to an increase in compensation expense of approximately $398,000 which is primarily related to share-based compensation. The share-based compensation expense is expected to continue as a result of the adoption of SFAS 123(R). The increase in general and administrative expense also resulted from legal fees of approximately $289,000; non-cash share-based compensation expense related to stock options issued to a consultant and board members of approximately $106,000; Sarbanes-Oxley compliance and auditing fees of approximately $64,000; and consultant and board of directors fees of approximately $46,000; offset by a decreases in Nasdaq re-listing fees of approximately $40,000; and insurance expense of approximately $20,000; and investor relations activities of approximately $17,000.

Interest. Interest expense for the three and nine months ended April 30, 2006 decreased by $8,000, or 100% and $51,000, or 100%, respectively; primarily due to the maturity and conversion of convertible notes payable into common stock during the last fiscal year ended July 31, 2005.

Income Taxes. New Jersey has enacted legislation permitting certain corporations located in New Jersey to sell a portion of our state tax loss carryforwards and state research and development credits, or net operating loss carryforwards, in order to obtain tax benefits. For the state fiscal year 2006 (July 1, 2005 to June 30, 2006), we had approximately $1,903,000 of total available net operating loss carryforwards that were saleable, of which New Jersey permitted us to sell approximately $356,000. In December 2005, we received approximately $317,000 from the sale of the $356,000 of net operating loss carryforwards, which was recognized as a tax benefit for the nine months ended April 30, 2006.

For the state fiscal year 2005 (July 1, 2004 to June 30, 2005), we had approximately $1,335,000 of total available net operating loss carryforwards that were saleable, of which New Jersey permitted us to sell approximately $339,000. In December 2004, we received approximately $288,000 from the sale of

the $339,000 of net operating loss carryforwards, which we recognized as a tax benefit for the nine months ended April 30, 2005.

If still available under New Jersey law, we will attempt to sell the remaining $1,547,000 of our net operating loss carryforwards between July 1, 2006 and June 30, 2007 (state fiscal year 2007). This amount, which is a carryover of our remaining net operating loss carryforwards from state fiscal

year 2006, may increase if we incur additional net losses and research and development credits during state fiscal year 2007. We cannot estimate, however, what percentage of our saleable net operating loss carryforwards New Jersey will permit us to sell, how much money we will receive in connection with the sale, if we will be able to find a buyer for our net operating loss carryforwards or if such funds will be available in a timely manner.

Net Loss. We have incurred net losses during each year since our inception. The net loss for the three months ended April 30, 2006 was $1,638,000 as compared to $1,675,000 for the same period last year, a decrease of $37,000. The net loss for the nine months ended April 30, 2006 was $5,323,000 as compared to $4,711,000 for the same period last year, an increase of $612,000. The cumulative loss from the date of inception, August 24, 1981 to April 30, 2006, amounted to $80,830,000. Such losses are attributable to the fact that we are still in the development stage and, accordingly, have not derived sufficient revenue from operations to offset the development stage expenses.

Liquidity and Capital Resources

We have financed our operations since inception through the sale of our equity securities and convertible debentures in registered offerings and private placements and the exercise of stock options and warrants. Additionally, we have raised capital through debt financings, the sale of our net operating loss carryforwards and research products, interest income and financing received from our Chief Executive Officer. During the nine months ended April 30, 2006, we had a net decrease in cash and cash equivalents of $2,140,000, which resulted primarily from net cash used in operating activities of $3,792,000 and net cash used in investing activities of $15,000, offset by net cash receipts of $1,667,000 from common stock subscribed and warrant and stock option exercises. Total cash resources as of April 30, 2006 were $2,323,000 compared to $4,463,000 at July 31, 2005.

Our current liabilities as of April 30, 2006 were $2,087,000 compared to $1,680,000 at July 31, 2005, an increase of $407,000. The increase was primarily due an increase in accounts payable of approximately $71,000 and accrued expenses of approximately $336,000. These increases were mainly for expenses related to pre-clinical studies of approximately $234,000 and clinical trials of approximately $201,000; offset by decreases in professional fees of approximately $14,000 and payroll accruals of approximately $14,000.

Our long-term continued operations will depend on our ability to raise additional funds through various potential sources such as equity and debt financing, collaborative agreements, strategic alliances, sale of tax benefits, revenues from the commercial sale of ONCONASE(R), licensing of our proprietary RNase technology and our ability to realize revenues from our technology and our drug candidates via out-licensing agreements with other companies. Such additional funds may not become available as we need them or may not be available on acceptable terms. As of April 30, 2006, we believe our cash balance is sufficient to fund our operations through July 31, 2006, based on our expected level of expenditures in relation to activities in preparing ONCONASE(R) for marketing registrations and other ongoing operations of the Company. However, to assure our ability to continue our operations beyond this date, we continue to seek additional financing through equity or debt financings and the sale of net operating loss carryforwards, but cannot be sure that we will be able to raise capital on favorable terms or

at all. We may also obtain additional capital through the exercise of outstanding options and warrants, although we cannot provide any assurance of

such exercises or estimate the amount of capital we will receive, if any. If we are unable to raise sufficient capital, our operations will be severely curtailed and our business and financial condition will be adversely affected.

We will continue to incur costs in conjunction with our U.S. and foreign registrations for marketing approval of ONCONASE(R). We are currently in discussions with potential strategic alliance partners to further the development and marketing of ONCONASE(R) and other related products in our pipeline. However, we cannot be sure that any such alliances will materialize.

The market price of our common stock is volatile, and the price of the stock could be dramatically affected one way or another depending on numerous factors. The market price of our common stock could also be materially affected by the marketing approval or lack of approval of ONCONASE(R).

Off-Balance Sheet Arrangements

As part of our ongoing business, we do not participate in transactions that generate relationships with unconsolidated entities, or financial partnerships, such as entities often referred to as structured finance or variable interest entities or VIE, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. As of April 30, 2006, we are not involved in any unconsolidated VIE transactions.

Critical Accounting Policies and Estimates

Critical accounting policies are those that involve subjective or complex judgments, often as a result of the need to make estimates. The following areas all require the use of judgments and estimates: research and development expenses, accounting for stock-based compensation, accounting for warrants issued with convertible debt and deferred income taxes. Estimates in each of these areas are based on historical experience and various assumptions that we believe are appropriate. Actual results may differ from these estimates. Our accounting practices are discussed in more detail in "Management's Discussion and Analysis of Financial Condition and Results of Operations" and Note 1 of "Notes to Consolidated Financial Statements" in our Annual Report on Form 10-K for the year ended July 31, 2005.

Contractual Obligations and Commercial Commitments

Our outstanding contractual obligations relate to our equipment operating leases. During the quarter ended April 30, 2006, we entered into an equipment operating lease, which obligates us to pay approximately $630.00 per month over the next forty-eight months.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 4. Controls And Procedures

(a) Evaluation of disclosure controls and procedures.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of April 30, 2006, the end of the period covered by this

report (the "evaluation date"). Based upon the evaluation, the Chief Executive Officer and Chief Financial Officer concluded that, as of the evaluation date, our disclosure controls and procedures are effective in timely alerting them to the material information relating to us required to be included in our periodic SEC filings.

(b) Changes in internal controls.

There were no changes made in our internal controls over financial reporting during the three months ended April 30, 2006 or, to our knowledge, in other factors that have materially affected, or are reasonably likely to materially affect, these controls.

PART II. OTHER INFORMATION

Item 1A. Risk Factors

An investment in our common stock is speculative and involves a high degree of risk. You should carefully consider the risks and uncertainties described below and the other information in this Form 10-Q and our other SEC filings before deciding whether to purchase shares of our common stock. If any of the following risks actually occur, our business and operating results could be harmed. This could cause the trading price of our common stock to decline, and you may lose all or part of your investment.

There are no material changes in the risk factors described below since our most recent 10-K.

We have incurred losses since inception and anticipate that we will incur continued losses for the foreseeable future. We do not have a current source of product revenue and may never be profitable.

We are a development stage company and since our inception one of the principal sources of our working capital has been private sales of our common stock. We incurred a net loss of approximately $5,323,000 for the nine months ended April 30, 2006 and net losses of approximately $6,462,000, $5,070,000 and $2,411,000 for the fiscal years ended July 31, 2005, 2004 and 2003, respectively. We have continued to incur losses since July 31, 2005. We may never achieve revenue sufficient for us to attain profitability.

Our profitability will depend on our ability to develop, obtain regulatory approvals for, and effectively market ONCONASE(R) as well as entering into strategic alliances for the development of new drug candidates from the out-licensing of our proprietary RNase technology. The commercialization of our pharmaceutical products involves a number of significant challenges. In particular our ability to commercialize ONCONASE(R) depends on the success of our clinical development programs, our efforts to obtain regulatory approval and our sales and marketing efforts or those of our marketing partners, if any, directed at physicians, patients and third-party payors. A number of factors could affect these efforts including:

- Our ability to demonstrate clinically that our products have utility and are safe;
- Delays or refusals by regulatory authorities in granting marketing approvals;
- Our limited financial resources relative to our competitors;
- Our ability to obtain an appropriate marketing partner;

- The availability and level of reimbursement for our products by third party payors;
- Incidents of adverse reactions to our products;
- Misuse of our products and unfavorable publicity that could result; and

- The occurrence of manufacturing or distribution disruptions.

We will seek to generate revenue through licensing, marketing and development arrangements prior to receiving revenue from the sale of our products. To date we have not consummated any licensing or marketing arrangements and we may not be able to successfully consummate any such arrangements. We have entered into several development arrangements, which have resulted in limited revenues for us. However, we cannot ensure that these arrangements or future arrangements, if any, will result in significant amounts of revenue for us. We, therefore, are unable to predict the extent of any future losses or the time required to achieve profitability, if at all.

We will need additional financing to continue operations, which may not be available on acceptable terms, if it is available at all.

We need additional financing in order to continue operations, including completion of our current clinical trials and filing marketing registrations for ONCONASE(R) with the FDA in the United States, with the EMEA in Europe and with the TGA in Australia. If the results from our current clinical trial do not demonstrate the efficacy and safety of ONCONASE(R) for malignant mesothelioma, our ability to raise additional capital will be adversely affected. Even if regulatory applications for marketing approvals are filed, we will need additional financing to continue operations. As of April 30, 2006, we believe that our cash balance is sufficient to fund our operations through July 31, 2006, based on our expected level of expenditures. However, to assure our ability to continue our operations beyond this date, we continue to seek additional financing through equity or debt financings and the sale of net operating loss carryforwards but we cannot be sure that we will be able to raise capital on favorable terms or at all. We may also obtain additional capital through the exercise of outstanding options and warrants, although we cannot provide any assurance of such exercises or estimate the amount of capital we will receive, if any. If we are unable to raise sufficient capital, our operations will be severely curtailed and our business and financial condition will be materially adversely affected.

We may be unable to sell certain state tax benefits in the future and if we are unable to do so, it would eliminate a source of financing that we have relied on in the past.

At July 31, 2005, we had federal net operating loss carryforwards of approximately $52,823,000 that expire from 2006 to 2025 (approximately $8,675,000 expires in the years 2006 to 2010). We also had research and experimentation tax credit carryforwards of approximately $1,955,000 that expire from 2006 to 2025 (approximately $152,000 expires in the years 2006 to 2010). New Jersey has enacted legislation permitting certain corporations located in New Jersey to sell a portion of its state tax loss carryforwards and state research and development credits in order to obtain tax benefits. The aggregate amount of tax benefits that New Jersey allows corporations to sell each state fiscal year (July 1st through June 30th) is determined annually and if New Jersey reduces such aggregate amount in any fiscal year we may be unable to sell

some or all of our available tax benefits as we have in the past. In addition, there is a limited market for these types of sales and we may not be able to find someone to purchase our tax benefits for a reasonable price. Our historical results of operations and our cash flows have been improved by our sale of tax benefits and if we continue to generate a limited amount of revenue and are unable in the future to sell our tax benefits, our results of operations and our cash flows will be negatively impacted.

For the state fiscal year 2006 (July 1, 2005 to June 30, 2006), we had approximately $1,903,000 total available tax benefits that were saleable, of which New Jersey permitted us to sell approximately $356,000. In December 2005, we received approximately $317,000 from the sale of the $356,000 of tax benefits, which we recognized as tax benefits for the nine months ended April 30, 2006. For the state

fiscal year 2005 (July 1, 2004 to June 30, 2005), we had approximately $1,335,000 total available tax benefits that were saleable; of which New Jersey permitted us to sell approximately $339,000. In December 2004, we received approximately $288,000 from the sale of the $339,000 of tax benefits, which we recognized as a tax benefit for the nine months ended April 30, 2006.

If still available under New Jersey law, we will attempt to sell the remaining $1,547,000 of our tax benefits between July 1, 2006 and June 30, 2007 (state fiscal year 2007). This amount, which is a carryover of our remaining tax benefits from state fiscal year 2006 and earlier, may increase if we incur additional tax losses during state fiscal year 2007. We cannot estimate, however, what percentage of our saleable tax benefits New Jersey will permit us to sell, how much money we will receive in connection with the sale, if we will be able to find a buyer for our tax benefits or if such funds will be available in a timely manner.

We cannot predict how long it will take us nor how much it will cost us to complete part two of our Phase III trial because it is a survival study.

We currently have ongoing a two-part Phase III trial of ONCONASE(R) as a treatment for malignant mesothelioma. The first part of the clinical trial has been completed and the second confirmatory part is still ongoing for which we have exceeded the full enrollment target of 316 patients. The first interim analysis results based on the 105 events (deaths) showed a two-month survival advantage of ONCONASE(R) + doxorubicin (12 months) vs. doxorubicin (10 months). These results were consistent with the results from the first part of the trial and were the basis for our decision to continue the trial. The primary endpoint of the Phase III clinical trial is survival, which tracks the length of time patients enrolled in the study live. According to the protocol, a sufficient number of patient deaths must occur in order to perform the required statistical analyses to determine the efficacy of ONCONASE(R) in patients with unresectable (inoperable) malignant mesothelioma. Since it is impossible to predict with certainty when these patient deaths in the Phase III trial will occur, we do not have the capability of reasonably determining when a sufficient number of deaths will occur, nor when we will be able to file for marketing registrations with the FDA, EMEA and TGA.

In addition, clinical trials are very costly and time consuming. The length of time required to complete a clinical trial depends on several factors including the size of the patient population, the ability of patients to get to the site of the clinical study, and the criteria for determining which patients are eligible to join the study. Although we believe we could modify some of our expenditures to reduce our cash outlays in relation to our clinical trials and

other NDA related expenditures, we cannot quantify which or the amount such expenditures might be modified. Hence, a delay in the commercial sale of ONCONASE(R) would increase the time frame of our cash expenditure outflows and may require us to seek additional financing. Such capital financing may not be available on favorable terms or at all.

If we fail to obtain the necessary regulatory approvals, we will not be allowed to commercialize our drugs and will not generate product revenue.

The FDA and comparable regulatory agencies in foreign countries impose substantial pre-market approval requirements on the introduction of pharmaceutical products. These requirements involve lengthy and detailed pre-clinical and clinical testing and other costly and time consuming procedures. Satisfaction of these requirements typically takes several years depending on the level of complexity and novelty of the product. We cannot apply for FDA, EMEA or TGA approval to market ONCONASE(R) until the clinical trials and all other registration requirements have been met. Drugs in late stages of clinical development may fail to show the desired safety and efficacy results despite having progressed through initial clinical testing. While limited trials with our product have produced certain favorable

results, we cannot be certain that we will successfully complete Phase I, Phase II or Phase III testing of any compound within any specific time period, if at all. Furthermore, the FDA or the company may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. In addition, we cannot apply for FDA, EMEA or TGA approval to market ONCONASE(R) until pre-clinical and clinical trials have been completed. Several factors could prevent the successful completion or cause significant delays of these trials including an inability to enroll the required number of patients or failure to demonstrate the product is safe and effective in humans. Also if safety concerns develop, the FDA, EMEA and TGA could stop our trials before completion.

All statutes and regulations governing the conduct of clinical trials are subject to change by various regulatory agencies, including the FDA, in the future, which could affect the cost and duration of our clinical trials. Any unanticipated costs or delays in our clinical studies would delay our ability to generate product revenues and to raise additional capital and could cause us to be unable to fund the completion of the studies.

We may not market or sell any product for which we have not obtained regulatory approval. We cannot assure you that the FDA or other regulatory agencies will ever approve the use of our products that are under development. Even if we receive regulatory approval, such approval may involve limitations on the indicated uses for which we may market our products. Further, even after approval, discovery of previously unknown problems could result in additional restrictions, including withdrawal of our products from the market.

If we fail to obtain the necessary regulatory approvals, we cannot market or sell our products in the United States, or in other countries and our long-term viability would be threatened. If we fail to achieve regulatory approval or foreign marketing authorizations for ONCONASE(R) we will not have a saleable product or product revenues for quite some time, if at all, and may not be able to continue operations.

We are and will be dependent upon third parties for manufacturing our products. If these third parties do not devote sufficient time and resources to our products our revenues and profits may be adversely affected.

We do not have the required manufacturing facilities to manufacture our products. We presently rely on third parties to perform certain of the manufacturing processes for the production of ONCONASE(R) for use in clinical trials. Currently, we contract with Scientific Protein Laboratories, LLC for the manufacturing of ranpirnase (protein drug substance) from the oocytes, or the unfertilized eggs, of the Rana pipiens frog, which is found in the Northwest United States and is commonly called the leopard frog. We contract with Ben Venue Corporation for the manufacturing of ONCONASE(R) and with Cardinal Health and Apptuit for the labeling, storage and shipping of ONCONASE(R) for clinical trial use. We utilize the services of these third party manufacturers solely on an as needed basis with terms and prices customary for our industry.

We use FDA GMP licensed manufacturers for ranpirnase and ONCONASE(R). We have identified substantial alternative service providers for the manufacturing services for which we may contract. In order to replace an existing service provider we must amend our IND to notify the FDA of the new manufacturer. Although the FDA generally will not suspend or delay a clinical trial as a result of replacing an existing manufacturer, the FDA has the authority to suspend or delay a clinical trial if, among other grounds, human subjects are or would be exposed to an unreasonable and significant risk of illness or injury as a result of the replacement manufacturer.

We intend to rely on third parties to manufacture our products if they are approved for sale by the appropriate regulatory agencies and are commercialized. Third party manufacturers may not be able to meet our needs with respect to the timing, quantity or quality of our products or to supply products on acceptable terms.

Because we do not have marketing, sales or distribution capabilities, we expect to contract with third parties for these functions and we will therefore be dependent upon such third parties to market, sell and distribute our products in order for us to generate revenues.

We currently have no sales, marketing or distribution capabilities. In order to commercialize any product candidates for which we receive FDA or non US approval, we expect to rely on established third party strategic partners to perform these functions. To date, we have not entered into any marketing or licensing agreements for ONCONASE(R). We cannot assure you we will be able to establish or maintain relationships with one or more biopharmaceutical or other marketing companies with existing distribution systems and direct sales forces to market any or all of our product candidates, on acceptable terms, if at all.

In addition, we expect to begin to incur significant expenses in determining our commercialization strategy with respect to one or more of our product candidates. The determination of our commercialization strategy with respect to a product candidate will depend on a number of factors, including:

- the extent to which we are successful in securing collaborative partners to offset some or all of the funding obligations with respect to product candidates;
- the extent to which our agreement with our collaborators permits us to exercise marketing or promotion rights with respect to the product candidate;
- how our product candidates compare to competitive products with respect to labeling, pricing, therapeutic effect, and method of

delivery; and

- whether we are able to establish agreements with third party collaborators, including large biopharmaceutical or other marketing companies, with respect to any of our product candidates on terms that are acceptable

A number of these factors are outside of our control and will be difficult to determine.

Our product candidates may not be accepted by the market.

Even if approved by the FDA and other regulatory authorities, our product candidates may not achieve market acceptance, which means we would not receive significant revenues from these products. Approval by the FDA does not necessarily mean that the medical community will be convinced of the relative safety, efficacy and cost-effectiveness of our products as compared to other products. In addition, third party reimbursers such as insurance companies and HMOs may be reluctant to reimburse expenses relating to our products.

We depend upon Kuslima Shogen and our other key personnel and may not be able to retain these employees or recruit qualified replacement or additional personnel, which would have a material adverse affect on our business.

We are highly dependent upon our founder, Chairman and Chief Executive Officer, Kuslima Shogen. Kuslima Shogen's talents, efforts, personality, vision and leadership have been, and continue to

be, critical to our success. The diminution or loss of the services of Kuslima Shogen, and any negative market or industry perception arising from that diminution or loss, would have a material adverse effect on our business. While our other employees have substantial experience and have made significant contributions to our business, Kuslima Shogen is our senior executive and also our primary supporter because she represents the Company's primary means of accessing the capital markets.

Because of the specialized scientific nature of our business, our continued success also is dependent upon our ability to attract and retain qualified management and scientific personnel. There is intense competition for qualified personnel in the pharmaceutical field. As our company grows our inability to attract qualified management and scientific personnel could materially adversely affect our research and development programs, the commercialization of our products and the potential revenue from product sales.

We do not have employment contracts with Kuslima Shogen or any of our other management and scientific personnel.

Our proprietary technology and patents may offer only limited protection against infringement and the development by our competitors of competitive products.

We own two patents jointly with the United States government. These patents expire in 2016. We also own ten United States patents with expiration dates ranging from 2006 to 2019, four European patents with expiration dates ranging from 2009 to 2016 and three Japanese patents with expiration dates ranging from 2010 to 2016. We also own patent applications that are pending in the United States, Europe and Japan. The scope of protection afforded by patents for biotechnological inventions is uncertain, and such uncertainty applies to our patents as well. Therefore, our patents may not give us competitive

advantages or afford us adequate protection from competing products. Furthermore, others may independently develop products that are similar to our products, and may design around the claims of our patents. Patent litigation and intellectual property litigation are expensive and our resources are limited. If we were to become involved in litigation, we might not have the funds or other resources necessary to conduct the litigation effectively. This might prevent us from protecting our patents, from defending against claims of infringement, or both. To date, we have not received any threats of litigation regarding patent issues.

Developments by competitors may render our products obsolete or non-competitive.

In February 2004, the Food and Drug Administration granted Eli Lilly & Company approval to sell its Alimta(R) medication as an orphan drug to treat patients with pleural mesothelioma. Alimta is a multi-targeted antifolate that is based upon a different mechanism of action than ONCONASE(R). To our knowledge, no other company is developing a product with the same mechanism of action as ONCONASE(R). However, there may be other companies, universities, research teams or scientists who are developing products to treat the same medical conditions our products are intended to treat. Eli Lilly is, and some of these other companies, universities, research teams or scientists may be more experienced and have greater clinical, marketing and regulatory capabilities and managerial and financial resources than we do. This may enable them to develop products to treat the same medical conditions our products are intended to treat before we are able to complete the development of our competing product.

Our business is very competitive and involves rapid changes in the technologies involved in developing new drugs. If others experience rapid technological development, our products may become obsolete before we are able to recover expenses incurred in developing our products. We will probably face new competitors as new technologies develop. Our success depends on our ability to remain

competitive in the development of new drugs or we may not be able to compete successfully.

We may be sued for product liability.

Our business exposes us to potential product liability that may have a negative effect on our financial performance and our business generally. The administration of drugs to humans, whether in clinical trials or commercially, exposes us to potential product and professional liability risks which are inherent in the testing, production, marketing and sale of new drugs for humans. Product liability claims can be expensive to defend and may result in large judgments or settlements against us, which could have a negative effect on our financial performance and materially adversely affect our business. We maintain product liability insurance to protect our products and product candidates in amounts customary for companies in businesses that are similarly situated, but our insurance coverage may not be sufficient to cover claims. Furthermore, liability insurance coverage is becoming increasingly expensive and we cannot be certain that we will always be able to maintain or increase our insurance coverage at an affordable price or in sufficient amounts to protect against potential losses. A product liability claim, product recall or other claim, as well as any claim for uninsured liabilities or claim in excess of insured liabilities, may significantly harm our business and results of operations. Even if a product liability claim is not successful, adverse publicity and time and expense of defending such a claim may significantly interfere with our business.

If we are unable to obtain favorable reimbursement for our product candidates, their commercial success may be severely hindered.

Our ability to sell our future products may depend in large part on the extent to which reimbursement for the costs of our products is available from government entities, private health insurers, managed care organizations and others. Third-party payors are increasingly attempting to contain their costs. We cannot predict actions third-party payors may take, or whether they will limit the coverage and level of reimbursement for our products or refuse to provide any coverage at all. Reduced or partial reimbursement coverage could make our products less attractive to patients, suppliers and prescribing physicians and may not be adequate for us to maintain price levels sufficient to realize an appropriate return on our investment in our product candidates or compete on price.

In some cases, insurers and other healthcare payment organizations try to encourage the use of less expensive generic brands and over-the-counter, or OTC, products through their prescription benefits coverage and reimbursement policies. These organizations may make the generic alternative more attractive to the patient by providing different amounts of reimbursement so that the net cost of the generic product to the patient is less than the net cost of a prescription brand product. Aggressive pricing policies by our generic product competitors and the prescription benefits policies of insurers could have a negative effect on our product revenues and profitability.

Many managed care organizations negotiate the price of medical services and products and develop formularies for that purpose. Exclusion of a product from a formulary can lead to its sharply reduced usage in the managed care organization patient population. If our products are not included within an adequate number of formularies or adequate reimbursement levels are not provided, or if those policies increasingly favor generic or OTC products, our market share and gross margins could be negatively affected, as could our overall business and financial condition.

The competition among pharmaceutical companies to have their products approved for reimbursement may also result in downward pricing pressure in the industry or in the markets where our products will compete. We may not be successful in any efforts we take to mitigate the effect of a decline

in average selling prices for our products. Any decline in our average selling prices would also reduce our gross margins.

In addition, managed care initiatives to control costs may influence primary care physicians to refer fewer patients to oncologists and other specialists. Reductions in these referrals could have a material adverse effect on the size of our potential market and increase costs to effectively promote our products.

We are subject to new legislation, regulatory proposals and managed care initiatives that may increase our costs of compliance and adversely affect our ability to market our products, obtain collaborators and raise capital.

There have been a number of legislative and regulatory proposals aimed at changing the healthcare system and pharmaceutical industry, including reductions in the cost of prescription products and changes in the levels at which consumers and healthcare providers are reimbursed for purchases of pharmaceutical products. For example, the Prescription Drug and Medicare Improvement Act of 2003 provides a new Medicare prescription drug benefit

beginning in 2006 and mandates other reforms. Although we cannot predict the full effects on our business of the implementation of this new legislation, it is possible that the new benefit, which will be managed by private health insurers, pharmacy benefit managers and other managed care organizations, will result in decreased reimbursement for prescription drugs, which may further exacerbate industry-wide pressure to reduce the prices charged for prescription drugs. This could harm our ability to market our products and generate revenues. It is also possible that other proposals will be adopted. As a result of the new Medicare prescription drug benefit or any other proposals, we may determine to change our current manner of operation, provide additional benefits or change our contract arrangements, any of which could harm our ability to operate our business efficiently, obtain collaborators and raise capital.

We have only recently been relisted on the Nasdaq SmallCap Market and our stock is thinly traded and you may not be able to sell our stock when you want to do so.

From April 1999, when we were delisted from Nasdaq, until September 9, 2004, when we were relisted on the Nasdaq SmallCap Market, there was no established trading market for our common stock. During that time, our common stock was quoted on the OTC Bulletin Board and was thinly traded. There is no assurance that we will be able to comply with all of the listing requirements necessary to remain listed on the Nasdaq SmallCap Market. In addition, our stock remains thinly traded and you may be unable to sell our common stock during times when the trading market is limited.

The price of our common stock has been, and may continue to be, volatile.

The market price of our common stock, like that of the securities of many other development stage biotechnology companies, has fluctuated over a wide range and it is likely that the price of our common stock will fluctuate in the future. Over the past three years, the sale price for our common stock, as reported by Nasdaq and the OTC Bulletin Board has fluctuated from a low of $0.50 to a high of $10.07. The market price of our common stock could be impacted by a variety of factors, including:

- announcements of technological innovations or new commercial products by us or our competitors,
- disclosure of the results of pre-clinical testing and clinical trials by us or our competitors,
- disclosure of the results of regulatory proceedings,
- changes in government regulation,

- developments in the patents or other proprietary rights owned or licensed by us or our competitors,
- public concern as to the safety and efficacy of products developed by us or others,
- litigation, and
- general market conditions in our industry.

In addition, the stock market continues to experience extreme price and volume fluctuations. These fluctuations have especially affected the market

price of many biotechnology companies. Such fluctuations have often been unrelated to the operating performance of these companies. Nonetheless, these broad market fluctuations may negatively affect the market price of our common stock.

Events with respect to our share capital could cause the price of our common stock to decline.

Sales of substantial amounts of our common stock in the open market, or the availability of such shares for sale, could adversely affect the price of our common stock. We had 37,453,062 shares of common stock outstanding as of April 30, 2006. The following securities that may be exercised into shares of our common stock were issued and outstanding as of April 30, 2006:

- Options. Stock options to purchase 4,026,400 shares of our common stock at a weighted average exercise price of approximately $3.14 per share.

- Warrants. Warrants to purchase 11,831,626 shares of our common stock at a weighted average exercise price of approximately $2.36 per share.

The shares of our common stock that may be issued under the options and warrants are currently registered with the SEC or are eligible for sale without any volume limitations pursuant to Rule 144(k) under the Securities Act.

Our incorporation documents may delay or prevent (i) the removal of our current management or (ii) a change of control that a stockholder may consider favorable.

We are currently authorized to issue 1,000,000 shares of preferred stock. Our Board of Directors is authorized, without any approval of the stockholders, to issue the preferred stock and determine the terms of the preferred stock. This provision allows the board of directors to affect the rights of stockholders, since the board of directors can make it more difficult for common stockholders to replace members of the board. Because the board of directors is responsible for appointing the members of our management, these provisions could in turn affect any attempt to replace current management by the common stockholders. Furthermore, the existence of authorized shares of preferred stock might have the effect of discouraging any attempt by a person, through the acquisition of a substantial number of shares of common stock, to acquire control of our company. Accordingly, the accomplishment of a tender offer may be more difficult. This may be beneficial to management in a hostile tender offer, but have an adverse impact on stockholders who may want to participate in the tender offer or inhibit a stockholder's ability to receive an acquisition premium for his or her shares.

The ability of our stockholders to recover against Armus Harrison & Co., or AHC, may be limited because we have not been able to obtain the reissued reports of AHC with respect to the financial statements included in this Form 10-K, nor have we been able to obtain AHC's consent to the use of such report herein.

Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") provides that any person acquiring or selling a security in reliance upon statements set forth in a Form 10-K may assert a claim against every accountant who has with its consent been named as having prepared or certified any part of the Form 10-K, or as having prepared or certified any report or valuation that is used in connection with the Form 10-K, if that part of the Form 10-K at the

time it is filed contains a false or misleading statement of a material fact, or omits a material fact required to be stated therein or necessary to make the statements therein not misleading (unless it is proved that at the time of such acquisition such acquiring person knew of such untruth or omission).

In June 1996, AHC dissolved and ceased all operations. Therefore, we have not been able to obtain the reissued reports of AHC with respect to the financial statements included in the Form 10-K for the fiscal year ended July 31, 2005 nor have we been able to obtain AHC's consent to the use of such report herein. As a result, in the event any persons seek to assert a claim against AHC under Section 18 of the Exchange Act for any untrue statement of a material fact contained in these financial statements or any omissions to state a material fact required to be stated therein, such persons will be barred. Accordingly, you may be unable to assert a claim against AHC under Section 18 of the Exchange Act for any purchases of the Company's Common Stock made in reliance upon statements set forth in the Form 10-K for the fiscal year ended July 31, 2005. In addition, the ability of AHC to satisfy any claims properly brought against it may be limited as a practical matter due to AHC's dissolution in 1996.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

(a) Recent Sales of Unregistered Securities

The following transactions were exempt from registrations under Section 4(2) of the Securities Act of 1933, as amended. The net proceeds from these transactions will be used for general corporate purposes.

During the quarter ended April 30, 2006, we issued an aggregate total of 294,967 shares of common stock upon the exercise of warrants by unrelated parties at exercise prices ranging from $0.75 to $1.50 per share, which resulted in gross proceeds of $316,223 to us. We have previously registered the resale of these shares by the stockholders on a Form S-3 registration statement.

Item 5. Other Information

Item 8.01 Other Events.

On February 27, 2006, we announced that the full enrollment target of 316 patients has been reached for the international, confirmatory Phase IIIb registration trial evaluating ONCONASE(R) (ranpirnase), our lead investigational drug candidate, as a treatment for unresectable malignant mesothelioma.

On April 27, 2006, we announced that 210 events (deaths) have been reached in our confirmatory Phase IIIb registration trial evaluating ONCONASE(R) (ranpirnase, our lead investigational drug candidate, as a treatment for unresectable malignant mesothelioma (UMM). This number of events represents two-

thirds of the required events for the study. We have the option to conduct a second interim analysis of the data at any point after 210 events (of the 316 total events planned). We also announced that the first interim analysis results based on 105 events (deaths) showed a two month survival advantage of ONCONASE(R) + doxorubicin (12 months) vs. doxorubicin (10 months). These results were consistent with the results from the first part of the trial and were the basis for our decision to continue the trial.

Item 6. Exhibits

Exhibits (numbered in accordance with Item 601 of Regulation S-K).

Exhibit No.	Item Title	Exhibit No. or Incorporation by Reference
3.1	Certificate of Incorporation, dated June 12, 1981 (incorporated by reference to Registration Statement on Form S-1, File No. 333-112865, filed on February 17, 2004)	*
3.2	Amendment to Certificate of Incorporation, dated February 18, 1994 (incorporated by reference to Registration Statement on Form S-1, File No. 333-112865, filed on February 17, 2004)	*
3.3	Amendment to Certificate of Incorporation, dated December 26, 1997 (incorporated by reference to Registration Statement on Form S-1, File No. 333-112865, filed on February 17, 2004)	*
3.4	Amendment to Certificate of Incorporation, dated January 14, 2004 (incorporated by reference to Registration Statement on Form S-1, File No. 333-112865, filed on February 17, 2004)	*
3.5	Certificate of Designation for Series A Preferred Stock, dated September 2, 2003 (incorporated by reference to Registration Statement on Form S-1, File No. 333-112865, filed on February 17, 2004)	*
3.6	Certificate of Elimination of Series A Preferred Stock, dated February 3, 2004 (incorporated by reference to Registration Statement on Form S-1, File No. 333-112865, filed on February 17, 2004)	*
3.7	By-Laws (incorporated by reference to Exhibit 3.4 to Registration Statement on Form S-1, File No. 333-111101, filed on December 11, 2003)	*
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	+
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	+
32.1	Certification Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	+
32.2	Certification Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	+

* Previously filed; incorporated herein by reference.

\+ Filed herewith.

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.

ALFACELL CORPORATION

(Registrant)

June 9, 2006

/s/ Robert D. Love

Robert D. Love
Chief Financial Officer (Principal Financial Officer and Chief Accounting Officer)