ALFACELL CORP
Form 10-Q
March 11, 2005

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

FORM 10-Q

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

January 31, 2005	0-11088
For the quarterly period ended	Commission file number

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)

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

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 an accelerated filer (as defined in Exchange Act Rule 12b-2). YES X NO
--- ---

The number of shares of common stock, $.001 par value, outstanding as of March 8, 2005 was 35,245,445 shares.

(A Development Stage Company)

PART I. FINANCIAL INFORMATION
Item 1. FINANCIAL STATEMENTS

CONDENSED BALANCE SHEETS
January 31, 2005 and July 31, 2004

	Janu 2 (UNA
ASSETS	
Current assets:	
Cash and cash equivalents	$ 5,6
Short-term investments at market which approximates cost	1,9
Other current assets	2
Total current assets	7,8
Property and equipment, net	
Loan receivable, related party	1
Total assets	$ 8,0
LIABILITIES AND STOCKHOLDERS' EQUITY	
Current liabilities:	
Notes payable, net of discount of $4,059 at January 31, 2005 and $34,120 at July 31, 2004	$ 1
Accounts payable	6
Accrued expenses	8
Total liabilities	1,7
Stockholders' equity:	
Preferred stock, $.001 par value; Authorized and unissued, 1,000,000 shares at January 31, 2005 and July 31, 2004	
Common stock, $.001 par value; Authorized 100,000,000 shares at January 31, 2005 and July 31, 2004; Issued and outstanding, 35,245,445 shares at January 31, 2005 and 34,347,885 shares at July 31, 2004	
Capital in excess of par value	78,3
Deficit accumulated during development stage	(72,0
Total stockholders' equity	6,3
Total liabilities and stockholders' equity	$ 8,0

See accompanying notes to condensed financial statements.

ALFACELL CORPORATION
(A Development Stage Company)

CONDENSED STATEMENTS OF OPERATIONS

Three months and six months ended January 31,
2005 and 2004, and the Period from
August 24, 1981
(Date of Inception) to January 31, 2005

(Unaudited)

	Three Months Ended January 31,		Six Months Ende January 31,	
	2005	2004	2005	
Revenue:				
Sales	$ -	$ -	$ -	$
Investment income	33,704	4,530	62,882	
Other income	-	-	-	
Total revenue	33,704	4,530	62,882	
Costs and expenses:				
Cost of sales	-	-	-	
Research and development	1,554,443	674,089	2,475,592	
General and administrative	422,406	420,243	868,003	
Interest:				
Related parties, net	-	-	-	
Others	12,165	109,786	43,422	
Total costs and expenses	1,989,014	1,204,118	3,387,017	
Loss before state tax benefit	(1,955,310)	(1,199,588)	(3,324,135)	(
State tax benefit	-	-	287,975	
Net loss	$ (1,955,310)	$ (1,199,588)	$ (3,036,160)	$ (
Loss per basic and diluted common share	$ (0.06)	$ (0.04)	$ (0.09)	
Weighted average number of shares outstanding	35,211,954	28,439,372	34,936,198	2

See accompanying notes to condensed financial statements.

ALFACELL CORPORATION
(A Development Stage Company)

CONDENSED STATEMENTS OF CASH FLOWS

Six months ended January 31, 2005 and 2004,
and the Period from August 24, 1981
(Date of Inception) to January 31, 2005

(Unaudited)

	Six Months Ended January 31,	
	2005	2004
Cash flows from operating activities:		
Net loss	$(3,036,160)	$(1,957,798)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on sale of marketable securities	-	-
Depreciation and amortization	14,220	3,414
Loss on disposal of property and equipment	-	-
Noncash operating expenses	13,500	147,893
Amortization of debt discount	30,061	174,039
Amortization of deferred compensation	-	-
Amortization of organization costs	-	-
Changes in operating assets and liabilities:		
Increase in other current assets	(163,349)	(238,950)
Increase in loan receivable-related party	(4,797)	(6,055)
Increase in interest payable-related party	-	-
Increase (decrease) in accounts payable	118,148	(92,846)
Increase in accrued payroll and expenses, related parties	-	-
Increase (decrease) in accrued expenses	293,544	(658,520)
Net cash used in operating activities	(2,734,833)	(2,628,823)
Cash flows from investing activities:		
Purchase of marketable equity securities	-	-
Purchase of short-term investments	(1,978,189)	-
Proceeds from sale of marketable equity securities	-	-
Purchase of property and equipment	(41,153)	(2,251)
Patent costs	-	-
Net cash used in investing activities	(2,019,342)	(2,251)

ALFACELL CORPORATION
(A Development Stage Company)

CONDENSED STATEMENTS OF CASH FLOWS, Continued

Six months ended January 31, 2005 and 2004
and the Period from August 24, 1981
(Date of Inception) to January 31, 2005

(Unaudited)

	Six Months Ended January 31, 2005
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	(6,730)
Proceeds from issuance of common stock, net	-
Proceeds from exercise of stock options and warrants, net	244,166
Proceeds from issuance of convertible debentures, related party	-
Proceeds from issuance of convertible debentures, unrelated party	
Net cash provided by financing activities	237,436
Net increase (decrease) in cash and cash equivalents	(4,516,739)
Cash and cash equivalents at beginning of period	10,147,694
Cash and cash equivalents at end of period	$ 5,630,955
Supplemental disclosure of cash flow information - interest paid	$ 305
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	$ -
Accounts payable settled in 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	$ -
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 January 31, 2005 and its results of operations and cash flows for the three and six month periods ended January 31, 2005 and 2004 and the period from August 24, 1981 (date of inception) to January 31, 2005. The results of operations for the three and six months ended January 31, 2005 are not necessarily indicative of the results to be expected for the full year. The condensed balance sheet presented herein has been derived from the audited financial statements included in the Form 10-K for the fiscal year ended July 31, 2004, 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 year ended July 31, 2004.

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 $5,070,000, $2,411,000, and $2,591,000 for the fiscal years ended July 31, 2004, 2003 and 2002, respectively. The loss from date of inception, August 24, 1981 to January 31, 2005 amounts to $72,081,000.

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 net operating loss carryforwards, revenues from the commercial sale of ONCONASE(R), licensing of its proprietary RNase technology and its ability to realize the full potential of its technology and its drug candidates via out-licensing agreements with other companies. Such additional funds may not become available as needed or be available on acceptable terms. Through February 28, 2005, a significant portion of the Company's financing has been through the sale of equity securities and convertible debentures in registered offerings and private placements and exercise of stock options and warrants. Additionally, the Company has raised capital through debt financings, sale of net operating loss carryforwards, 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 its operations from the sources of capital previously described. There can be no assurance that the Company will be able to raise the capital needed on acceptable terms, if at all. As of January 31, 2005, management believes that the Company's cash balance is sufficient to fund its expanded operations at least through February 28, 2006 based on our expected level of expenditures in relation to activities in preparing ONCONASE(R) for marketing registrations in the US and Europe and other ongoing operations of the Company. However, the Company will continue to seek additional financing through equity or debt financings and the sale of net operating loss carryforwards but

1. ORGANIZATION AND BASIS OF PRESENTATION, CONTINUED

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 the amount of capital it will receive, if any.

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 is in a loss position and the assumed exercise of stock options and warrants and conversion of convertible notes would be anti-dilutive. The number of shares subject to outstanding options and warrants that could dilute earnings per share in future periods was 15,208,029 and 9,543,637 at January 31, 2005 and 2004, respectively. These also exclude the potential dilution that could occur upon the conversion of convertible notes into 1,199,890 and 4,787,795 shares of common stock and additional warrants to purchase 1,399,890 and 5,778,817 shares of common stock at January 31, 2005 and 2004, respectively.

3. STOCK-BASED COMPENSATION

The Company measures compensation expense for its stock-based employee compensation plans using the intrinsic value method. As the exercise price of all options granted under these plans was equal to the fair market price of the underlying common stock on the grant date, no stock-based employee compensation cost is recognized in the condensed statements of operations.

In accordance with Statement of Financial Accounting Standards No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure - An Amendment of FASB Statement No. 123" (SFAS 148) and Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation" (SFAS 123), the Company's pro forma option expense is computed using the Black-Scholes option pricing model. To comply with SFAS 148, the Company is presenting the following table to illustrate the effect on the net loss and loss per share if it had applied the fair value recognition provisions of SFAS 123, as amended, to options granted under the stock-based employee compensation plans. For purposes of this pro forma disclosure, the estimated value of the options is amortized ratably to expense over the options' vesting periods.

ALFACELL CORPORATION
(A Development Stage Company)

NOTES TO CONDENSED FINANCIAL STATEMENTS, Continued

(Unaudited)

3. STOCK-BASED COMPENSATION, CONTINUED

	Three Months Ended January 31,		Six Mo Janu
	2005	2004	2005
Net loss applicable to common shares			
As reported	$ (1,955,310)	$ (1,199,588)	$ (3,036,160)
Less total stock-based employee compensation expense determined under fair value method for all awards, net of related tax effects	(604,671)	(109,184)	(1,223,942)
Pro forma	$ (2,559,981)	$ (1,308,772)	$ (4,260,102)

Basic and diluted loss per common share			
As reported	$ (0.06)	$ (0.04)	$ (0.09
Pro forma	(0.07)	(0.05)	(0.12

The fair value was estimated using the Black-Scholes options pricing model based on the following assumptions:

	Six Months Ended January 31,	
	2005	2004
Expected dividend yield	0%	0%
Risk-free interest rate	4.25%	2% - 6%
Expected stock price volatility	100%	40.79% - 114.54%
Expected term until exercise (years)	8.67	5.82

As a result of amendments to SFAS 123, the Company will be required to expense the fair value of employee stock options beginning with its fiscal quarter ending September 30, 2005.

4. LOAN RECEIVABLE, RELATED PARTY

Amounts due from the Company's CEO totaling $156,612 and $151,815 at January 31, 2005 and July 31, 2004, respectively, are classified as a long-term asset as the loans have no specified due dates, and the Company does not expect repayment of these amounts within one year. As of January 31, 2005, the Company earned interest at 8% per annum (approximately $4,800 for the six months then ended) on the unpaid principal balance.

5. CAPITAL STOCK

During the quarter ended October 31, 2004, the Company issued 320,157 shares of restricted common stock and five-year warrants to purchase 420,157 shares of common stock with an exercise price of $1.00 per share upon the conversion of notes payable and accrued interest in the amount of $112,055 by an unrelated party.

During the quarter ended October 31, 2004, the Company also issued an aggregate of 326,472 shares of common stock upon the exercise of warrants and stock options by unrelated parties, employees and a director at per share exercise prices ranging from $0.29 to $1.50. The Company realized aggregate net proceeds of $209,545 from these exercises.

During the quarter ended January 31, 2005, the Company issued 224,931 shares of restricted common stock and five-year warrants to purchase 224,931 shares of common stock with an exercise price of $1.00 per share upon the conversion of notes payable and accrued interest in the amount of $112,465 by an

unrelated party.

During the quarter ended January 31, 2005, the Company also issued an aggregate of 23,000 shares of common stock upon the exercise of warrants and stock options by an unrelated party and an employee at per share exercise prices ranging from $0.26 to $1.25. The Company realized aggregate net proceeds of $34,621 from these exercises.

During the quarter ended January 31, 2005, the Company also issued 3,000 shares of restricted common stock as payment for services rendered. A non-cash expense of $13,500 was recorded by the Company for these shares, based upon the fair value of the common stock at the date of issuance.

6. SALE OF NET OPERATING LOSS CARRYFORWARDS

New Jersey has enacted legislation permitting certain corporations located in New Jersey to sell 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 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 six months ended January 31, 2005.

For the state fiscal year 2004 (July 1, 2003 to June 30, 2004), the Company had approximately $1,378,000 of total available net operating loss carryforwards that were saleable; of which New Jersey permitted the Company to sell approximately $261,000. In December 2003, the Company received approximately $222,000 from the sale of the $261,000 of net operating loss carryforwards, which was recognized as a tax benefit for the six months ended January 31, 2004.

6. SALE OF NET OPERATING LOSS CARRYFORWARDS, CONTINUED

If still available under New Jersey law, the Company will attempt to sell the remaining $996,000 of its net operating loss carryforwards between July 1, 2005 and June 30, 2006. This amount, which is a carryover of the Company's remaining net operating loss carryforwards from state fiscal year 2005, may increase if the Company incurs additional net losses and research and development credits during state fiscal year 2006. 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 such 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 herein under the caption "Risk Factors" 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 for the treatment of malignant mesothelioma, 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 the 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.

Almost all of our research and development expenses since our inception of $47,431,000 have gone toward the development of ONCONASE(R) and related drug candidates. For the six months ended January 31, 2005 and fiscal years 2004, 2003 and 2002, our research and development expenses were $2,476,000, $3,353,000, $1,700,000 and $2,033,000, respectively. 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. 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 malignant mesothelioma. If the results of the clinical trials are positive, we expect to file for marketing registrations (NDA and MAA) 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. Hence, the timing of

the filing is data driven as to when we will be able to file for marketing registrations in the US and EU. Therefore, we cannot predict with certainty what our total cost will be associated with obtaining marketing approvals, or when and if such approvals will be granted, and when actual sales will occur.

We fund the research and development of our products from cash receipts resulting primarily from the sale of our equity securities and convertible debentures in registered offerings and private placements. Additionally, we have raised capital through debt financings, the sale of our net operating

loss carryforwards, research products, interest income and financing received from our Chief Executive Officer. Presently, we believe that our cash balance is sufficient to fund our expanded operations at least through February 28, 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, we will continue to seek additional financing through equity or debt financings and the sale of our 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 the amount of capital we will receive, if any.

RESULTS OF OPERATIONS

THREE AND SIX MONTH PERIODS ENDED JANUARY 31, 2005 AND 2004

REVENUES. We are a development stage company as defined in the Statement of Financial Accounting Standards No. 7. We are devoting substantially all of our present efforts to establishing and developing new drug products. Our planned principal operations of marketing and/or licensing of 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 six month periods ended January 31, 2005 and 2004. Our investment income for the three months ended January 31, 2005 was $34,000 compared to $5,000 for the same period last year, an increase of $29,000. Investment income for the six months ended January 31, 2005 was $63,000 compared to $8,000 for the same period last year, an increase of $55,000. These increases were due to higher balances of cash and cash equivalents and higher interest rates.

RESEARCH AND DEVELOPMENT. Research and development expense for the three months ended January 31, 2005 was $1,554,000 compared to $674,000 for the same period last year, an increase of $880,000, or 131%. Research and development expense for the six months ended January 31, 2005 was $2,476,000 compared to $1,311,000 for the same period last year, an increase of $1,165,000, or 89%. These increases were primarily due to increases in data management and clinical trial consulting fees related to our pivotal Phase III clinical trial for malignant mesothelioma of approximately $544,000, sponsored research and development expenses of $240,000, expansion of our Phase III clinical trial for malignant mesothelioma primarily in Europe of approximately $199,000, patent expenses of approximately $146,000, and sponsored conferences related to mesothelioma of approximately $36,000.

GENERAL AND ADMINISTRATIVE. General and administrative expense for the three months ended January 31, 2005 was $422,000 compared to $420,000 for the same period last year, an increase of $2,000. General and administrative expense for the six months ended January 31, 2005 was $868,000 compared to $648,000 for the same period last year, an increase of $220,000, or 34%. These increases were

primarily due to increases in personnel expenses of approximately $247,000, Nasdaq re-listing and membership fees of approximately $72,000, professional fees related to board of directors fees and Sarbanes Oxley compliance fees of approximately $46,000, public relations and insurance expenses of approximately $10,000 and $9,000, respectively, offset by a decrease in non-cash expense related to stock and stock options issued for consulting services of approximately $143,000 and decreases in legal expenses of approximately $21,000.

INTEREST. Interest expense for the three months ended January 31, 2005 was $12,000 compared to $110,000 for the same period last year, a decrease of $98,000, or 89%. Interest expense for the six months ended January 31, 2005 was $43,000 compared to $228,000 for the same period last year, a decrease of $185,000, or 81%. These decreases were primarily due to the maturity and conversion of convertible notes payable.

INCOME TAXES. New Jersey has enacted legislation permitting certain corporations located in New Jersey to sell 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 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 was recognized as a tax benefit for the six months ended January 31, 2005.

For the state fiscal year 2004 (July 1, 2003 to June 30, 2004), we had approximately $1,378,000 of total available net operating loss carryforwards that were saleable; of which New Jersey permitted us to sell approximately $261,000. In December 2003, we received approximately $222,000 from the sale of the $261,000 of net operating loss carryforwards, which we recognized as a tax benefit for the six months ended January 31, 2004.

If still available under New Jersey law, we will attempt to sell the remaining $996,000 of our net operating loss carryforwards between July 1, 2005 and June 30, 2006. This amount, which is a carryover of our remaining net operating loss carryforwards from state fiscal year 2005, may increase if we incur additional net losses and research and development credits during state fiscal year 2006. 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 January 31, 2005 was $1,955,000 as compared to $1,200,000 for the same period last year, an increase of $755,000. The net loss for the six months ended January 31, 2005 was $3,036,000 as compared to $1,958,000 for the same period last year, an increase of $1,078,000. The cumulative loss from the date of inception, August 24, 1981 to January 31, 2005, amounted to $72,081,000. Such losses are attributable to the fact that we are still in the development stage and, accordingly, we have not derived sufficient revenues 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. Additionally, we have raised capital through debt financings, the sale of our net operating loss carryforwards, research products, interest income and financing received from our Chief Executive Officer. During the six months ended January 31, 2005, we had a net decrease in cash and cash equivalents of $4,517,000, which resulted primarily from net cash used in operating activities of $2,735,000 and net cash used in investing activities due to the purchase of short-term investments of $1,978,000 and purchase of property and equipment of $41,000, offset by net cash provided by financing activities of $237,000 from warrant and stock option exercises for $244,000 net of a $7,000 reduction of debt. Total cash resources as of January 31, 2005 were $5,631,000 compared to $10,148,000 at July 31, 2004.

Our current liabilities as of January 31, 2005 were $1,750,000 compared to $1,539,000 at July 31, 2004, an increase of $211,000. The increase was primarily due to increases in accrued expenses of approximately $269,000 and accounts payable of approximately $118,000, offset by maturity and conversion of convertible notes payable of approximately $176,000.

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 net operating loss carryforwards, 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 be available on acceptable terms. To date, a significant portion of our financing has been through the sale of our equity securities and convertible debentures in registered offerings and private placements and exercise of stock options and warrants. Additionally, we have raised capital through debt financings, the sale of our net operating loss carryforwards, research products, interest income and financing received from our Chief Executive Officer. Until and unless our operations generate significant revenues, we expect to continue to fund operations from the sources of capital previously described. There can be no assurance that we will be able to raise the capital we need on acceptable terms, if at all. Presently, we believe that our cash balance is sufficient to fund our expanded operations at least through February 28, 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, we will continue to seek additional financing through equity or debt financings and the sale of our 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 the amount of capital we will receive, if any.

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 January 31, 2005, we are not involved in any material 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, 2004.

CONTRACTUAL OBLIGATIONS AND COMMERCIAL COMMITMENTS

Our outstanding contractual obligations relate to our equipment operating lease. The following table presents our contractual obligations and commercial commitments as of January 31, 2005:

		PAYMENTS DUE BY FISCAL YEAR	
	TOTAL	2005	2006 AND THEREAFTER
Operating lease	$ 8,760	$ 8,760	$ - 0 -
Total contractual cash obligations	$ 8,760	$ 8,760	$ - 0 -

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.

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 inception our source of working capital has been public and private sales of our stock. We incurred a net loss of approximately $3,036,000 for the six months ended January 31, 2005 and our cumulative loss from the date of inception amounted to approximately $72,081,000. We have continued to incur losses since July 2004. We may never achieve revenue sufficient for us to attain profitability.

We incurred net losses of approximately $5,070,000, $2,411,000 and $2,591,000 for the fiscal years ended July 31, 2004, 2003 and 2002, respectively.

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;

- Side effects or 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 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) in the United States with the FDA and in Europe with the EMEA. 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. Presently, we believe that our cash balance is sufficient to fund our expanded operations at least through February 28, 2006, based on our expected level of expenditures. However, taking into consideration all of the uncertainties related to drug development and our industry, we will continue to seek additional financing through equity or debt financings and the sale of our 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 assurance of such exercises or the amount of capital we will receive, if any.

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.

New Jersey has enacted legislation permitting certain corporations located in New Jersey to sell state tax loss carryforwards and state research and development credits, or net operating loss carryforwards, in order to obtain tax benefits. The aggregate amount of net operating loss carryforwards 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 net operating loss carryforwards 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 net operating loss carryforwards for a reasonable price. Our historical results of operations have been improved by our sale of net operating loss carryforwards and if we continue to generate a limited amount of revenue and are unable in the future to sell our net operating loss carryforwards, our results of operations will be negatively impacted.

For the state fiscal year 2005 (July 1, 2004 to June 30, 2005), we had approximately $1,335,000 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 six months ended January 31, 2005. For the state fiscal year 2004 (July 1, 2003 to June 30, 2004), we had approximately $1,378,000 of total available net operating loss carryforwards that were saleable, of which New Jersey permitted us to sell approximately $261,000. In December 2003, we received approximately $222,000 from the sale of the $261,000 of net operating loss carryforwards, which we recognized as a tax benefit for the six months ended January 31, 2004.

If still available under New Jersey law, we will attempt to sell the remaining $996,000 of our net operating loss carryforwards, between July 1, 2005 and June 30, 2006. This amount, which is a carryover of our remaining net operating loss carryforwards from state fiscal year 2005, may increase if we incur additional net losses and research and development credits during state fiscal year 2006. 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.

WE CANNOT PREDICT HOW LONG IT WILL TAKE US NOR HOW MUCH IT WILL COST US TO COMPLETE OUR PHASE III TRIAL BECAUSE IT IS A SURVIVAL STUDY AND WE ARE STILL IN PATIENT ENROLLMENT IN PART TWO OF THIS PHASE III TRIAL.

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. 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 terminal events 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 and EMEA.

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. Delays in patient enrollment, could delay achieving a sufficient number of deaths required for statistical analyses, which therefore may delay the marketing registrations. 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.

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 type, complexity and novelty of the product. We cannot apply for FDA or EMEA approval to market ONCONASE(R) until the clinical trials and all other registration requirements have been met.

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. 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 or

EMEA 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 and EMEA could stop our trials before completion.

In December 2002, we received Fast Track Designation from the Food and Drug Administration, or the FDA for ONCONASE(R) for the treatment of malignant mesothelioma. In February 2001, we received an Orphan Medicinal Product Designation for ONCONASE(R) from the European Agency for the Evaluation of Medicinal Products, or the EMEA.

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 Labs 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 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.

Our use of manufacturers for ranpirnase and ONCONASE(R) have been approved by the FDA. We have identified substantial alternative service providers for the manufacturing services for which we 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 approval, we expect to rely on established third party strategic partners to perform these functions. For example, if we are successful in our Phase III clinical trials with ONCONASE(R), and are granted marketing approval for the commercialization of ONCONASE(R), we will be unable to introduce the product to market without establishing a marketing collaboration with a pharmaceutical company with those resources. If we establish 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, we cannot assure you that we will be able to enter into or maintain agreements with these companies on acceptable terms, if at all. Further, it is likely that we will have limited or no control over the manner in which product candidates are marketed or the resources devoted to such markets.

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 one Japanese patent that expires in 2010. 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 which was recently enacted, 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 relisted 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 $0.18 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 35,245,445 shares of common stock outstanding as of January 31, 2005. The following securities that may be exercised for, or are convertible into, shares of our common stock were issued and outstanding as of January 31, 2005:

- Stock options to purchase 3,438,245 shares of our common stock at a weighted average exercise price of approximately $3.59 per share.
- Warrants to purchase 11,769,784 shares of our common stock at a

weighted average exercise price of approximately $2.50 per share.

- Convertible Notes which will convert into 1,199,890 shares of our common stock at an average conversion price of $0.20 per share and warrants which are exercisable for 1,399,890 shares of our common stock at an exercise price of $1.00 per share.

The shares of our common stock that may be issued under the options, warrants and upon conversion of the notes 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 OUR FORM 10-K FOR THE FISCAL YEAR ENDED JULY 31, 2004, NOR HAVE WE BEEN ABLE TO OBTAIN AHC'S CONSENT TO THE USE OF SUCH REPORT THEREIN.

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, 2004 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, 2004. 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 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 January 31, 2005, 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 significant changes made in our internal controls over financial reporting during the three months ended January 31, 2005 or, to our knowledge, in other factors that have materially affected, or are materially likely to affect, these controls.

We are currently undergoing a comprehensive effort to ensure compliance with Section 404 of the Sarbanes-Oxley Act of 2002. As an accelerated filer with a fiscal year end of July 31, we must first begin to comply with the requirements of Section 404 for the fiscal year ending July 31, 2005. We believe that our present internal control program has been effective at a reasonable assurance level to ensure that our financial reporting has not been materially misstated. Nonetheless, during the remaining periods through July 31, 2005, we will continue to review, and where necessary, enhance our internal control design and documentation, management review, and ongoing risk assessment as part of our internal control program.

PART II. OTHER INFORMATION

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

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 January 31, 2005, we issued 224,931 shares of restricted common stock and five-year warrants to purchase 224,931 shares of common stock with an exercise price of $1.00 per share upon the conversion of notes payable in the amount of $112,465 by an unrelated party.

During the quarter ended January 31, 2005, we issued 20,000 shares of common stock upon the exercise of warrants by an unrelated party, which resulted in aggregate gross proceeds of $25,000 to us. We have previously registered the resale of these shares by the stockholders on a Form S-1 registration statement.

During the quarter ended January 31, 2005, we issued 3,000 shares of restricted common stock as payment for services rendered. A non-cash expense of $13,500 was recorded by the Company for these shares, based upon the fair value of the common stock at the date of issuance.

ISSUER PURCHASES OF EQUITY SECURITIES

We did not repurchase any shares of our common stock during the second quarter of fiscal 2005.

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

(a) An annual meeting of stockholders was held on January 27, 2005.

(b) All of our current directors, Kuslima Shogen, John P. Brancaccio, Stephen K. Carter, Donald R. Conklin, James J. Loughlin, Andrew P. Savadelis, David Sidransky and Paul M. Weiss, were elected at the annual meeting.

(c) The matters voted upon at the annual meeting and the results of the voting, including broker non-votes where applicable, are set forth below:

(i) For the election of directors

Director	Number of Shares of Common Stock Voted For	Number of Shares of Common Stock Withheld	N
Kuslima Shogen	27,595,108	108,339	
John P. Brancaccio	27,611,830	91,617	
Stephen K. Carter	27,615,260	88,187	
Donald R. Conklin	27,594,430	109,017	
James J. Loughlin	27,594,350	109,097	
Andrew P. Savadelis	27,567,458	135,989	
David Sidransky	27,615,500	87,947	
Paul M. Weiss	27,593,652	109,795	

(ii) Proposal to ratify the appointment of J.H. Cohn LLP as Alfacell's independent registered public accounting

firm for the year ending July 31, 2005.

Number of Shares of Common Stock Voted For	Number of Shares of Common Stock Voted Against	Number of Shares of Common which Abstained from Voting
27,599,247	93,687	10,513

ITEM 6. EXHIBITS

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

Exhibit No.	Item Title
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)

Exhibit No.	Item Title
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)

March 11, 2005

/s/ Andrew P. Savadelis

Chief Financial Officer (Principal Financial Officer and Chief Accounting Officer)