ALFACELL CORP
Form 10-Q
June 14, 2004

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

April 30, 2004	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 Rule 12b-2 of the Exchange Act) Yes |_| No |X|

The number of shares of common stock, $.001 par value, outstanding as of June 10, 2004 was 32,601,461 shares.

ALFACELL CORPORATION
(A Development Stage Company)

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

CONDENSED BALANCE SHEETS
April 30, 2004 and July 31, 2003

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ASSETS	(Un
Current assets:	
Cash and cash equivalents	$ 1
Other current assets	
Total current assets	1
Property and equipment, net	
Loan receivable, related party	
Total assets	$ 1

LIABILITIES AND STOCKHOLDERS' DEFICIENCY	
Current liabilities:	
Current portion of long-term debt, net of debt discount of $82,219 at April 30, 2004 and $187,121 at July 31, 2003	$
Accounts payable	
Accrued expenses	
Total current liabilities	2
Long-term debt, less current portion, net of debt discount of $16,233 at April 30, 2004 and $163,687 at July 31, 2003	
Total liabilities	2
Stockholders' deficiency:	
Preferred stock, $.001 par value	
Authorized and unissued, 1,000,000 shares at April 30, 2004 and July 31, 2003	
Common stock $.001 par value	
Authorized 100,000,000 shares at April 30, 2004 and 40,000,000 shares at July 31, 2003;	
Issued and outstanding, 30,588,708 shares at April 30, 2004 and 25,026,129 shares at July 31, 2003	
Capital in excess of par value	66
Deficit accumulated during the development stage	(67
Total stockholders' deficiency	
Total liabilities and stockholders' deficiency	$ 1

See accompanying notes to condensed financial statements.

ALFACELL CORPORATION
(A Development Stage Company)

CONDENSED STATEMENTS OF OPERATIONS

Three months and nine months ended April 30, 2004 and 2003,
and the Period from August 24, 1981
(Date of Inception) to April 30, 2004

(Unaudited)

	Three Months Ended April 30,		Nine Months Ended April 30,	
	2004	2003	2004	2003
Revenue:				
Sales	$ --	$ --	$ --	$
Investment income	3,081	43	11,311	
Other income	--	--	--	30,
Total revenue	3,081	43	11,311	30,
Costs and expenses:				
Cost of sales	--	--	--	
Research and development	927,151	374,183	2,238,437	1,173,
General and administrative	329,388	138,131	977,576	426,
Interest:				
Related parties, net	--	653	--	1,
Others	97,091	54,831	325,492	293,
Total costs and expenses	1,353,630	567,798	3,541,505	1,894,
Loss before state tax benefit	(1,350,549)	(567,755)	(3,530,194)	(1,864,
State tax benefit	--	--	221,847	229,
Net loss	$ (1,350,549)	$ (567,755)	$ (3,308,347)	$ (1,635,
Loss per basic common share	$ (0.05)	$ (.02)	$ (0.12)	$ (
Weighted average number of shares outstanding - basic	29,548,812	23,079,250	28,290,878	22,911,

See accompanying notes to condensed financial statements.

ALFACELL CORPORATION
(A Development Stage Company)

CONDENSED STATEMENTS OF CASH FLOWS

Nine months ended April 30, 2004 and 2003,
and the Period from August 24, 1981
(Date of Inception) to April 30, 2004

(Unaudited)

	Nine Months Ended April 30,		August 24, (Date Inceptio
	2004	2003	April 30,
Cash flows from operating activities:			
Net loss	$(3,308,347)	$(1,635,077)	$(67,282
Adjustments to reconcile net loss to net cash used in operating activities:			
Gain on sale of marketable securities	--	--	(25
Depreciation and amortization	5,440	13,615	1,552
Loss on disposal of property and equipment	--	--	18
Noncash operating expenses	371,137	20,161	6,488
Amortization of debt discount	252,356	242,452	495
Amortization of deferred compensation	--	--	11,442
Amortization of organization costs	--	--	4
Changes in assets and liabilities:			
(Increase) decrease in other current assets	(264,167)	38,770	(334
Increase in loan receivable, related party	(8,404)	(4,176)	(54
Increase in interest payable, related party	--	--	744
Increase (decrease) in accounts payable	211,215	(126,202)	1,365
Increase in accrued payroll and expenses, related parties	--	--	2,348
(Decrease) increase in accrued expenses	(670,410)	437,133	1,279
Net cash used in operating activities	(3,411,180)	(1,013,324)	(41,957
Cash flows from investing activities:			
Purchase of marketable equity securities	--	--	(290
Proceeds from sale of marketable equity securities	--	--	316
Purchase of property and equipment	(7,432)	--	(1,414
Patent costs	--	--	(97
Net cash used in investing activities	(7,432)	--	(1,486

(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, 2004 and 2003,
and the Period from August 24, 1981
(Date of Inception) to April 30, 2004

(Unaudited)

	Nine Months Ended April 30,	
	2004	2003
Cash flows from financing activities:		
Proceeds from short-term borrowings	$ --	$ 25,00
Payment of short-term borrowings	--	(25,00
(Decrease) increase in loans payable - related party, net	--	(33,68
Proceeds from bank debt and other long-term debt, net of deferred issuance costs	--	750,00
Reduction of bank debt and long-term debt	(6,799)	(6,04
Proceeds from issuance of common stock, net	1,527,925	241,78
Proceeds from exercise of stock options and warrants, net	2,772,422	20,00
Proceeds from issuance of convertible debentures, related party	--	-
Proceeds from issuance of convertible debentures, unrelated party	--	-
Net cash provided by financing activities	4,293,548	972,06
Net increase (decrease) in cash and cash equivalents	874,936	(41,25
Cash and cash equivalents at beginning of period	330,137	85,84
Cash and cash equivalents at end of period	$1,205,073	$ 44,58
Supplemental disclosure of cash flow information - interest paid	$ 31,737	$ 4,41
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	$ 42,729	$ 10,00
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 and accrued interest, other	$ 514,597	$ -
Issuance of common stock for services rendered	$ 210,000	$ -
Issuance of warrants with notes payable	$ --	$ 196,68

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 accruals) necessary to present fairly the Company's financial position as of April 30, 2004 and its results of operations and cash flows for the three and/or nine month periods ended April 30, 2004 and 2003 and the period from August 24, 1981 (date of inception) to April 30, 2004. The results of operations for the nine months ended April 30, 2004 are not necessarily indicative of the results to be expected for the full year.

Certain footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles 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, 2003.

The Company is a development stage company as defined in the Financial Accounting Standards Board's 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 since its inception and has limited liquid resources. The report of the Company's independent registered public accountants on the Company's July 31, 2003 financial statements included an explanatory paragraph which states that the Company's recurring losses, working capital deficit and limited liquid resources raise substantial doubt about the Company's ability to continue as a going concern. The Company has continued to incur losses through April 30, 2004 and has a working capital deficiency as of April 30, 2004. The condensed financial statements at July 31, 2003 and April 30, 2004 and for the periods ended April 30, 2004 and 2003 do not include any adjustments that might result from the outcome of this uncertainty.

The Company's continued operations will depend on its ability to raise additional funds through various potential sources such as equity and debt financing (see Notes 5 and 7), 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 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 May 31, 2004, 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 (see Notes 5 and 7). Additionally, the Company has raised capital through debt financings, sale of

tax benefits and

ALFACELL CORPORATION
(A Development Stage Company)

NOTES TO CONDENSED FINANCIAL STATEMENTS, Continued

Unaudited

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 terms which are acceptable, if at all. As of April 30, 2004, the Company's cash balance is sufficient to fund its expanded operations at least through July 31, 2005 (see Note 7), based on its 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 capital financing through the sale of equity in private placements, sale of tax benefits and exercise of stock options and warrants but cannot be sure that the Company will be able to raise capital on favorable terms or at all.

2. EARNINGS (LOSS) PER COMMON SHARE

"Basic" loss per common share equals net loss divided by weighted average common shares outstanding during the period. "Diluted" loss per common share equals net income divided by the sum of weighted average common shares outstanding during the period plus the effect of potentially dilutive securities. The Company's Basic and Diluted per share amounts are the same since the effects of the assumed exercise of stock options and warrants and the conversion of convertible notes are all anti-dilutive. The number of shares issuable upon the exercise of options and warrants excluded from the calculation was 11,856,030 and 10,070,773 at April 30, 2004 and 2003, respectively. This also excludes the potential dilution that could occur upon the conversion of convertible notes into 3,319,402 shares of common stock and warrants to purchase 3,860,424 shares of common stock.

3. STOCK-BASED COMPENSATION

During the third fiscal quarter of 2003, Statement of Financial Accounting Standards No. 148 (SFAS 148), "Accounting for Stock-Based Compensation - Transition and Disclosure - An Amendment of FASB Statement No. 123" became effective for the Company.

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 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

	Three Months Ended April 30,		Nine Months April 3
	2004	2003	2004
Net loss			
As reported	$(1,350,549)	$(567,755)	$(3,308,347)
Stock-based employee compensation expense under fair value method	(979,883)	(38,398)	(1,160,246)
Pro forma	$(2,330,432)	$(606,153)	$(4,468,593)
Net loss per common share			
As reported - basic	$ (0.05)	$ (0.02)	$ (0.12)
Pro forma - basic	(0.08)	(0.03)	(0.16)

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

	Three Months Ended April 30,		Nine Months Ended April 30,	
	2004	2003	2004	2003
Expected dividend yield	0%	0%	0%	0%
Risk-free interest rate	2% - 6%	2% - 6%	2% - 6%	2% - 6%
Expected stock price volatility	40.79% - 114.54%	40.79% - 114.54%	40.79% - 114.54%	40.79% - 114.54%
Expected term until exercise (years)	5.96 - 10	6 - 7	5.96 - 10	6 - 7

4. LOAN RECEIVABLE, RELATED PARTY

Amounts due from the Company's CEO totaling $150,691 as of April 30, 2004 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. These loans were made prior to July 30, 2002 and have not since been materially modified. The Company earns interest on these loans at a rate of 8% per annum.

5. CAPITAL STOCK

In August 2003, the Company issued an aggregate of 120,000 shares of common stock to private investors resulting in aggregate gross proceeds of $60,000 to the Company. In addition, the private investors were granted five-year warrants to purchase 120,000 shares of common stock at an exercise price of $1.25 per share.

In August 2003, the Company issued 3,996 five-year stock options to a consultant as payment for services rendered. The options vested immediately and have a per share exercise price of $0.60. The Company recorded a total of $5,235 of non-cash expenses for these options, based upon the fair value on the date of the issuance as estimated by the Black-Scholes options pricing model.

In September 2003, Alfacell entered into a two-part financing agreement with SF Capital Partners, Ltd. for the initial private placement of 1,704,546 shares of common stock and warrants to purchase 852,273 shares of common stock, at an exercise price of $1.50 per share. As consideration, Alfacell received $1,500,000. In addition, the Company agreed to grant SF Capital Partners, Ltd. a warrant to invest an additional $1,500,000 to purchase the Company's common stock at an exercise price based upon a 20-day trailing average of the closing price per share of the Company's common stock (the "Additional Warrants"). The Company also issued 38,710 shares of restricted common stock to a third party as finder's fee.

On January 16, 2004, the Company issued the Additional Warrants to SF Capital. On January 29, 2004, SF Capital exercised the Additional Warrant and invested an additional $1,500,000 to purchase the Company's common stock at a 20-day trailing average exercise price of $3.96. In exchange, SF Capital received 379,170 shares of common stock and an Exercise Warrant to purchase an additional 189,585 shares of common stock at a per share exercise price of $4.75. Pursuant to the terms of the financing agreement entered into in the September 2003 private placement, the Company is registering the resale by SF Capital of 379,170 shares of common stock and 189,585 shares of common stock underlying warrants. The Company also issued 15,166 shares of restricted common stock to a third party as finder's fee.

In November 2003, the Company issued 25,000 five-year stock options to a board member as payment for non-board related services. The options vested immediately and have a per share exercise price of $3.46. The Company recorded a total of $52,658 of non-cash expenses for these options, based upon the fair value on the date of the issuance as estimated by the Black-Scholes options pricing model.

In December 2003, the Company issued 12,604 restricted shares of common stock as payment of accounts payable in the amount of $42,729.

On January 14, 2004 at the Company's annual stockholders' meeting, the Company's stockholders approved an amendment to the Company's Certificate of Incorporation, as amended, to increase the number of shares of common stock authorized. Since no notes payable had been converted as of such date, the terms

of the Company's notes payable relating to conversion and exercise which was amended because of insufficient number of authorized shares available for issuance upon conversion, reverted to their original terms so that they are again convertible into shares of common stock, rather than shares of Series A Preferred Stock.

In January 2004, the Company issued an aggregate of 50,000 shares of restricted common stock as payment for services rendered in an aggregate amount of $90,000.

In March 2004, the Company recorded an aggregate of $223,244 non-cash expenses for 110,000 five-year stock options that were issued to various consultants for services rendered. The options vested immediately and have a per share exercise price of $3.46. The non-cash expenses were based upon the fair value of the options on the date of issuance as estimated by the Black-Scholes options pricing model.

During the quarter ended April 30, 2004, the Company issued an aggregate 1,468,393 shares of restricted Common Stock and five-year warrants to purchase 1,918,393 shares of common stock with an exercise price of $1.00 per share upon the conversion of notes payable in the amount of approximately $514,600 by unrelated parties.

During the nine months ended April 30, 2004, the Company issued, an aggregate of 1,773,990 shares of common stock upon the exercise of warrants by unrelated parties and stock options by unrelated parties, employees, a director and former director at per share exercise prices ranging from $0.26 to $3.12. The Company realized aggregate gross proceeds of $1,480,017 from these exercises.

During the nine months ended April 30, 2004, the Company incurred an aggregate of $239,673 of costs relating to various private placements.

6. SALE OF NET OPERATING LOSSES

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 tax benefits. For the state fiscal year 2004 (July 1, 2003 to June 30, 2004), the Company had approximately $1,378,000 total available tax benefits that were saleable; of which New Jersey permitted the Company to only sell approximately $261,000. The Company received approximately $222,000 from the sale of the $261,000 of tax benefits, which was recognized as tax benefits for the nine months ended April 30, 2004. For the state fiscal year 2003 (July 1, 2002 to June 30, 2003), the Company had approximately $1,373,000 in total available tax benefits that were saleable; of which New Jersey permitted the Company to only sell approximately $273,000. The Company received approximately $229,000 from the sale of the $273,000 of tax benefits, which was recognized as tax benefits for the nine months ended April 30, 2003.

If still available under New Jersey law, the Company will attempt to sell the remaining $1,117,000 of its tax benefits, between July 1, 2004 and June 30,

2005. This amount, which is a carryover of the Company's remaining tax benefits from state fiscal year 2004, may increase if the Company incurs additional tax benefits during state fiscal year 2005. The Company can not estimate, however, what percentage of its saleable tax benefits New Jersey will permit 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 tax benefits or if such funds will be available in a timely manner.

ALFACELL CORPORATION
(A Development Stage Company)

NOTES TO CONDENSED FINANCIAL STATEMENTS, Continued

Unaudited

7. SUBSEQUENT EVENTS

In May 2004, the Company issued, an aggregate of 675,000 shares of common stock upon the exercise of warrants and stock options by unrelated parties, at per share exercise prices ranging from $0.75 to $1.50. The Company realized aggregate gross proceeds of $888,750 from these exercises.

In May 2004, the Company issued 1,210,654 shares of common stock to an institutional investor, resulting in gross proceeds of $10,000,000 to the Company. In addition, the institutional investor was granted five-year warrants to purchase 1,210,654 shares of common stock at an exercise price of $12.39 per share. The Company paid a 5% finder's fee to a third party in connection with the private placement, which included a five-year warrant to purchase 60,533 shares of common stock at an exercise price of $12.39 per share.

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

Information contained 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 be sure 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 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 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 $43,840,372 has gone toward the development of ONCONASE(R) and related drug candidates. For the fiscal years 2003, 2002 and 2001 our research and development expenses were $1,699,962, $2,032,938 and $1,900,678, respectively, almost all of which was 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 patient enrollment is expected to be completed by the end of this year. 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. 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 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 tax benefits and research products, interest income and financing received from our Chief Executive Officer. Presently, our cash balance is sufficient to fund our expanded operations through July 31, 2005 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 continue to seek additional capital financing through the sale of equity in private placements, sale of our tax benefits and exercise of stock options and warrants but cannot be sure that we will be able to raise capital on favorable terms or at all.

Results of Operations

Three and nine month periods ended April 30, 2004 and 2003

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 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 nine month periods ended April 30, 2004 and 2003. For the nine months ended April 30, 2004, our other income was $11,300.

Research and Development. Research and development expense for the three months ended April 30, 2004 was $927,000 compared to $374,000 for the same period last year, an increase of $553,000. Research and development expense for the nine months ended April 30, 2004 was $2,238,000 compared to $1,174,000 for the same period last year, an increase of $1,064,000. The increase in the current nine month period was due primarily to increases in data management and consulting fees related to our pivotal Phase III clinical trial for malignant mesothelioma of approximately $819,000, non-cash expense related to stock options issued for consulting services of approximately $146,000, regulatory consulting costs of approximately $111,000, costs associated with sponsored research studies of approximately $68,000 and costs associated with patent and trademark applications for ONCONASE(R) of approximately $10,000, offset by a decreases in personnel costs and insurance expenses of approximately $69,000 and $21,000, respectively.

General and Administrative. General and administrative expense for the three months ended April 30, 2004 was $329,000 compared to $138,000 for the same period last year, an increase of $191,000. General and administrative expense for the nine months ended April 30, 2004 was $978,000 compared to $426,000 for the same period last year, an increase of $552,000. The increase in the current nine month period was due primarily to increases in non-cash expense related to stock and stock options issued for consulting services associated with business development activities of approximately $196,000, increases in legal, public relations, insurance, personnel and accounting expenses of approximately $161,000, $71,000, $45,000, $44,000 and $35,000, respectively.

Interest. Interest expense for the three months ended April 30, 2004 was $97,000 compared to $55,000 for the same period last year, an increase of $42,000. Interest expense for the nine months ended April 30, 2004 was $325,000 compared to $295,000 for the same period last year, an increase of $30,000.

The increase in the current nine month period was due primarily to the interest expense on the beneficial conversion feature of the notes payable issued to unrelated parties and its related warrants. The interest expense was based on the fair value of the warrants using the Black-Scholes method, amortized over the life of the 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 tax benefits. For the state fiscal year 2004 (July 1, 2003 to June 30, 2004), we had approximately $1,378,000 total available tax benefits that were saleable; of which New Jersey permitted us to only sell approximately $261,000. We received approximately $222,000 from the sale of the $261,000 of tax benefits, which we recognized as tax benefits for the nine months ended April 30, 2004. For the state fiscal year 2003 (July 1, 2002 to June 30, 2003), we had approximately $1,373,000 in total available tax benefits that were saleable; of which New Jersey permitted us to only sell approximately $273,000. We received approximately $229,000 from the sale of the $273,000 of tax benefits, which we recognized as tax benefits for the nine months ended April 30, 2003.

If still available under New Jersey law, we will attempt to sell the remaining $1,117,000 of our tax benefits, between July 1, 2004 and June 30, 2005. This amount, which is a carryover of our remaining tax benefits from state fiscal year 2004, may increase if we incur additional tax benefits during state fiscal year 2005. We can not estimate, however, what percentage of our sellable 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.

Net Loss. We have incurred net losses during each year since our inception. The net loss for the three months ended April 30, 2004 was $1,351,000 as compared to $568,000 for the same period last year, an increase of $783,000. The net loss for the nine months ended April 30, 2004 was $3,308,000 as compared to $1,635,000 for the same period last year, an increase of $1,673,000. The cumulative loss from the date of inception, August 24, 1981 to April 30, 2004, amounted to $67,283,000. We are a development stage company 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 tax benefits and research products, interest income and financing received from our Chief Executive Officer. During the nine months ended April 30, 2004, we had a net increase in cash and cash equivalents of $875,000, which resulted primarily from net cash provided by financing activities of $4,293,000, which resulted from $1,500,000 in gross proceeds from a private placement of common stock and warrants with an institutional investor in September 2003, $1,293,000 in net proceeds from warrants and stock options exercises and $1,500,000 in gross proceeds from a private placement of common stock and warrants in January 2004, offset by net cash used in operating activities of $3,411,000 and net cash used in investing activities of $7,000. Total cash resources as of April 30, 2004 were $1,205,000 compared to $330,000 at July 31, 2003.

Our current liabilities as of April 30, 2004 were $2,033,000 compared to $2,744,000 at July 31, 2003, a decrease of $711,000. The decrease was primarily due to decreased accrued expenses. As of

April 30, 2004, our current liabilities exceeded our current assets and we had a working capital deficit of $553,000.

Our 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 be available on acceptable terms. Through May 31, 2004, 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 tax benefits and 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 terms which are acceptable, if at all. Presently, our cash balance is sufficient to fund our expanded operations at least through July 31, 2005, 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 continue to seek additional capital financing through the sale of equity in private placements, sale of our tax benefits and exercise of stock options and warrants but cannot be sure that we will be able to raise capital on favorable terms or at all. The report of our independent registered public accountants on our July 31, 2003 financial statements included an explanatory paragraph which states, and we also believe, that our recurring losses, working capital deficit and limited liquid resources raise substantial doubt about our ability to continue as a going concern. As of April 30, 2004, we continued to incur losses, had a working capital deficiency and limited liquid resources which raise substantial doubt about our ability to continue as a going concern. Our condensed financial statements at April 30, 2004 and July 31, 2003 and for the periods ended April 30, 2004 and 2003 do not include any adjustments that might result from the outcome of this uncertainty.

In May 2004, we issued, an aggregate of 675,000 shares of common stock upon the exercise of warrants and stock options by unrelated parties, at per share exercise prices ranging from $0.75 to $1.50. We realized aggregate gross proceeds of $888,750 from these exercises.

In May 2004, we issued 1,210,654 shares of common stock to an institutional investor, resulting in gross proceeds of $10,000,000 to us. In addition, the institutional investor was granted five-year warrants to purchase 1,210,654 shares of common stock at an exercise price of $12.39 per share. We paid a 5% finder's fee to a third party in connection with the private placement, which included a five-year warrant to purchase 60,533 shares of common stock at an exercise price of $12.39 per share.

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.

Our Common Stock was delisted from The Nasdaq SmallCap Market effective at the close of business April 27, 1999 for failing to meet the minimum bid price requirements set forth in the NASD Marketplace Rules. Since April 28, 1999, our Common Stock has traded on the OTC Bulletin Board under the symbol "ACEL.OB". Delisting of our Common Stock from Nasdaq could have a material

adverse effect on our ability to raise additional capital, our stockholders' liquidity and the price of our common stock. We intend to reapply for Nasdaq SmallCap Market listing as soon as all listing criteria are met.

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 special purpose entities or SPE, 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, 2004, we are not involved in any material unconsolidated SPE transactions.

Contractual Obligations and Commercial Commitments

Our major outstanding contractual obligations relate to our equipment operating lease. Below is a table that presents our contractual obligations and commercial commitments as of April 30, 2004:

		Payments Due by Fiscal Year		
	Total	2004	2005	2006 and Thereafter
Operating lease	$17,480	$4,380	$13,100	$ - 0 -
Total contractual cash obligations	$17,480	$4,380	$13,100	$ - 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 quarterly report and our other SEC filings before deciding whether to purchase shares of our Common Stock. The risks described below are not the only ones facing our company. Additional risks not presently known to us or that we currently believe to be immaterial may also adversely affect our business. 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 our inception our source of working capital has been public and private sales of our stock. We incurred a net loss of approximately $3,308,000 for the nine months ended April 30, 2004. We have continued to incur losses since April 2004. In addition, we

had a working capital deficit of approximately $553,000 and an accumulated deficit of approximately $67,283,000 as of April 30, 2004. We may never achieve revenue sufficient for us to attain profitability.

We incurred net losses of approximately $2,412,000, $2,591,000 and $2,295,000 for the fiscal years ended July 31, 2003, 2002 and 2001, 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. As a result of our continuing losses and lack of capital, the report of our independent registered public accounting firm on our July 31, 2003 financial statements included an explanatory paragraph which states that our recurring losses, working capital deficit and limited liquid resources raise substantial doubt about our ability to continue as a going concern. Our financial statements at July 31, 2003 do not include any adjustments that might result from the outcome of this uncertainty. 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. In connection with the recent private placement from which we realized $10.0 million in gross proceeds from an institutional investor, we plan to expand our operations in preparing ONCONASE(R) for marketing registrations in the US and outside the US as well as fund our

ongoing operations. Presently, our cash balance is sufficient to fund our expanded operations through July 31, 2005, based on our expected level of expenditures. However, taking into consideration all of the uncertainties related to drug development and our industry, we continue to seek additional capital financing through the sale of equity in private placements, sale of our tax benefits and exercise of stock options and warrants but cannot be sure that we will be able to raise capital on favorable terms or at all.

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, 2003, we had federal net operating loss carryforwards of approximately $39,600,000 that expire from 2004 to 2023. We also had research and experimentation tax credit carryforwards of approximately $1,186,000 that expire from 2004 to 2023. 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 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 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 will be negatively impacted.

For the state fiscal year 2004 (July 1, 2003 to June 30, 2004), we had approximately $1,378,000 total available tax benefits that were saleable; of which New Jersey permitted us to only sell approximately $261,000. We received approximately $222,000 from the sale of the $261,000 of tax benefits, which we recognized as tax benefits for the nine months ended April 30, 2004. For the state fiscal year 2003 (July 1, 2002 to June 30, 2003), we had approximately $1,373,000 in total available tax benefits that were saleable; of which New Jersey permitted us to only sell approximately $273,000. We received approximately $229,000 from the sale of the $273,000 of tax benefits, which we recognized as tax benefits for the nine months ended April 30, 2003.

If still available under New Jersey law, we will attempt to sell the remaining $1,117,000 of our tax benefits, between July 1, 2004 and June 30, 2005. This amount, which is a carryover of our remaining tax benefits from state fiscal year 2004, may increase if we incur additional tax benefits during state fiscal year 2005. We can not estimate, however, what percentage of our sellable 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 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 for which patient enrollment is expected to be completed by the end of this year. 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 and increase its costs which could delay the commercial sale of ONCONASE(R).

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 completed.

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 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 to us.

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 currently co-own two patents with the United States government that expire in 2016. We also own ten United States patents outright 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. In addition, we have patent applications that are pending in the United States, Europe and Japan. We do not license patent rights from any domestic or international companies or institutions. 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, legal actions or negotiations 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 was recently enacted. This legislation 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.

Our stock is thinly traded and you may not be able to sell our stock when you want to do so.

There has been no established trading market for our common stock since the stock was delisted from Nasdaq in April 1999. Since then our common stock has been quoted on the OTC Bulletin Board, and is currently thinly traded. Over the past three years, the weekly trading volume was as low as 4,160 shares per week and as high as 706,280 shares for any week in such period. You may be unable to sell our common stock when you want to do so if the trading market continues to be limited. We intend to reapply for Nasdaq SmallCap Market listing as soon as all listing criteria are met.

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 or sale, could adversely affect the price of our common stock. We had 32,499,362 shares of common stock outstanding as of May 31, 2004. The following securities that may be exercised for, or are convertible into, shares of our common stock were issued and outstanding as of May 31, 2004:

- Options. Stock options to purchase 2,765,695 shares of our common stock at a weighted average exercise price of approximately $2.27 per share.
- Warrants. Warrants to purchase 9,676,522 million shares of our common stock at a weighted average exercise price of approximately $2.82 per share.
- Convertible Notes. Notes which will convert into 3,319,402 shares of our common stock at an average conversion price of $0.26 per share and warrants which are convertible into 3,860,424 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 this prospectus, nor have we been able to obtain AHC's consent to the use of such report herein.

Section 11 of the Securities Act of 1933 (the "Securities Act") provides that any person acquiring a security pursuant to a registration statement may assert a claim against every accountant who has with its consent been named as having prepared or certified any part of the registration statement, or as having prepared or certified any report or valuation that is used in connection with the registration statement, if that part of the registration statement at the time it becomes effective contains an untrue 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 this registration statement of which this prospectus is a part 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 11 of the Securities 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 11 of the Securities Act for any purchases of the Company's Common Stock pursuant to this registration statement. 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 defined in Rule 13a-15(e) under the Exchange Act) as of April 30, 2004, 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 during the period covered by this report or, to our knowledge, in other factors that could significantly affect these controls subsequent to the date of their evaluation.

PART II. OTHER INFORMATION

Item 2. Changes in Securities and Use of Proceeds

(c) 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.

From February 2004 through April 7, 2004, we issued an aggregate 1,468,393 shares of restricted common stock and five-year warrants to purchase 1,918,393 shares of common stock with an exercise price of $1.00 per share upon the conversion of notes payable in the amount of $514,597 by unrelated parties.

Item 6. Exhibits and Reports on Form 8-K

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

Exhibit No.	Item Title	Exhibit No Incorporati Referen
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)	*
10.18	Form of Securities Purchase Agreement used in May 2004 private placement with Knoll Capital Fund II, Europa International, Inc. and Clifford and Phyllis Kalista JTWROS (incorporated by reference to Exhibit 4.3 to Registration Statement on Form S-1, File No. 333-112865, filed on May 18, 2004)	*

Exhibit No.	Item Title	Exhibit No Incorporati Referen
10.19	Form of Registration Rights Agreement used in May 2004 private placement with Knoll Capital Fund II, Europa International, Inc. and Clifford and Phyllis Kalista JTWROS (incorporated by reference to Exhibit 4.4 to Registration Statement on Form S-1, File No. 333-112865, filed on May 18, 2004)	*
10.20	Form of Warrant Certificate issued on May 11, 2004 to Knoll Capital Fund II, Europa International, Inc. and Clifford and Phyllis Kalista JTWROS (incorporated by reference to Exhibit 4.5 to Registration Statement on Form S-1, File No. 333-112865, filed on May 18, 2004)	*
31.1	Certification of Chief Executive pursuant to Rule 13a-14(a), as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002 (Section 302 Certification)	+
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a), as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002 (Section 302 Certification)	+
32.1	Certification Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Section 906 Certification)	+
32.2	Certification Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Section 906 Certification)	+

* Previously filed; incorporated herein by reference.

\+ Filed herewith.

(b) Reports on Form 8-K.

On February 2, 2004, we filed a report on Form 8-K which reported under Item 5 thereof that we completed a private placement to an institutional investor resulting in the issuance of 379,170 shares of common stock at a price of $3.96 per share and warrants to purchase an additional 189,585 shares of common stock at an exercise price of $4.75 per share. We received gross proceeds of $1,500,000 from such private placement.

On March 8, 2004, we filed a report on Form 8-K which reported under Item 5 thereof the appointment of Andrew P. Savadelis as our Chief Financial Officer and Senior Vice President of Finance.

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 14, 2004

/s/ Andrew P. Savadelis

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