

Edgar Filing: ALFACELL CORP - Form 10-Q

ALFACELL CORP  
Form 10-Q  
December 11, 2006

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

For the quarterly period ended: October 31, 2006

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 0-11088

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

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

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

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

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

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

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

Large Accelerated Filer  Accelerated Filer  Non-accelerated Filer

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

The number of shares of Common Stock, \$.001 par value, outstanding as of  
December 7, 2006 was 45,008,401 shares.

ALFACELL CORPORATION  
(A Development Stage Company)

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### PART I. FINANCIAL INFORMATION

#### Item 1. Financial Statements

#### CONDENSED BALANCE SHEETS October 31, 2006 and July 31, 2006

	Octo 2 (Una -----
<b>ASSETS</b>	
Current assets:	
Cash and cash equivalents	\$ 9,
Other current assets	-----
Total current assets	9,
Property and equipment, net	
Loan receivable, related party	-----
Total assets	\$ 9, =====
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>	
Current liabilities:	
Accounts payable	\$ 1,
Accrued expenses	-----
Total liabilities	2, -----
Commitments and contingencies	
Stockholders' equity:	
Preferred stock, \$.001 par value;	
Authorized and unissued, 1,000,000 shares at October 31, 2006 and July 31, 2006	
Common Stock, \$.001 par value;	
Authorized 100,000,000 shares at October 31, 2006 and July 31, 2006;	
Issued and outstanding, 44,458,401 shares at October 31, 2006 and 44,289,161 shares at July 31, 2006	
Capital in excess of par value	93,
Deficit accumulated during development stage	(85, -----
Total stockholders' equity	7, -----
Total liabilities and stockholders' equity	\$ 9, =====

See accompanying notes to condensed financial statements.

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## ALFACELL CORPORATION (A Development Stage Company)

### CONDENSED STATEMENTS OF OPERATIONS

Three months ended October 31, 2006 and 2005,  
and the Period from August 24, 1981  
(Date of Inception) to October 31, 2006

(Unaudited)

	Three Months Ended October 31, -----		August (Date of
	2006 ----	2005 ----	October -----
		(As restated)	
		-----	
Revenue:			
Sales	\$           --	\$           --	\$           --
Investment income	123,333	31,995	1
Other income	--	--	
	-----	-----	-----
Total revenue	123,333	31,995	2
	-----	-----	-----
Costs and expenses:			
Cost of sales	--	--	
Research and development	1,570,185	1,222,012	56
General and administrative	926,038	666,348	29
Interest:			
Related parties	--	--	1
Others	46	10	2
	-----	-----	-----
Total costs and expenses	2,496,269	1,888,370	90
	-----	-----	-----
Loss before state tax benefit	(2,372,936)	(1,856,375)	(88)
State tax benefit	--	317,382	2
	-----	-----	-----
Net loss	\$ (2,372,936)	\$ (1,538,993)	\$ (85)
	=====	=====	=====
Loss per basic and diluted common share	\$           (0.05)	\$           (0.04)	
	=====	=====	
Weighted average common shares outstanding, basic and diluted	44,345,739	36,593,020	
	=====	=====	

See accompanying notes to condensed financial statements.

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ALFACELL CORPORATION  
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CONDENSED STATEMENTS OF CASH FLOWS

Three months ended October 31, 2006 and 2005,  
and the Period from August 24, 1981  
(Date of Inception) to October 31, 2006

(Unaudited)

	Three Months Ended October 31,	
	2006	2005
	-----	-----
		(As restated)
		-----
Cash flows from operating activities:		
Net loss	\$ (2,372,936)	\$ (1,538,993)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on sale of marketable securities	--	--
Depreciation and amortization	9,085	6,830
Loss on disposal of property and equipment	--	--
Issuance of common stock, stock options and warrants for services rendered	584,326	350,756
Amortization of debt discount	--	--
Amortization of deferred compensation	--	--
Changes in assets and liabilities:		
Increase in receivable from the sale of net operating loss carryforwards	--	(317,382)
(Increase) decrease in other current assets	(279,214)	106,934
Increase in loan receivable-related party	(2,382)	(2,382)
Increase in interest payable-related party	--	--
(Decrease) increase in accounts payable	(70,174)	178,000
Increase in accrued payroll and expenses, related parties	--	--
(Decrease) increase in accrued expenses	(474,867)	129,398
Net cash used in operating activities	(2,606,162)	(1,086,839)
	-----	-----
Cash flows from investing activities:		
Purchase of marketable equity securities	--	--
Purchase of short-term investments	--	--
Proceeds from sale of marketable equity securities	--	--
Proceeds from sale of short-term investments	--	--
Purchase of property and equipment	(21,886)	(2,461)
Patent costs	--	--
Net cash used in investing activities	(21,886)	(2,461)
	-----	-----

(continued)

See accompanying notes to condensed financial statements.

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ALFACELL CORPORATION  
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CONDENSED STATEMENTS OF CASH FLOWS, Continued

Three months ended October 31, 2006 and 2005  
and the Period from August 24, 1981  
(Date of Inception) to October 31, 2006

(Unaudited)

	Three Months Ended October 31,	
	2006	2005
	-----	-----
		(As restated)
	-----	-----
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	--	
Proceeds from issuance of common stock, net	(29,210)	
Proceeds from exercise of stock options and warrants, net	180,250	53,
Proceeds from issuance of convertible debentures, related party	--	
Proceeds from issuance of convertible debentures, unrelated party	--	
	-----	-----
Net cash provided by financing activities	151,040	53,
	-----	-----
Net increase (decrease) in cash and cash equivalents	(2,477,008)	(1,036,
Cash and cash equivalents at beginning of period	11,518,540	4,462,
	-----	-----
Cash and cash equivalents at end of period	\$ 9,041,532	\$ 3,426,
	=====	=====
Supplemental disclosure of cash flow information - Interest Paid	\$       46	\$
	-----	-----
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	\$       --	\$
	=====	=====

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Repurchase of stock options from related party	\$	--	\$
	=====		=====
Conversion of accrued interest to stock options	\$	--	\$
	=====		=====
Conversion of accounts payable to Common Stock	\$	--	\$
	=====		=====

(continued)

See accompanying notes to condensed financial statements.

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ALFACELL CORPORATION  
(A Development Stage Company)

CONDENSED STATEMENTS OF CASH FLOWS, Continued

Three months ended October 31, 2006 and 2005  
and the Period from August 24, 1981  
(Date of Inception) to October 31, 2006

(Unaudited)

	Three Months Ended October 31,		Au
	2006	2005	Oc
	----	----	----
	(As restated)		
	-----		
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	\$	--	\$
	=====		=====
Issuance of Common Stock for services rendered	\$	--	\$
	=====		=====
Issuance of warrants with notes payable	\$	--	\$
	=====		=====

See accompanying notes to condensed financial statements.

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ALFACELL CORPORATION  
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NOTES TO CONDENSED FINANCIAL STATEMENTS

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(Unaudited)

## 1. ORGANIZATION AND BASIS OF PRESENTATION

In the opinion of management, the accompanying unaudited Condensed Financial Statements of Alfacell Corporation ("Alfacell" or the "Company") have been prepared in accordance with accounting principles generally accepted in the United States of America and contain all adjustments (consisting of normal recurring adjustments) necessary to present fairly the Company's financial position as of October 31, 2006 and its results of operations and cash flows for the three month periods ended October 31, 2006 and 2005 and the period from August 24, 1981 (date of inception) to October 31, 2006. The results of operations for the three months ended October 31, 2006 are not necessarily indicative of the results to be expected for the full year. The July 31, 2006 condensed balance sheet presented herein has been derived from the audited financial statements included in the Company's Form 10-K for the fiscal year ended July 31, 2006, 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 rules and regulations of the Securities and Exchange Commission. The condensed financial statements in this report should be read in conjunction with the financial statements and notes thereto included in the Form 10-K for the fiscal year ended July 31, 2006.

The Company is a development stage company as defined in Statement of Financial Accounting Standards No. 7, "Accounting and Reporting by Development Stage Enterprises". 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 \$2,373,000, \$7,810,000, \$6,462,000 and \$5,070,000 for the three months ended October 31, 2006 and the fiscal years ended July 31, 2006, 2005 and 2004, respectively. The loss from date of inception, August 24, 1981, to October 31, 2006 amounts to approximately \$85,690,000.

The Company's long-term continued operations will depend on its ability to raise additional funds through various potential sources such as equity and debt financing, collaborative agreements, strategic alliances, sale of tax benefits, revenues from the commercial sale of ONCONASE(R), licensing of its proprietary RNase technology and its ability to realize revenues from its technology and its drug candidates via out-licensing agreements with other companies. Such additional funds may not become available as the Company may need them or be available on acceptable terms. Until and unless the Company's operations generate significant revenues, the Company expects to continue to fund operations primarily from equity financing and through the exercise of outstanding options and warrants and the sale of its tax benefits. There can be no assurance that the Company will be able to raise the capital it needs on terms which are acceptable, if at all. As of October 31, 2006, management believes that the Company's cash balance will be sufficient to fund its operations through its fiscal year ending July 31, 2008 based on its expected level of expenditures.

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.

ALFACELL CORPORATION  
(A Development Stage Company)

NOTES TO CONDENSED FINANCIAL STATEMENTS, Continued

(Unaudited)

2. EARNINGS (LOSS) PER COMMON SHARE

Basic earnings (loss) per common share equals net income (loss) divided by weighted average common shares outstanding during the period. Diluted earnings per common share equals net income divided by the sum of weighted average common shares outstanding during the period, adjusted for the effects of potentially dilutive securities. The Company's basic and diluted per share amounts are the same since the Company had losses in all periods and the assumed exercise of stock options and warrants prior to October 31, 2006 would be anti-dilutive. The number of outstanding options and warrants that could dilute earnings per share in future periods was 21,853,487 and 16,093,437 at October 31, 2006 and 2005, respectively.

3. STOCK-BASED COMPENSATION

In December 2004, the Financial Accounting Standards Board issued SFAS No. 123(R) (revised 2004), "Share-Based Payment" ("SFAS 123(R)"), which amended SFAS 123. The new standard requires all share-based payments, including stock option grants to employees, to be recognized as an operating expense in the statement of operations. The cost is recognized over the requisite service period based on fair values measured on the date of grant. The Company adopted SFAS 123(R) effective August 1, 2005 using the modified prospective method and, accordingly, prior period amounts have not been restated. Under the modified prospective method, the fair value of all new stock options issued after July 31, 2005 and the unamortized fair value of unvested outstanding stock options at August 1, 2005 are recognized as expense as services are rendered. The Company recorded approximately \$581,000 or \$0.01 per basic and diluted common share and approximately \$348,000 (as restated) or \$0.01 per basic and diluted common share of stock-based compensation expense for employees under SFAS 123(R) for the three months ended October 31, 2006 and 2005, respectively, based on the fair value of stock options.

The fair value of the stock options at the grant date was estimated using the Black-Scholes option pricing model based on the weighted-average assumptions as noted in the following table. The risk-free interest rate for periods approximating the expected life of the option is based on the U.S. Treasury yield curve in effect at the time of grant. The expected stock price volatility is based on historical volatility of the Company's stock price. For post July 31, 2005 grants, the expected term until exercise is derived using the "simplified" method as allowed under the provisions of the Securities and Exchange Commission's Staff Accounting Bulletin No. 107, "Disclosures about Fair Value of Financial Instruments" and represents the period of time that options granted are expected to be outstanding. As of October 31, 2006, there was approximately \$2,363,000 of total unrecognized compensation cost related to unvested options granted that is expected to be recognized over a weighted average period of 1.77 years. The total intrinsic value of options exercised by employees during the three months ended October 31, 2006 and 2005 was approximately \$68,000 and \$21,000, respectively.



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ALFACELL CORPORATION  
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NOTES TO CONDENSED FINANCIAL STATEMENTS, Continued

(Unaudited)

3. STOCK-BASED COMPENSATION, (continued)

	Three Months Ended October 31,	
	2006	2005
	----	----
Expected dividend yield	0%	0%
Risk-free interest rate	4.61%	4.49%
Expected stock price volatility	113.60%	82.01%
Expected term (years)	6.06	7.02

The following table summarizes the stock option activity for the period August 1, 2006 to October 31, 2006:

	Stock Options Outstanding	Weighted Average Exercise Price Per Share
	-----	-----
Balance August 1, 2006	3,830,350	\$3.10
Granted	335,000	1.29
Exercised	(84,000)	0.62
Expired/Cancelled	(10,000)	3.66
	-----	
Balance October 31, 2006	4,071,350	3.00
	=====	
Exercisable as of October 31, 2006	2,334,800	3.23
	=====	

The remaining weighted average contractual term for options granted during the three months ended October 31, 2006 is 10 years.

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

4. LOAN RECEIVABLE, RELATED PARTY

Amounts due from the Company's Chief Executive Officer totaling \$173,252 at October 31, 2006 and \$170,870 at July 31, 2006, are classified as a long-term asset in loan receivable, related party as the Company does not expect repayment of these amounts within one year. In each of the three months ended October 31, 2006 and 2005, the Company accrued 8% interest in the amount of approximately \$2,400 on the unpaid principal balance.

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## ALFACELL CORPORATION (A Development Stage Company)

### NOTES TO CONDENSED FINANCIAL STATEMENTS, Continued

(Unaudited)

#### 5. CAPITAL STOCK

During the quarter ended October 31, 2006, the Company issued an aggregate of 169,240 shares of its Common Stock upon the exercise of warrants and stock options by unrelated parties and employees at per share exercise prices ranging from \$0.49 to \$1.50. The Company realized aggregate gross proceeds of \$180,250 from these exercises.

During the quarter ended October 31, 2006, the Company recorded under EITF 96-18, an aggregate total of \$3,645 of non-cash expense for options issued to consultants during the fiscal years 2006 and 2005.

#### 6. SALE OF NET OPERATING LOSS CARRYFORWARDS

New Jersey has enacted legislation permitting certain corporations located in New Jersey to sell a portion of their 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 2007 (July 1, 2006 to June 30, 2007), the Company had approximately \$2,338,000 of total available net operating loss carryforwards that were saleable, of which New Jersey permitted the Company to sell approximately \$574,000. Based on an agreement the Company entered into, the Company will receive approximately \$510,000 from the sale of the \$574,000 of net operating loss carryforwards, which will be recognized as a tax benefit when the funds are received.

For the state fiscal year 2006 (July 1, 2005 to June 30, 2006), the Company had approximately \$1,903,000 of total available net operating loss carryforwards that were saleable; of which New Jersey permitted the Company to sell approximately \$356,000. In December 2005, the Company received approximately \$317,000 from the sale of the \$356,000 of net operating loss carryforwards, which was recognized as a tax benefit for the quarter ended October 31, 2005.

If still available under New Jersey law, the Company will attempt to sell the remaining \$1,764,000 of its net operating loss carryforwards between July 1, 2007 and June 30, 2008 (state fiscal year 2008). This amount, which is a carryover of the Company's remaining net operating loss carryforwards from state fiscal year 2007, may increase if the Company incurs additional net losses and research and development credits during state fiscal year 2008. The Company can not 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 any, 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.

#### 7. RESTATEMENT OF UNAUDITED QUARTERLY FINANCIAL DATA

As previously reported in the Form 10-K for the fiscal year ended July 31, 2006, in connection with its audit of the Company's financial statements for the fiscal year ended July 31, 2006, the Company's independent registered public accounting firm brought to the attention of the Company's management that the

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Company's estimate of the impact of forfeitures on non-cash compensation cost was, as a percentage, significantly higher than the historical rate of such pre-vesting forfeitures and that the true-up of the value of options vesting during the reporting period was not recorded. After reviewing

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NOTES TO CONDENSED FINANCIAL STATEMENTS, Continued

(Unaudited)

7. RESTATEMENT OF UNAUDITED QUARTERLY FINANCIAL DATA, (continued)

the matter, the Company's management agreed to calculate the forfeiture rate using primarily historical experience and record the value of the options that vested during the reporting period. The original computation had understated non-cash compensation costs and net losses in the Company's unaudited Condensed Financial Statements included in Form 10-Q for the quarter ended October 31, 2005. The Company's management believes that the adjustment to the amount of non-cash compensation expense in the affected quarterly period is not material and that the quarterly report for the period ended October 31, 2005 does not require refiling.

Although management believes that the changes in the affected quarterly report were not material, the Company is presenting certain restated unaudited statement of operations information. Presented in the following table are the total costs and expenses, the net loss and the loss per basic and diluted common share as originally reported and the restated amounts for the quarter.

Quarter Ended October 31, 2005	As Originally Reported for the Three Months Ended October 31, 2005 -----	As Restated for the Three Months Ended October 31, 2005 -----
Statement of Operations:		
Research and development	\$ 1,159,000	\$ 1,222,000
General and administrative	590,000	666,000
	-----	-----
Total costs and expenses	\$ 1,749,000	\$ 1,888,000
	=====	=====
Net loss	\$ (1,400,000)	\$ (1,539,000)
	=====	=====
Loss per basic and diluted common share	\$ (0.04)	\$ (0.04)
	=====	=====

8. SUBSEQUENT EVENTS

In November and December 2006, the Company issued an aggregate total of 50,000 and 500,000 shares of restricted common stock upon the exercise of warrants by unrelated parties at per share exercise prices of \$0.60 and \$1.00, respectively. The Company realized aggregate gross proceeds of \$530,000 from these exercises.

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

Information herein contains, in addition to historical information, forward-looking statements that involve risks and uncertainties. All statements, other than statements of historical fact, regarding our financial position, potential, business strategy, plans and objectives for future operations are "forward-looking statements." These statements are commonly identified by the use of forward-looking terms and phrases as "anticipates," "believes," "estimates," "expects," "intends," "may," "seeks," "should," or "will" or the negative thereof or other variations thereon or comparable terminology, or by discussions of strategy. We cannot assure you that the future results covered by these forward-looking statements will be achieved. The matters set forth in Part I, Item 1A. "Risk Factors" in our annual report on Form 10-K, filed on October 16, 2006, 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. There have been no material changes to the discussion of risk factors included in our most recent annual report on Form 10-K.

Overview

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

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

We received an Orphan Medicinal Product Designation for ONCONASE(R) from the European Agency for the Evaluation of Medicinal Products, or EMEA. We continue to fulfill the EMEA requirements regarding the Marketing Authorization Application, or MAA, registration requirements for ONCONASE(R) for the treatment of malignant mesothelioma. This designation in the European Union entitles us to several financial incentives such as registration fee reductions and a ten-year marketing exclusivity for the therapeutic indication for which it was granted.

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

Almost all of the approximately \$56,837,000 of research and development expenses we have incurred since our inception has gone toward the development of ONCONASE(R) and related drug candidates. For the three months ended October 31, 2006 and the fiscal years 2006, 2005 and 2004 our research and development expenses were approximately \$1,570,000, \$5,230,000, \$5,082,000 and \$3,353,000, respectively, almost all of which were used for the development of ONCONASE(R) and related drug candidates. ONCONASE(R) is currently in an international, centrally randomized, confirmatory Phase IIIb registration trial. The first part

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of the trial has been completed. The second confirmatory part of the trial is ongoing. The primary endpoint of the trial is overall survival. The first interim analysis results based on one third of the required events (deaths) of the study, which evaluates the efficacy, safety and tolerability of the combination of

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ONCONASE(R) + doxorubicin as compared to doxorubicin alone have been reported. The overall median survival time (MST) demonstrated a trend favoring the ONCONASE(R) + doxorubicin treatment group (12 months) over the doxorubicin group (10 months). A two month improvement in median survival had previously been observed in the Treatment Target Group (n=104) analysis from the completed Phase III single agent study that favored the ONCONASE(R) over doxorubicin treatments (11.6 months vs. 9.6 months). The Company's Phase IIIb confirmatory registration trial was designed based on the conclusions drawn from the TTG analysis but powered to reach a statistically significant difference in MST between the ONCONASE(R) + doxorubicin treatment group and the doxorubicin treatment group at 316 events. The interim data which represented only one third of the planned number of events was sufficient for us to continue the trial as planned, but was not sufficient for supporting the filing for marketing approvals at that time. At this time, we cannot predict with certainty when a sufficient number of deaths will occur to achieve statistical significance. The timing of when we will be able to file for marketing registrations in the US, EU and Australia is data driven. Therefore, we cannot predict with certainty what our total cost associated with obtaining marketing approvals will be, or when and if such approvals will be granted, or when actual sales will occur. We have completed the chemistry, manufacturing and controls (CMC) section of the NDA and will submit it after receipt of the Pharmaceutical Drug User Fee Application (PDUFA) waiver for small business exemption.

We fund the research and development of our products primarily from cash receipts resulting from the sale of our equity securities and convertible debentures in registered offerings and private placements. Additionally, we have raised capital through other debt financings, the sale of our tax benefits and research products, interest income and financing received from our Chief Executive Officer. During the fiscal year ended July 31, 2006, we received net proceeds of approximately \$12.3 million as a result of private placements of Common Stock and warrants and from exercises of stock options and warrants. These proceeds will be used to support our strategic plan, including the anticipated filing of an NDA of ONCONASE(R) for malignant mesothelioma, assuming satisfactory results from the ongoing clinical trial, the expansion of the ONCONASE(R) oncology franchise, and the development of other pipeline products. We have incurred losses since inception and to date we have not consummated any licensing, or marketing agreements for ONCONASE(R) or any of our early drug candidates.

### 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, 2006.

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### Recently Issued Accounting Standards

In June 2006, the Financial Accounting Standards Board issued Interpretation No. 48 ("FIN 48"), "Accounting for Uncertainty in Income Taxes - an Interpretation of FASB Statement No. 109." FIN 48 clarifies the accounting for uncertainty in income taxes recognized in a company's financial statements in accordance with Statement No. 109, "Accounting for Income Taxes." FIN 48 prescribes a recognition threshold and measurement of a tax position taken or expected to be taken in a company's tax return. The provisions of FIN 48 will be effective for our fiscal year ended July 31, 2008. We are currently evaluating the impact of the adoption of FIN 48 will have, if any, on our financial statements.

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### Results of Operations

Three month periods ended October 31, 2006 and 2005

**Revenues.** We are a development stage company as defined in the Financial Accounting Standards Board's Statement of Financial Accounting Standards No. 7, "Accounting and Reporting by Development Stage Enterprises." We are devoting substantially all of our present efforts to establishing a new business and developing new drug products. Our planned principal operations of marketing and/or licensing new drugs have not commenced and, accordingly, we have not derived any significant revenue from these operations. We focus most of our productive and financial resources on the development of ONCONASE(R) and as such we have not had any sales in the three months ended October 31, 2006 and 2005. For the three months ended October 31, 2006, our investment income was approximately \$123,000 compared to \$32,000 for the same period last year, an increase of \$91,000 due to higher balances of cash and cash equivalents.

**Research and Development.** Research and development expense for the three months ended October 31, 2006 was \$1,570,000 compared to \$1,222,000 (as restated) for the same period last year, an increase of \$348,000, or 28%. The increase was primarily due to an increase in expenses in connection with preparing our NDA for ONCONASE(R) of approximately \$336,000. The research and development increase also resulted from an increase in compensation expense related to share-based compensation of approximately \$54,000; offset by a decreases in patent expenses of approximately \$21,000 and pre-clinical sponsored research and development expenses of approximately \$21,000.

**General and Administrative.** General and administrative expense for the three months ended October 31, 2006 was \$926,000 compared to \$666,000 (as restated) for the same period last year, an increase of \$260,000, or 39%. The increase was due primarily to an increase in compensation expense of approximately \$170,000 of which approximately \$144,000 is related to share-based compensation. General and administrative increase also resulted from board of directors fees and consulting fees of approximately \$48,000; non-cash expense related to stock options issued to board members and consultant of approximately \$35,000; accounting and auditing fees of \$33,000; public relations related expenses of approximately \$16,000; and Sarbanes-Oxley compliance and auditing fees of approximately \$8,000; offset by a reduction in legal fees of approximately \$39,000; and a decrease in NASDAQ membership fees of approximately \$11,000.

**Income Taxes.** New Jersey has enacted legislation permitting certain corporations located in New Jersey to sell a portion of our state tax loss carryforwards and state research and development credits, or net operating loss

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carryforwards, in order to obtain tax benefits. For the state fiscal year 2007 (July 1, 2006 to June 30, 2007), we had approximately \$2,338,000 of total available net operating loss carryforwards that were saleable, of which New Jersey permitted us to sell approximately \$574,000. Based on an agreement we entered into, we will receive approximately \$510,000 from the sale of the \$574,000 of net operating loss carryforwards, which will be recognized as a tax benefit when the funds are received.

For the state fiscal year 2006 (July 1, 2005 to June 30, 2006), we had approximately \$1,903,000 of total available net operating loss carryforwards that were saleable; of which New Jersey permitted us to sell approximately \$356,000. In December 2005, we received approximately \$317,000 from the sale of the \$356,000 of net operating loss carryforwards, which we recognized as a tax benefit for the quarter ended October 31, 2005.

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If still available under New Jersey law, we will attempt to sell the remaining \$1,764,000 of our net operating loss carryforwards between July 1, 2007 and June 30, 2008 (state fiscal year 2008). This amount, which is a carryover of our remaining net operating loss carryforwards from state fiscal year 2007, may increase if we incur additional net losses and research and development credits during state fiscal year 2008. We can not 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 any, 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 October 31, 2006 was \$2,373,000 as compared to \$1,539,000 (as restated) for the same period last year, an increase of \$834,000. The cumulative loss from the date of inception, August 24, 1981 to October 31, 2006, amounted to \$85,690,000. Such losses are attributable to the fact that we are still in the development stage and, accordingly, 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 and research products, interest income and financing received from our Chief Executive Officer. During the three months ended October 31, 2006, we had a net decrease in cash and cash equivalents of \$2,477,000, which resulted primarily from net cash used in operating activities of \$2,606,000 and net cash used in investing activities of \$22,000, offset by net cash provided by financing activities of \$151,000 primarily from warrant and stock option exercises. Total cash resources as of October 31, 2006 were \$9,042,000 compared to \$11,519,000 at July 31, 2006.

Our current liabilities as of October 31, 2006 were \$2,048,000 compared to \$2,593,000 at July 31, 2006, a decrease of \$545,000. The decrease was primarily due to the payment of accrued expenses related to pre-clinical studies.

Until and unless our operations generate significant revenues, we expect to continue to fund operations primarily from equity financing and through the exercise of outstanding options and warrants and the sale of our tax benefits. There can be no assurance that we will be able to raise the capital we need on terms which are acceptable, if at all. As of October 31, 2006, we believe our

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cash balance is sufficient to fund our operations through our fiscal year ending July 31, 2008 based on our expected level of expenditures. These proceeds will be used to support our strategic plan, including the anticipated filing of an NDA of ONCONASE(R) for malignant mesothelioma, assuming satisfactory results from the ongoing clinical trial, the expansion of the ONCONASE oncology franchise, and the development of other pipeline products.

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.

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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 October 31, 2006, we are not involved in any unconsolidated VIE transactions.

### Contractual Obligations and Commercial Commitments

Our outstanding contractual obligations relate to our equipment operating lease. Since July 31, 2006, there has been no material change with respect to our contractual obligations as disclosed in "Management's Discussion and Analysis of Financial Condition and Results of Operations - Contractual Obligations and Commercial Commitments" in our annual report on Form 10-K for the fiscal year ended July 31, 2006.

### 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 Securities Exchange Act of 1934 ("The Exchange Act") as of October 31, 2006, the end of the period covered by this report. Based on this evaluation, the Chief Executive Officer and the Chief Financial Officer concluded that the Company's disclosure controls and procedures were not effective as of October 31, 2006 since we have not yet completed the remediation of the material weakness discussed in Item 9A, "Controls and Procedures", of our Annual Report on Form 10-K ("2006 Form 10-K") for the year ended July 31, 2006 filed with the SEC on October 16, 2006.

Management's internal control assessment as of July 31, 2006, as detailed



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in our 2006 Form 10-K, identified a material weakness due to lack of personnel with financial reporting expertise sufficient to properly record and report non-routine and complex transactions and accounting pronouncements. Our management is treating the material weakness identified above very seriously and in response, plans to continue to review and make necessary changes to the overall design of our control environment. We have begun to remediate the material weakness described above and as a result management has undertaken and plans to undertake the following steps to remediate this weakness:

(i) We plan to form an accounting oversight committee ("Oversight Committee"), comprised of members of our senior management and a third party GAAP advisor, charged with the task of discussing

and reviewing all significant transactions that have financial recognition, either to be recorded or disclosed. Additionally, the Oversight Committee will consult with our outside corporate counsel;

(ii) We have retained a third party GAAP advisor to assist and advise the CFO and Audit Committee on a timely basis on tasks including quarter end and year end review of proposed accounting for and disclosure of significant financial transactions and changes in GAAP. Members of the accounting staff of the third party advisory firm will work under the supervision of the CFO and the firm, and we can retain the third party advisory firm to provide additional resources, for example, to provide a technical accounting expert to assist us with current and future GAAP analysis, on an as needed basis; and

(iii) We plan to enhance staff training, including relevant continuing education seminars for financial staff on newly issued technical accounting pronouncements.

Management is committed to the execution of this remediation plan. We will continue to monitor the improvements in the internal control over financial reporting to ensure the remediation of this material weakness.

(b) Changes in internal controls.

There were no changes in our internal controls over financial reporting during the three months ended October 31, 2006 or, to our knowledge, in other factors that have materially affected, or are reasonably likely to materially affect, these controls.

PART II. OTHER INFORMATION

Item 6. Exhibits

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

Exhibit No.	Item Title	Exhibi Incorpor Refe
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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	

Exhibi  
Incorpor  
Refe  
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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

+ Filed herewith.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ALFACELL CORPORATION

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(Registrant)

December 11, 2006

/s/ Robert D. Love

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

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