ALFACELL CORP
Form 10-Q
December 10, 2008

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

FORM 10-Q

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

For the quarterly period ended: October 31, 2008

o 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.)

300 Atrium Drive, Somerset, NJ 08873

(Address of principal executive offices) (Zip Code)

(732) 652-4525

(Registrant's telephone number, including area code)

NOT APPLICABLE

(Former name, former address, and former fiscal year, if changed since last report.)

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

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 o Accelerated Filer x Non-accelerated Filer o Smaller Reporting Company o

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

The number of shares of Common Stock, $.001 par value, outstanding as of December 8, 2008 was 47,313,880 shares.

ALFACELL CORPORATION
(A Development Stage Company)

FORM 10-Q

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

ALFACELL CORPORATION
(A Development Stage Company)

CONDENSED BALANCE SHEETS
October 31, 2008 and July 31, 2008

	October 31, 2008 (Unaudited)	July 31, 2008 (See Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,959,146	$ 4,661,656
Prepaid expenses	228,751	165,259
Total current assets	2,187,897	4,826,915
Property and equipment, net of accumulated depreciation and amortization of $351,368 at October 31, 2008 and $342,031 at July 31, 2008	133,784	143,121
Other assets	350,000	350,000
Total assets	$ 2,671,681	$ 5,320,036
LIABILITIES AND STOCKHOLDERS' DEFICIENCY		
Current liabilities:		
Accounts payable	$ 1,134,067	$ 1,252,478
Accrued clinical trial expenses	687,470	882,386
Accrued professional service fees	323,000	511,779
Accrued compensation expense	302,006	227,803
Current portion of obligations under capital lease	3,648	3,453
Other accrued expenses	3,663	4,135
Total current liabilities	2,453,854	2,882,034
Other liabilities:		
Obligations under capital lease, net of current portion	15,952	16,940
Accrued retirement benefits	433,500	510,000
Deferred rent	281,890	267,668
Deferred revenue	5,200,000	5,200,000
Total other liabilities	5,931,342	5,994,608

Total liabilities	8,385,196	8,876,642
Stockholders' deficiency:		
Preferred stock, $.001 par value. Authorized and unissued, 1,000,000 shares at October 31, 2008 and July 31, 2008	—	—
Common stock $.001 par value. Authorized 100,000,000 shares at October 31, 2008 and July 31, 2008; issued and outstanding 47,313,880 shares and 47,276,880 shares at October 31, 2008 and July 31, 2008, respectively	47,314	47,277
Capital in excess of par value	101,435,430	100,788,973
Deficit accumulated during development stage	(107,196,259)	(104,392,856)
Total stockholders' deficiency	(5,713,515)	(3,556,606)
Total liabilities and stockholders' deficiency	$ 2,671,681	$ 5,320,036

See accompanying notes to condensed financial statements.

ALFACELL CORPORATION
(A Development Stage Company)

CONDENSED STATEMENTS OF OPERATIONS

Three months ended October 31, 2008 and 2007,
and the Period from August 24, 1981
(Date of Inception) to October 31, 2008

(Unaudited)

	Three Months Ended October 31,		August 24, 1981 (Date of Inception) to October 31, 2008
	2008	**2007**	
Sales	$ —	$ —	$ 553,489
Operating expenses:			
Cost of sales	—	—	336,495
Research and development	1,727,381	1,615,791	71,040,913
General and administrative	1,093,473	1,171,516	39,626,241
Total operating expenses	2,820,854	2,787,307	111,003,649
Loss from operations	(2,820,854)	(2,787,307)	(110,450,160)
Investment income	18,563	60,507	2,295,011
Other income	—	—	99,939
Interest expense:			
Related parties, net	—	—	(1,147,547)
Others	(1,112)	—	(2,878,891)
Loss before state tax benefit	(2,803,403)	(2,726,800)	(112,081,648)
State tax benefit	—	—	4,885,389
Net loss	$ (2,803,403)	$ (2,726,800)	$ (107,196,259)
Loss per common share - basic and diluted	$ (0.06)	$ (0.06)	

Weighted average number of common shares outstanding – basic and diluted	47,310,510	46,429,978

See accompanying notes to condensed financial statements.

ALFACELL CORPORATION
(A Development Stage Company)

CONDENSED STATEMENT OF STOCKHOLDERS' DEFICIENCY

Period from July 31, 2008 to October 31, 2008

(Unaudited)

	Common Stock		Capital In Excess of par Value	Deficit Accumulated During Development Stage	Total Stockholders' Deficiency
	Number of Shares	Amount			
Balance at July 31, 2008	47,276,880	$ 47,277	$ 100,788,973	$ (104,392,856)	$ (3,556,606)
Exercise of stock options and warrants	37,000	37	13,183	—	13,220
Stock-based compensation	—	—	633,274	—	633,274
Net loss	—	—	—	(2,803,403)	(2,803,403)
Balance at October 31, 2008	47,313,880	$ 47,314	$ 101,435,430	$ (107,196,259)	$ (5,713,515)

See accompanying notes to condensed financial statements.

ALFACELL CORPORATION
(A Development Stage Company)

CONDENSED STATEMENTS OF CASH FLOWS

Three months ended October 31, 2008 and 2007,
and the Period from August 24, 1981
(Date of Inception) to October 31, 2008

(Unaudited)

	Three Months Ended October 31,		August 24, 1981 (Date of Inception) to October 31, 2008
	2008	2007	
Cash flows from operating activities:			
Net loss	$ (2,803,403)	$ (2,726,800)	$ (107,196,259)
Adjustments to reconcile net loss to net cash used in operating activities:			
Gain on sale of marketable securities	—	—	(25,963)
Depreciation and amortization	9,337	11,520	1,719,828
Loss on disposal of property and equipment	—	—	18,926
Loss on lease termination	—	—	30,964
Stock-based compensation expense	633,274	1,000,098	13,564,790
Amortization of deferred rent	14,222	39,441	183,926
Amortization of debt discount	—	—	594,219
Amortization of deferred compensation	—	—	11,442,000
Changes in assets and liabilities:			
Increase in prepaid expenses	(63,492)	(160,442)	(288,618)
(Increase) decrease in loan receivable-related party	—	(2,382)	96,051
Increase in other assets	—	—	(350,000)
Increase in interest payable-related party	—	—	744,539
(Decrease) increase in accounts payable	(118,411)	194,647	1,640,702
Increase in accrued payroll and expenses, related parties	—	—	2,348,145
Increase in accrued retirement benefits	—	—	612,000
(Decrease) increase in accrued expenses	(386,464)	(101,563)	1,856,522
Increase in deferred revenue	—	—	5,200,000
Net cash used in operating activities	(2,714,937)	(1,745,481)	(67,808,228)
Cash flows from investing activities:			
Purchase of marketable equity securities	—	—	(290,420)
Purchase of short-term investments	—	—	(1,993,644)
Proceeds from sale of marketable equity securities	—	—	316,383
Proceeds from sale of short-term investments	—	—	1,993,644
Capital expenditures	—	(23,843)	(1,605,066)
Patent costs	—	—	(97,841)

Net cash used in investing activities	—	(23,843)	(1,676,944)

(continued)

See accompanying notes to condensed financial statements.

ALFACELL CORPORATION
(A Development Stage Company)

CONDENSED STATEMENTS OF CASH FLOWS, Continued

Three months ended October 31, 2008 and 2007
and the Period from August 24, 1981
(Date of Inception) to October 31, 2008

(Unaudited)

	Three Months Ended October 31,		August 24, 1981 (Date of Inception) to October 31, 2008
	2008	2007	
Cash flows from financing activities:			
Proceeds from short-term borrowings	$ —	$ —	$ 874,500
Payment of short-term borrowings	—	—	(653,500)
Increase in loans payable - related party, net	—	—	2,628,868
Proceeds from bank debt and other long-term debt, net of costs	—	—	3,667,460
Reduction of bank debt and long-term debt	—	—	(2,966,568)
Payment of capital lease obligations	(793)	—	(4,178)
Proceeds from issuance of common stock, net	—	—	53,102,893
Proceeds from exercise of stock options and warrants, net	13,220	198,920	14,080,850
Proceeds from issuance of convertible debentures, related party	—	—	297,000
Proceeds from issuance of convertible debentures, unrelated party	—	—	416,993
Net cash provided by financing activities	12,427	198,920	71,444,318
Net increase (decrease) in cash and cash equivalents	(2,702,510)	(1,570,404)	1,959,146
Cash and cash equivalents at beginning of period	4,661,656	6,968,172	—
Cash and cash equivalents at end of period	$ 1,959,146	$ 5,397,768	$ 1,959,146
Supplemental disclosure of cash flow information – interest paid	$ 1,112	$ —	$ 1,718,945
Noncash financing activities:			
Issuance of convertible subordinated debenture for loan payable to officer	$ —	$ —	$ 2,725,000
Issuance of common stock upon the conversion of convertible subordinated debentures, related party	$ —	$ —	$ 3,242,000
Conversion of short-term borrowings to common stock	$ —	$ —	$ 226,000
Conversion of accrued interest, payroll and expenses by related parties to stock options	$ —	$ —	$ 3,194,969

Repurchase of stock options from related party	$ —	$ —	$ (198,417)
Conversion of accrued interest to stock options	$ —	$ —	$ 142,441
Conversion of accounts payable to common stock	$ —	$ —	$ 506,725

(continued)

See accompanying notes to condensed financial statements.

ALFACELL CORPORATION
(A Development Stage Company)

CONDENSED STATEMENTS OF CASH FLOWS, Continued

Three months ended October 31, 2008 and 2007
and the Period from August 24, 1981
(Date of Inception) to October 31, 2008

(Unaudited)

	Three Months Ended October 31,		August 24, 1981 (Date of Inception) to October 31, 2008
	2008	2007	
Conversion of notes payable, bank and accrued interest to long-term debt	$ —	$ —	$ 1,699,072
Conversion of loans and interest payable, related party and accrued payroll and expenses, related parties to long-term accrued payroll and other, related party	$ —	$ —	$ 1,863,514
Issuance of common stock upon the conversion of convertible subordinated debentures, other	$ —	$ —	$ 1,584,364
Issuance of common stock for services rendered	$ —	$ —	$ 2,460
Lease incentive allowance	$ —	$ —	$ 67,000
Issuance of warrants with notes payable	$ —	$ —	$ 594,219
Acquisition of equipment through capital lease obligation	$ —	$ —	$ 23,778

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 of Alfacell Corporation ("Alfacell" or the "Company") have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not contain all of the information and notes required by U.S. GAAP for complete financial statements. In the opinion of the management, the accompanying unaudited condensed interim financial statements contain all adjustments (consisting of normal recurring adjustments) necessary to present fairly the Company's financial position as of October 31, 2008, the results of its operations for the three months ended October 31, 2008 and 2007, and the period from August 24, 1981 (date of inception) to October 31, 2008, the changes in stockholders' deficiency for the three months ended October 31, 2008, and its cash flows for the three month periods ended October 31, 2008 and 2007, and the period from August 24, 1981 (date of inception) to October 31, 2008. The results of operations for the three months ended October 31, 2008 are not necessarily indicative of operating results for fiscal year 2009 or future interim periods. The July 31, 2008 balance sheet presented herein has been derived from the audited financial statements included in the Company's Annual Report on Form 10-K for the fiscal year ended July 31, 2008, 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 Company's Annual Report on Form 10-K for the fiscal year ended July 31, 2008.

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 establishing its business. Its planned principal operations have not commenced and, accordingly, no significant revenue has been derived therefrom.

The Company is continuing to develop its drug product candidates, which require substantial capital for research, product development, and market development activities. The Company has not yet initiated marketing of a commercial drug product. Future product development will require clinical testing, regulatory approval, and substantial additional investment prior to commercialization. The future success of the Company is dependent on its ability to make progress in the development of its drug product candidates and, ultimately, upon its ability to attain future profitable operations through the successful manufacturing and marketing of those drug product candidates. There can be no assurance that the Company will be able to obtain the necessary financing or regulatory approvals to be able to successfully develop, manufacture, and market its products, or attain successful future operations. Accordingly, the Company's future success is uncertain.

2. LIQUIDITY

The Company has reported net losses of approximately $2,803,000, $12,321,000, $8,755,000 and $7,810,000 for the three months ended October 31, 2008 and the fiscal years ended July 31, 2008, 2007 and 2006, respectively. As of October 31, 2008, the Company had a working capital deficit of $266,000 and cash and cash equivalents of $1,959,000. The loss from date of inception, August 24, 1981, to October 31, 2008 amounts to approximately $107,196,000.

The Company expects that its cash balances as of October 31, 2008, including its expected level of receipts and expenditures, will be sufficient to support its activities into the fourth quarter of its fiscal year 2009, which assumes receipt of the proceeds from the sale of its state tax benefit and successful submission of the ONCONASE® New Drug Application ("NDA"). 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®, 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. The Company has engaged a financial advisor to assist in the pursuit of available strategic alternatives. These alternatives will focus on, but not be limited to, strategic partnership transactions, and could include a possible sale of the Company. Such additional funds and various alternatives may not become available as the Company may need them or be available on terms acceptable to the Company, if at all. Insufficient funds could require the Company to delay, scale back, or eliminate one or more of its research and development programs or to out-license to third parties drug product candidates or technologies that the Company would otherwise seek to develop and commercialize without relinquishing its rights thereto. Unless and until the Company's operations generate significant revenues and cash flow, the Company will attempt to continue to fund operations from cash on hand and through the sources of capital described above. 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. The Company may also obtain additional capital through the exercise of outstanding options and warrants and the sale of its tax benefits, although it cannot provide any assurance that such exercises or sales will take place or the amount of capital it will receive, if any.

The audit report of the Company's independent registered public accounting firm on the Company's fiscal year ended July 31, 2008 financial statements expressed substantial doubt about the Company's ability to continue as a going concern. Continued operations are dependent on the Company's ability to raise additional capital from various sources such as those described above. Such capital raising opportunities may not be available or may not be available on reasonable terms. The Company's financial statements do not include any adjustments that may result from the outcome of this uncertainty.

3. (LOSS) PER COMMON SHARE

The following table sets forth the computation of basic and diluted net loss per common share:

	Three Months Ended October 31,	
	2008	**2007**
Numerator:		
Net loss	$ (2,803,403)	$ (2,726,800)
Denominator:		
Weighted average number of common shares outstanding	47,310,510	46,429,978
Loss per common share - basic and diluted	$ (0.06)	$ (0.06)
Potentially dilutive securities:		
Warrants	13,810,261	15,535,034
Stock options	5,176,150	4,679,067
Total potentially dilutive securities	18,986,411	20,214,101

As the Company has incurred a net loss for all periods presented, basic and diluted per common share amounts are the same, since the inclusion of all potentially dilutive securities would be anti-dilutive.

4. 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 expense 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.

In December 2007, the SEC issued SAB No. 110 ("SAB 110") to permit entities, under certain circumstances to continue to use the "simplified" method, in developing estimates of the expected term of "plain-vanilla" share options in accordance with Statement No. 123R, "Share-Based Payment". SAB 110 amended Securities and Exchange Commission's Staff Accounting Bulletin No. 107, ("SAB 107") to permit the use of the "simplified" method beyond December 31, 2007. The adoption of SAB 110 did not have a material impact on the Company's financial statements.

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 ("EITF") 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 as an 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. STOCK-BASED COMPENSATION, Continued

The Company recorded the following stock-based compensation expense under SFAS 123(R) and EITF 96-18 based on the fair value of stock options.

	Three Months Ended October 31,	
	2008	**2007**
Research and development	$ 241,216	$ 457,075
General and administrative	392,058	543,023
Total stock-based compensation expense	$ 633,274	$ 1,000,098
Basic and diluted loss per common share	$ (0.01)	$ (0.02)

The fair value of the stock options at the grant dates 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 the 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 SAB 107 and SAB 110 and represents the period of time that options granted are expected to be outstanding. There were no stock options granted during the three months ended October 31, 2008 and 2007.

The following table summarizes the stock option activity for the period August 1, 2008 to October 31, 2008:

	Stock Options Outstanding	**Weighted Average Exercise Price Per Share**	**Weighted Average Remaining Contractual Term (Years)**	**Aggregate Intrinsic Value**
Balance August 1, 2008	6,353,067	$ 2.69	6.72	
Granted	—	—	—	—
Exercised	(37,000)	0.36		
Expired	(1,128,405)	2.04		
Forfeited	(11,512)	3.73		
Balance October 31, 2008	5,176,150	$ 2.85	6.15	$ 25,125
Exercisable as of October 31, 2008	3,306,816	$ 3.42	4.80	$ 25,125

As of October 31, 2008, there was approximately $1,659,000 of total unrecognized compensation expense related to unvested options granted that is expected to be recognized over a weighted average period of 0.70 years.

5. OTHER ASSETS

Lease security deposit held by a bank as collateral for a standby letter of credit in favor of the Company. The cash held by the bank is restricted as to use for the term of the standby letter of credit.	$ 350,000

6. CAPITAL STOCK

During the quarter ended October 31, 2008, the Company issued an aggregate of 37,000 shares of its common stock upon the exercise of stock options by employees at per share exercise prices ranging from $0.26 to $0.54. The Company realized aggregate gross proceeds of $13,220 from these exercises.

7. COMMITMENTS AND CONTINGENCIES

Employment and Retirement Agreements

Since July 31, 2008, there have been no material changes with respect to the Company's employment and retirement agreements as disclosed in the "Notes to the Financial Statements – Commitments" in the Company's Annual Report on Form 10-K for the fiscal year ended July 31, 2008.

Lease Commitments

Since July 31, 2008, there have been no material change with respect to the Company's operating leases as disclosed in the "Notes to the Financial Statements – Commitments" in the Company's Annual Report on Form 10-K for the fiscal year ended July 31, 2008.

Contingencies

The Company has product liability insurance coverage for clinical trials in the U.S. and in other countries where it conducts its clinical trials. No product liability claims have been filed against the Company. If a claim arises and the Company is found liable in an amount that significantly exceeds the policy limits, it may have a material adverse effect upon the financial condition and results of operations of the Company.

8. SUBSEQUENT EVENT

New Jersey permits certain corporations located in New Jersey to sell a portion of their state tax loss carryforwards and state research and development credits. For the state fiscal year 2009 (July 1, 2008 to June 30, 2009), the Company had approximately $1,274,000 of total available state tax benefit that were saleable. On December 1, 2008, the Company received approximately $1,140,000 from the sale of its total available state tax benefit, which will be recognized as state tax benefit in the next fiscal quarter.

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 co 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 most recent annual report on Form 10-K, filed on October 14, 2008, 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

We are a biopharmaceutical company engaged in the research, development, and commercialization of drugs for life threatening-diseases, such as malignant mesothelioma and other cancers. Our corporate strategy is to become a leader in the discovery, development, and commercialization of novel ribonuclease (RNase) therapeutics for cancer and other life-threatening diseases. As of October 31, 2008, we had 13 full time employees who conducted all administrative and research and development operations at our facility in Somerset, NJ.

We are a development stage company as defined in the Financial Accounting Standards Board's ("FASB") Statement of Financial Accounting Standards ("SFAS") No. 7, "Accounting and Reporting by Development Stage Enterprises" ("SFAS 7"). We are devoting substantially all of our present efforts to establishing a new business and developing new drug products. Our planned principal operations of marketing and/or licensing new drugs have not commenced and, accordingly, we have not derived any significant revenue from these operations.

Since our inception in 1981, we have devoted the vast majority of our resources to the research and development of ONCONASE®, our lead drug candidate, as well as other related drug candidates. In recent years we have focused our resources towards the completion of the clinical program for ONCONASE® in patients suffering from unresectable, or inoperable, malignant mesothelioma ("UMM"). We have incurred losses since inception and we have not received Food and Drug Administration ("FDA") approval of any of our drug candidates. We expect to continue to incur losses for the foreseeable future as we continue our research and development activities, which may include the sponsorship of human clinical trials for our drug candidates. Until we are able to consistently generate revenue through the sale of products, we anticipate that we will be required to fund the development of our pre-clinical compounds and drug product candidates primarily by other means, including, but not limited to, licensing the development or marketing rights to some of our drug candidates to third parties, collaborating with third parties to develop our drug candidates, or selling Company issued securities.

ONCONASE® has been granted orphan drug designation by the FDA. Orphan drug designation permits us to be awarded seven years of marketing exclusivity for ONCONASE® for the malignant mesothelioma indication upon FDA approval for this indication. Other benefits for which we are eligible with the orphan drug designation include protocol assistance by the FDA in the preparation of a dossier

that will meet regulatory requirements, tax credits, research and development grant funding, and reduced filing fees for the marketing application. Previously, our ONCONASE® development program received Fast Track Designation from the FDA for the treatment of malignant mesothelioma patients.

We also have received an Orphan Medicinal Product Designation for ONCONASE® from the European Agency for the Evaluation of Medicinal Products, or EMEA, as well as Orphan Drug Designation for ONCONASE® for malignant mesothelioma in Australia from the Therapeutics Goods Administration, or TGA. Orphan drug designation from these agencies provides benefits such as marketing exclusivity, reduced filing fees and regulatory guidance.

On May 28, 2008, we announced that the results of the preliminary statistical analysis of data from our ONCONASE® confirmatory Phase IIIb clinical trial did not meet statistical significance for the primary endpoint of survival in UMM. However, a statistically significant improvement in survival was seen in the treatment of UMM patients who failed one prior chemotherapy regimen, a currently unmet medical need and one of the predefined primary sub-group data sets for patients in the trial. During our fiscal quarter ended October 31, 2008, management's efforts were primarily focused on preparing a pre-NDA meeting request and the ONCONASE® rolling NDA. We have requested a pre-NDA meeting with the FDA to discuss our proposed NDA submission and have been granted a meeting date at the end of January 2009. We will seek the FDA's guidance at the pre-NDA meeting on whether we should complete the submission of the rolling NDA for UMM patients that fail a prior chemotherapy regimen. If the FDA advises us that we should proceed with the submission, inference can be made concerning the FDA's ultimate decision on whether or not to approve the NDA. It is also possible that the FDA will advise the Company that the Company should not complete the submission of the NDA or the FDA will not accept the filing of the NDA.

We have retained an investment bank to pursue strategic alternatives, including strategic partnership transactions or a possible sale of the Company. Also, during the quarter, James Loughlin, a member of our Board of Directors and Chairman of the Audit Committee, announced his intention not to stand for reelection at our next annual shareholders' meeting. Mr. Loughlin advised us that he will continue to serve on the board until the next annual shareholders' meeting.

Almost all of the $71 million of research and development expenses we have incurred since our inception has gone toward the development of ONCONASE® and related drug candidates. For the three months ended October 31, 2008 and for fiscal years ended July 31, 2008, 2007 and 2006, our research and development expenses were approximately $1.7 million, $8.5 million, $5.5 million, and $5.2 million, respectively, almost all of which were used for the development of ONCONASE® and related drug candidates. Until we meet with the FDA regarding our proposed NDA submission, we cannot predict with certainty what our total cost associated with obtaining marketing approvals will be, and we will be unable to predict when and if such approvals will be granted, or if and when actual sales will occur.

We fund the research and development of our products primarily from cash receipts resulting from the sale of our equity securities and convertible debentures in registered offerings and private placements. 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 three months ended October 31, 2008, we received gross proceeds of $13,220 from exercises of stock options. On December 1, 2008, we received approximately $1.1 million from the sale of our total available tax benefits. Our current cash reserves will be used primarily to support our filing of an NDA of ONCONASE® for malignant mesothelioma, assuming the FDA advises us to complete the submission of our NDA. We have incurred losses since inception and, to date, we have generated only small amounts of capital from marketing and distribution agreements for ONCONASE®. If we are advised to complete and submit our NDA, we will need to obtain additional financing in order to maintain our operations until such time as the FDA makes a decision on whether or not to approve our

NDA. If the FDA advises us not to complete the submission of our NDA, in order to continue our operations we will need to pursue strategic alternatives for the further development of ONCONASE®, which could involve the possible sale of the Company or its assets.

Results of Operations

Three month periods ended October 31, 2008 and 2007

We focus most of our productive and financial resources on the development of ONCONASE® and as such we did not have any sales in the three month periods ended October 31, 2008 and 2007.

Research and development expense for the three month period ended October 31, 2008 was approximately $1.7 million compared to approximately $1.6 million for the same period in 2007, an increase of approximately $0.1 million, or 7%. The increase was primarily related to increased expenses of approximately $0.4 million related to costs incurred for the ongoing ONCONASE® rolling NDA submission, offset by decreased compensation expense of approximately $0.2 million from decreased stock-based compensation expense and a decrease of approximately $0.1 in expenses from the completion of the Phase I component of our Phase I/II ONCONASE® clinical trials.

General and administrative expense for the three month period ended October 31, 2008 was approximately $1.1 million compared to approximately $1.2 million for the same period in 2007, a decrease of approximately $0.1 million, or 7%. This decrease was primarily due to decreased stock-based compensation expense.

The net loss for the three month period ended October 31, 2008 was approximately $2.8 million as compared to $2.7 million for the same period last year, an increase of approximately $0.1 million.

Liquidity and Capital Resources

We have reported cumulative net losses of approximately $28.9 million for the three most recent fiscal years ended July 31, 2008. The net losses from date of inception, August 24, 1981, to October 31, 2008 amount to approximately $107.2 million. As of October 31, 2008, we have a working capital deficit of approximately $0.3 million.

We have financed our operations since inception primarily through 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 state tax benefit and research products, and investment income and financing received from our Chief Executive Officer. As of October 31, 2008, we had approximately $2.0 million in cash and cash equivalents. On December 1, 2008 we received approximately $1.1 million from the sale of our state tax benefit. We currently believe that our cash reserves can support our activities into the fourth quarter of our fiscal year 2009, based upon our anticipated expenditures.

The primary use of cash over the next 12 months will be to fund our regulatory and commercial efforts for ONCONASE® and our clinical and pre-clinical research and development efforts. The most significant expenses will be incurred in relation to completing the work necessary for the planned submission of the final components of our rolling NDA submission for ONCONASE®. Additional expenses are also expected to be incurred as we attempt to move our drug product candidates towards the next phase of clinical and pre-clinical development.

If we are advised by the FDA to complete and submit our NDA, we will need to obtain additional financing in order to maintain our operations until such time as the FDA makes a decision on whether or not to approve our NDA. Given current market conditions, it may be very difficult, if not impossible, to obtain such financing. If the FDA advises us not to complete the submission of our NDA, in order to continue our operations we will need to pursue strategic alternatives for the further development of ONCONASE®, which could involve the possible sale of the Company or its assets. We have retained an investment bank to pursue strategic alternatives, including strategic partnership transactions or a possible sale of the Company. Strategic transactions may not be available when needed or on terms acceptable to us.

The audit report of our independent registered public accounting firm on our fiscal year ended July 31, 2008 financial statements expressed substantial doubt about our ability to continue as a going concern. Continued operations are dependent on our ability to raise additional capital from various sources such as those described above. Such capital raising opportunities may not be available or may not be available on reasonable terms. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty.

Off-balance Sheet Arrangements

We have no debt, no exposure to off-balance sheet arrangements, no special purpose entities, nor activities that include non-exchange-traded contracts accounted for at fair value as of October 31, 2008.

Contractual Obligations and Commercial Commitments

Since July 31, 2008, there has been no material change with respect to our commitments and contingencies as disclosed in the "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, 2008.

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, 2008.

Recently Issued Accounting Standards

In May 2008, the FASB issued SFAS No. 162 "Hierarchy of GAAP", ("SFAS 162"). SFAS 162 identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements of nongovernmental entities that are presented in conformity with GAAP in the United States. SFAS 162 is effective 60 days following the SEC's approval of the Public Company Accounting Oversight Board amendments to AU Section 411, "The Meaning of Present Fairly in Conformity with GAAP". We will adopt this pronouncement once it becomes effective and are currently evaluating the impact it will have on our reported financial results, if any.

In September 2006, the FASB issued SFAS No. 157 “Fair Value Measurements” (“SFAS 157”). SFAS 157 defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. SFAS 157 does not require new fair value measurements. We adopted SFAS 157 as of August 1, 2008, and determined that it did not have a material impact on our reported financial results.

In February 2008, the FASB issued FASB Staff Position (“FSP”) SFAS No. 157-1, “Application of FASB Statement No. 157 to SFAS Statement No. 13 and Other Accounting Pronouncements that Address Fair Value Measurements for Purposes of Lease Classification or Measurement under Statement 13”, (“FSP 157-1”). FSP 157-1 amends SFAS 157 to exclude SFAS 13 and other accounting pronouncements that address fair value measurements for purposes of lease classifications under SFAS 13. However, this scope exception does not apply to assets acquired and liabilities assumed in a business combination that are required to be measured at fair value under FASB Statement No. 141, “Business Combinations”, or SFAS 141(R), regardless of whether those assets and liabilities are related to leases. FSP 157-1 is effective upon initial adoption of SFAS 157. We adopted SFAS 157 as of August 1, 2008, and determined that it did not have a material impact on our reported financial results.

In February 2008, the FASB issued FSP SFAS No. 157-2, “Effective Date of FASB SFAS No. 157”, (“FSP 157-2”). FSP 157-2 delays the effective date of SFAS 157 for non financial assets and non financial liabilities, except for items that are recognized or disclosed at fair value in the financial statements on a recurring basis at least annually. This delay is intended to allow the FASB and constituents additional time to consider the effect of various implementation issues that have arisen from the application of SFAS 157. We have reviewed FSP 157-2 and will wait to hear for additional positions taken by the FASB before proceeding further.

In October 2008 the FASB issued FSP SFAS No. 157-3, “Determining the Fair Value of a Financial Asset when the Market for that Asset is not Active” (“FSP 157-3”). FSP 157-3 clarifies the application of FASB No. 157 in a market that is not active and provides key considerations in determining the fair value of a financial asset when the market for that financial asset is not active. This FSP shall become effective upon issuance. We believe that this new pronouncement will not have a material impact on our financial statements in future periods.

In December 2007, the FASB issued SFAS No. 141(R) “Business Combinations” (“SFAS 141(R)”). SFAS 141(R) establishes principles and requirements for how the acquirer of a business recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquiree. SFAS 141(R) also provides guidance for recognizing and measuring the goodwill acquired in the business combination and determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. The guidance will become effective as of the beginning of a company’s fiscal year beginning after December 15, 2008. We believe that this new pronouncement will not have a material impact on our financial statements in future periods.

In June 2007, the FASB issued EITF Issue No. 07-03, “Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities,” (“EITF 07-03”). EITF 07-03 addresses the diversity that exists with respect to the accounting for the nonrefundable portion of a payment made by a research and development entity for future research and development activities. The EITF concluded that an entity must defer and capitalize nonrefundable advance payments made for research and development activities and expense these amounts as the related goods are delivered or the related services are performed. EITF 07-03 will be effective for interim or annual

reporting periods in fiscal years beginning after December 15, 2007. We adopted EITF 07-03 as of August 1, 2008, and determined that it did not have a material impact on our reported financial results.

In February 2007, the FASB issued SFAS No. 159 "The Fair Value Option for Financial Assets and Financial Liabilities" ("SFAS 159"). SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. We adopted SFAS 159 as of August 1, 2008, and determined that it did not have a material impact on our reported financial results.

In June 2006, the FASB issued Interpretation No. 48, "Accounting for Uncertainty in Income Taxes - an Interpretation of FASB Statement No. 109" ("FIN 48"). 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 attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a company's tax return. We adopted FIN 48 and determined that it did not have a material impact on our reported financial results.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

As of October 31, 2008, we were exposed to market risks, primarily changes in U.S. interest rates. As of October 31, 2008, we held total cash and cash equivalents of approximately $2.0 million. All cash equivalents have a maturity less than 90 days. Declines in interest rates over time would reduce our interest income from our investments. Based upon our balance of cash and cash equivalents as of October 31, 2008, a decrease in interest rates of 1.0% would cause a corresponding decrease in our annual interest income of approximately $20,000.

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, as amended ("the Exchange Act") as of October 31, 2008, the end of the period covered by this report. Based on this evaluation, the Chief Executive Officer and the Chief Financial Officer have concluded that our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission including without limitation, controls and procedures that are designed to ensure that the information required to be disclosed in reports by us that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, as appropriate to allow timely discussion regarding required disclosures.

(b) Changes in internal controls.

There have been no changes in our internal control over financial reporting during the quarter ended October 31, 2008 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting subsequent to the date of the evaluation referred to above.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors

There have been no material changes to the discussion of risk factors included in our most recent Annual Report on Form 10-K.

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

(a) Recent Sales of Unregistered Securities

None.

(b) Purchases of Equity Securities by Issuer and Affiliated Purchasers

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Submission of Matters to a Vote of Security Holders

None.

Item 5. Other Information

None.

Item 6. Exhibits

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

Exhibit No.	Item Title
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

SIGNATURE PAGE

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)

December 10, 2008

/s/ Lawrence A. Kenyon

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