

ALFACELL CORP
Form 10-Q
March 12, 2009

**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: January 31, 2009

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

(State or other jurisdiction of
organization)

22-2369085

(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 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 Smaller Reporting Company

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

Edgar Filing: ALFACELL CORP - Form 10-Q

The number of shares of Common Stock, \$.001 par value, outstanding as of March 10, 2009 was 47,313,880 shares.

PART I. FINANCIAL INFORMATIONItem 1. Financial Statements**ALFACELL CORPORATION**
(A Development Stage Company)CONDENSED BALANCE SHEETS
January 31, 2009 and July 31, 2008

| | January 31, 2009 (Unaudited) | July 31, 2008 (See Note 1) |
|--|---------------------------------|-------------------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 1,196,373 | \$ 4,661,656 |
| Prepaid expenses | 159,788 | 165,259 |
| Total current assets | 1,356,161 | 4,826,915 |
| Property and equipment, net of accumulated depreciation and amortization of \$360,474 at January 31, 2009 and \$342,031 at July 31, 2008 | 124,679 | 143,121 |
| Other assets | 350,000 | 350,000 |
| Total assets | \$ 1,830,840 | \$ 5,320,036 |
| LIABILITIES AND STOCKHOLDERS' DEFICIENCY | | |
| Current liabilities: | | |
| Accounts payable | \$ 837,691 | \$ 1,252,478 |
| Accrued clinical trial expenses | 631,156 | 882,386 |
| Accrued professional service fees | 330,200 | 511,779 |
| Accrued compensation expense | 369,180 | 227,803 |
| Current portion of obligations under capital lease | 3,853 | 3,453 |
| Other accrued expenses | 33,966 | 4,135 |
| Total current liabilities | 2,206,046 | 2,882,034 |
| Other liabilities: | | |
| Obligations under capital lease, net of current portion | 14,908 | 16,940 |
| Accrued retirement benefits | 357,000 | 510,000 |
| Deferred rent | 289,107 | 267,668 |
| Deferred revenue | 5,200,000 | 5,200,000 |
| Total other liabilities | 5,861,015 | 5,994,608 |
| Total liabilities | 8,067,061 | 8,876,642 |

Edgar Filing: ALFACELL CORP - Form 10-Q

| | | |
|--|---------------|---------------|
| | _____ | _____ |
| Stockholders' deficiency: | | |
| Preferred stock, \$.001 par value. Authorized and unissued, 1,000,000 shares at January 31, 2009 and July 31, 2008 | — | — |
| Common stock \$.001 par value. Authorized 100,000,000 shares at January 31, 2009 and July 31, 2008; issued and outstanding 47,313,880 shares and 47,276,880 shares at January 31, 2009 and July 31, 2008, respectively | 47,314 | 47,277 |
| Capital in excess of par value | 101,566,495 | 100,788,973 |
| Deficit accumulated during development stage | (107,850,030) | (104,392,856) |
| | _____ | _____ |
| Total stockholders' deficiency | (6,236,221) | (3,556,606) |
| | _____ | _____ |
| Total liabilities and stockholders' deficiency | \$ 1,830,840 | \$ 5,320,036 |
| | _____ | _____ |

See accompanying notes to condensed financial statements.

ALFACELL CORPORATION
(A Development Stage Company)

CONDENSED STATEMENTS OF OPERATIONS

Three and six months ended January 31, 2009 and 2008,
and the Period from August 24, 1981
(Date of Inception) to January 31, 2009

(Unaudited)

| | Three Months Ended January 31, | | Six Months Ended January 31, | | August 24, 1981 (Date of Inception) to January 31, 2009 |
|---|-----------------------------------|----------------|---------------------------------|----------------|--|
| | 2009 | 2008 | 2009 | 2008 | |
| Sales | \$ — | \$ — | \$ — | \$ — | \$ 553,489 |
| Operating expenses: | | | | | |
| Cost of sales | — | — | — | — | 336,495 |
| Research and development | 1,097,853 | 2,033,500 | 2,825,234 | 3,649,291 | 72,138,766 |
| General and administrative | 700,236 | 1,473,736 | 1,793,709 | 2,645,252 | 40,326,477 |
| Total operating expenses | 1,798,089 | 3,507,236 | 4,618,943 | 6,294,543 | 112,801,738 |
| Loss from operations | (1,798,089) | (3,507,236) | (4,618,943) | (6,294,543) | (112,248,249) |
| Investment income | 5,519 | 66,063 | 24,083 | 126,570 | 2,300,531 |
| Other income | — | — | — | — | 99,939 |
| Interest: | | | | | |
| Related parties, net | — | — | — | — | (1,147,547) |
| Others | (1,068) | (1,256) | (2,181) | (1,256) | (2,879,960) |
| Loss before state tax benefit | (1,793,638) | (3,442,429) | (4,597,041) | (6,169,229) | (113,875,286) |
| State tax benefit | 1,139,867 | 1,755,380 | 1,139,867 | 1,755,380 | 6,025,256 |
| Net loss | \$ (653,771) | \$ (1,687,049) | \$ (3,457,174) | \$ (4,413,849) | \$ (107,850,030) |
| Loss per basic and diluted common share | \$ (0.01) | \$ (0.04) | \$ (0.07) | \$ (0.10) | |

Edgar Filing: ALFACELL CORP - Form 10-Q

| | | | | |
|---|------------|------------|------------|------------|
| Weighted average number of shares outstanding | 47,313,880 | 46,861,347 | 47,312,195 | 46,645,663 |
|---|------------|------------|------------|------------|

See accompanying notes to condensed financial statements.

ALFACELL CORPORATION
(A Development Stage Company)

CONDENSED STATEMENT OF STOCKHOLDERS' DEFICIENCY

Period from July 31, 2008 to January 31, 2009

(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 |
| Share-based compensation | — | — | 764,339 | — | 764,339 |
| Net loss | — | — | — | (3,457,174) | (3,457,174) |
| Balance at January 31, 2009 | 47,313,880 | \$ 47,314 | \$ 101,566,495 | \$ (107,850,030) | \$ (6,236,221) |

See accompanying notes to condensed financial statements.

ALFACELL CORPORATION
(A Development Stage Company)

CONDENSED STATEMENTS OF CASH FLOWS

Six months ended January 31, 2009 and 2008,
and the Period from August 24, 1981
(Date of Inception) to January 31, 2009

(Unaudited)

| | Six Months Ended January 31, | | August 24, 1981 (Date of Inception) to January 31, 2009 |
|--|---------------------------------|----------------|--|
| | 2009 | 2008 | |
| Cash flows from operating activities: | | | |
| Net loss | \$ (3,457,174) | \$ (4,413,849) | \$ (107,850,030) |
| Adjustments to reconcile net loss to net cash provided by (used in) operating activities: | | | |
| Gain on sale of marketable equity securities | — | — | (25,963) |
| Depreciation and amortization | 18,443 | 24,155 | 1,728,934 |
| Loss on disposal of property and equipment | — | — | 18,926 |
| Loss on lease termination | — | — | 30,964 |
| Share-based compensation | 764,339 | 1,864,789 | 13,695,855 |
| Amortization of deferred rent | 21,439 | 78,143 | 191,143 |
| Amortization of debt discount | — | — | 594,219 |
| Amortization of deferred compensation | — | — | 11,442,000 |
| Changes in assets and liabilities: | | | |
| Decrease (increase) in prepaid expenses | 5,471 | (141,099) | (219,655) |
| (Increase) decrease in loan receivable, related party | — | (4,764) | 96,051 |
| Decrease (increase) in other assets | — | 35,000 | (350,000) |
| Increase in interest payable-related party | — | — | 744,539 |
| (Decrease) increase in accounts payable | (414,787) | 459,933 | 1,344,326 |
| Increase in accrued payroll and expenses, related parties | — | — | 2,348,145 |
| Increase in accrued retirement benefits | — | — | 612,000 |
| (Decrease) increase in accrued expenses | (414,601) | (129,712) | 1,828,385 |
| Increase in deferred revenue | — | 5,100,000 | 5,200,000 |
| Net cash (used in) provided by operating activities | (3,476,870) | 2,872,596 | (68,570,161) |
| 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) |

Edgar Filing: ALFACELL CORP - Form 10-Q

| | | | |
|---------------------------------------|-------------------|-------------------|-------------------|
| Net cash used in investing activities | <u> </u> | <u> </u> | <u> </u> |
| | — | (23,843) | (1,676,944) |
| | <u> </u> | <u> </u> | <u> </u> |

(continued)

See accompanying notes to condensed financial statements.

ALFACELL CORPORATION
(A Development Stage Company)

CONDENSED STATEMENTS OF CASH FLOWS, Continued

Six months ended January 31, 2009 and 2008,
and the Period from August 24, 1981
(Date of Inception) to January 31, 2009

(Unaudited)

| | Six Months Ended January 31, | | August 24, 1981 (Date of Inception) to January 31, 2009 |
|--|---------------------------------|----------------------|--|
| | 2009 | 2008 | |
| 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 obligation | (1,633) | (1,921) | (5,018) |
| Proceeds from issuance of common stock, net | — | — | 53,102,893 |
| Proceeds from exercise of stock options and warrants, net | 13,220 | 392,920 | 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 | 11,587 | 390,999 | 71,443,478 |
| Net increase (decrease) in cash and cash equivalents | (3,465,283) | 3,239,752 | 1,196,373 |
| Cash and cash equivalents at beginning of period | 4,661,656 | 6,968,172 | — |
| Cash and cash equivalents at end of period | \$ 1,196,373 | \$ 10,207,924 | \$ 1,196,373 |
| Supplemental disclosure of cash flow information – interest paid | \$ 2,181 | \$ 1,256 | \$ 1,720,014 |
| 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 |

Edgar Filing: ALFACELL CORP - Form 10-Q

| | | | | | | |
|---|----|---|----|---|----|-----------|
| 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, Concluded

Six months ended January 31, 2009 and 2008,
and the Period from August 24, 1981
(Date of Inception) to January 31, 2009

(Unaudited)

| | Six Months Ended January 31, | | August 24, 1981 (Date of Inception) to January 31, 2009 |
|---|---------------------------------|-----------|--|
| | 2009 | 2008 | |
| 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 | \$ 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 January 31, 2009, the results of its operations for the three and six months ended January 31, 2009 and 2008, and the period from August 24, 1981 (date of inception) to January 31, 2009, the changes in stockholders’ deficiency for the six months ended January 31, 2009, and its cash flows for the three and six month periods ended January 31, 2009 and 2008, and the period from August 24, 1981 (date of inception) to January 31, 2009. The results of operations for the three and six months ended January 31, 2009 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 \$654,000 and \$3,457,000 for the three and six months ended January 31, 2009, respectively, and \$12,321,000, \$8,755,000 and \$7,810,000 for the fiscal years ended July 31, 2008, 2007 and 2006, respectively. As of January 31, 2009, the Company had a working capital deficit of approximately \$850,000 and cash and cash equivalents of approximately \$1,196,000. The loss from date of inception, August 24, 1981, to January 31, 2009 amounts to approximately \$107,850,000.

The Company expects that its cash balances as of January 31, 2009, will be sufficient to support its activities through July 2009, based upon its reduced level of operations. The Company's continued operations will depend on its ability to raise additional capital or conclude a strategic transaction which may include a strategic partnership or a possible sale of the Company or its assets. The Company has engaged a financial advisor to assist in the pursuit of available strategic alternatives. 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. The Company may also obtain additional capital through the sale of its tax benefit, although it cannot provide any assurance that such sale will take place, 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 January 31, | | Six Months Ended January 31, | |
|--|-----------------------------------|----------------|---------------------------------|----------------|
| | 2009 | 2008 | 2009 | 2008 |
| Numerator: | | | | |
| Net loss | \$ (653,771) | \$ (1,687,049) | \$ (3,457,174) | \$ (4,413,849) |
| Denominator: | | | | |
| Weighted average number of common shares outstanding | 47,313,880 | 46,861,347 | 47,312,195 | 46,645,663 |
| Loss per common share - basic and diluted | \$ (0.01) | \$ (0.04) | \$ (0.07) | \$ (0.10) |
| Potentially dilutive securities: | | | | |
| Warrants | 12,721,840 | 15,235,034 | 12,721,840 | 15,235,034 |
| Stock options | 5,224,650 | 5,299,067 | 5,224,650 | 5,299,067 |
| Total potentially dilutive securities | 17,946,490 | 20,534,101 | 17,946,490 | 20,534,101 |

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. SHARE-BASED COMPENSATION

Effective August 1, 2005, the Company adopted Statement of Financial Accounting Standards (“SFAS”) 123(R), “Share-Based Payment” (“SFAS 123(R)”), which 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) 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 market value of unvested outstanding stock options at August 1, 2005 are recognized as expense as services are rendered.

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, “Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring or In Conjunction with Selling Goods or Services” (“EITF 96-18”). The fair value of such securities is recorded as an expense and capital in excess of par value in stockholders’ equity over the applicable service periods using variable accounting through the vesting date based on the fair market value of the securities at the end of each period or the vesting date.

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

| | Three Months Ended January 31, | | Six Months Ended January 31, | |
|---|-----------------------------------|-------------------|---------------------------------|---------------------|
| | 2009 | 2008 | 2009 | 2008 |
| Research and development | \$ 26,927 | \$ 485,323 | \$ 268,144 | \$ 942,398 |
| General and administrative | 104,137 | 379,368 | 496,195 | 922,391 |
| Total share-based compensation expense | \$ 131,064 | \$ 864,691 | \$ 764,339 | \$ 1,864,789 |
| Basic and diluted loss per common share | \$ 0.00 | \$ 0.02 | \$ 0.02 | \$ 0.04 |

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. In accordance with SFAS 123(R), the calculated Black-Scholes value was reduced by applying a forfeiture rate, based upon historical pre-vesting cancellations of stock options. Estimated forfeitures are reassessed at each reporting period and may change based on new facts and circumstances. 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 the Securities and Exchange Commission’s Staff Accounting Bulletin No. 110, and represents the period of time that options granted are expected to be outstanding. The “simplified” method was used since the Company does not have sufficient historical data to provide a basis to estimate a justifiable expected term.

4. SHARE-BASED COMPENSATION, Concluded

| | Three Months Ended January 31, | | Six Months Ended January 31, | |
|--|-----------------------------------|---------|---------------------------------|---------|
| | 2009 | 2008 | 2009 | 2008 |
| Expected dividend yield | 0% | 0% | 0% | 0% |
| Risk-free interest rate | 1.00% | 3.08% | 1.00% | 3.08% |
| Expected stock price volatility | 102.13% | 95.90% | 102.13% | 95.90% |
| Expected term (years) | 3.5 | 4.58 | 3.5 | 4.58 |
| Weighted average grant date fair value | \$ 0.16 | \$ 1.24 | \$ 0.16 | \$ 1.24 |

The following table summarizes the stock option activity for the period August 1, 2008 to January 31, 2009:

| | 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 | 265,000 | 0.24 | | |
| Exercised | (37,000) | 0.36 | | \$ 8,126 |
| Expired | (1,300,905) | 2.13 | | |
| Forfeited | (55,512) | 1.95 | | |
| Balance January 31, 2009 | 5,224,650 | 2.73 | 6.08 | |
| Exercisable as of January 31, 2009 | 3,622,650 | 3.23 | 5.03 | |
| Unvested as of January 31, 2009 | 1,602,000 | 1.62 | 8.47 | |

As of January 31, 2009, there was approximately \$1,542,000 of total unrecognized compensation expense related to unvested options granted that is expected to be recognized over a weighted average period of 2.59 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. SALE OF NET OPERATING LOSS CARRYFORWARDS

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

Edgar Filing: ALFACELL CORP - Form 10-Q

available state tax benefit that was saleable. On December 1, 2008, the Company received approximately \$1,140,000 from the sale of its total available state tax benefit, which was recognized as state tax benefit for the six months ended January 31, 2009.

- 11 -

6. SALE OF NET OPERATING LOSS CARRYFORWARDS, Concluded

For the state fiscal year 2008 (July 1, 2007 to June 30, 2008), the Company had approximately \$2,496,000 of total available state tax benefit that was saleable, of which New Jersey permitted the Company to sell approximately \$1,969,000. In December 2007, the Company received approximately \$1,755,000 from the sale of the \$1,969,000 saleable state tax benefit, which was recognized as state tax benefit for the six months ended January 31, 2008.

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 changes 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.

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 other 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, and as such risk factors have been revised in Part II, Item 1A "Risk Factors" in this quarterly report on Form 10-Q, constitute cautionary statements identifying important factors with respect to these forward-looking statements, including certain risks and uncertainties, that could cause actual results to vary significantly from the future results indicated in these forward-looking statements. Other factors could also cause actual results to differ significantly from the future results indicated in these forward-looking statements.

Overview

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 January 31, 2009, we had five 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. 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. In January 2009, we met with the FDA to discuss our proposed NDA submission of the final components of the ONCONASE[®] rolling NDA. At the pre-NDA meeting, the FDA recommended that an additional clinical trial be conducted in UMM patients that have failed one prior chemotherapy regimen, prior to filing an NDA.

We have retained a financial advisor to pursue strategic alternatives, including strategic partnership transactions or a possible sale of our Company or our assets. Also, during the quarter, Lawrence A. Kenyon, the Company's President, Chief Financial Officer and Corporate Secretary resigned as an employee of the Company and served as acting president, chief financial officer and corporate secretary until February 17, 2009. Mr. Kenyon remained on the Company's board of directors.

Almost all of the \$72 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 and six months ended January 31, 2009 and for fiscal years ended July 31, 2008, 2007 and 2006, our research and development expenses were approximately \$1.1 million, \$2.8 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. We cannot predict with certainty what our total cost associated with obtaining marketing approvals will be, and we are 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 six months ended January 31, 2009, we received gross proceeds of \$13,220 from exercises of stock options and approximately \$1.1 million from the sale of our total available tax benefits. Our current cash reserves will be used to continue our operations and to explore strategic alternatives. We have incurred losses since inception and in order to continue our operations we will need to obtain additional capital or conclude a strategic transaction, which could involve the possible sale of our Company or our assets.

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 January 31, 2009 amount to approximately \$107.8 million. As of January 31, 2009, we have a working capital deficit of approximately \$0.8 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 January 31, 2009, we had approximately \$1.2 million in cash and cash equivalents. We effected a reduction in force in January 2009 and have otherwise reduced our operations to the minimum sustainable level required to pursue strategic alternatives and additional capital. Based upon these actions, we currently believe that our cash reserves can support our activities through July 2009.

The primary use of cash will be to continue our operations while we seek additional capital or strategic alternatives. We will need to obtain additional financing or conclude a strategic transaction in order to continue our operations and continue to seek marketing approval for ONCONASE[®]. Given current market conditions, it may be extremely difficult, if not impossible, to obtain such financing. We have retained a financial advisor to pursue strategic alternatives, including strategic partnership transactions or a possible sale of our Company or our assets. Strategic transactions may not be available when needed or on terms acceptable to us. We may also obtain additional capital through the sale of our tax benefit, although we cannot provide any assurance that such sale will take place, if any.

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.

Results of Operations

Three month periods ended January 31, 2009 and 2008

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 January 31, 2009 and 2008.

Research and development expense for the three month period ended January 31, 2009 was approximately \$1.1 million compared to approximately \$2.0 million for the same period in 2008, a decrease of approximately \$0.9 million, or 46%. The decrease was primarily related to decreased expenses of approximately \$0.6 million related to costs incurred for the ongoing ONCONASE[®] rolling NDA submission; decreased compensation expense of approximately \$0.2 million from decreased share-based compensation expense; and a decrease of approximately \$0.1 million in expenses due to 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 January 31, 2009 was approximately \$0.7 million compared to approximately \$1.5 million for the same period in 2008, a decrease of approximately \$0.8 million, or 52%. This decrease was primarily due to decreased compensation expense of approximately \$0.3 million, mostly related to share-based compensation;

decreased legal expenses of approximately \$0.3 million primarily related to negotiations that resulted in commercial partnerships for ONCONASE® in 2008; decreased fees for professional services of approximately \$0.1 million; and decreased general office expenses of approximately \$0.1 million.

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), we had approximately \$1,274,000 of total available state tax benefit that was saleable. On December 1, 2008, we received approximately \$1,140,000 from the sale of our total available state tax benefit, which was recognized as state tax benefit for the three months ended January 31, 2009.

For the state fiscal year 2008 (July 1, 2007 to June 30, 2008), we had approximately \$2,496,000 of total available state tax benefit that was saleable, of which New Jersey permitted us to sell approximately \$1,969,000. In December 2007, we received approximately \$1,755,000 from the sale of the \$1,969,000 saleable state tax benefit, which was recognized as state tax benefit for the three months ended January 31, 2008.

The net loss for the three month period ended January 31, 2009 was approximately \$0.7 million as compared to \$1.7 million for the same period last year, a decrease of approximately \$1.0 million.

Six month periods ended January 31, 2009 and 2008

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 six month periods ended January 31, 2009 and 2008.

Research and development expense for the six month period ended January 31, 2009 was approximately \$2.8 million compared to approximately \$3.6 million for the same period in 2008, a decrease of approximately \$0.8 million, or 23%. The decrease was primarily due to decreased share-based compensation expense of approximately \$0.4 million; decreased expenses of approximately \$0.2 million related to costs incurred for the ongoing ONCONASE® rolling NDA submission of our confirmatory Phase IIIb ONCONASE® clinical trial; and a decrease of approximately \$0.2 in expenses due to the completion of the Phase I component of our Phase I/II ONCONASE® clinical trials.

General and administrative expense for the six month period ended January 31, 2009 was approximately \$1.8 million compared to \$2.6 million for the same period in 2008, a decrease of \$0.8, or 32%. This decrease was primarily due to decreased compensation expense of approximately \$0.5 million, mostly related to share-based compensation and decreased legal expenses of approximately \$0.3 million primarily related to negotiations that resulted in commercial partnerships for ONCONASE® in 2008.

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), we had approximately \$1,274,000 of total available state tax benefit that was saleable. On December 1, 2008, we received approximately \$1,140,000 from the sale of our total available state tax benefit, which was recognized as state tax benefit for the six months ended January 31, 2009.

For the state fiscal year 2008 (July 1, 2007 to June 30, 2008), we had approximately \$2,496,000 of total available state tax benefit that was saleable, of which New Jersey permitted us to sell approximately \$1,969,000. In December 2007, we received approximately \$1,755,000 from the sale of

the \$1,969,000 saleable state tax benefit, which was recognized as state tax benefit for the six months ended January 31, 2008.

The net loss for the six month period ended January 31, 2009 was approximately \$3.5 million as compared to \$4.4 million for the same period last year, a decrease of \$0.9 million. The cumulative loss from the date of inception, August 24, 1981 to January 31, 2009, amounted to \$107.8 million. We have incurred net losses during each year since our inception. 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 our development stage expenses.

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 January 31, 2009.

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 share-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 Financial Statements" in our Annual Report on Form 10-K for the year ended July 31, 2008.

Recently Issued Accounting Standards

In June 2008, the FASB issued EITF No. 07-05 "Determining Whether an Instrument (or Embedded Feature) is Indexed to an Entity's Own Stock", ("EITF 07-05"). EITF 07-05 provides guidance for determining whether an equity-linked financial instrument (or embedded feature) is indexed to an entity's own stock, which would qualify as a scope exception under SFAS No 133, "Accounting for Derivative Instruments and Hedging Activities." EITF 07-05 is effective for fiscal years beginning after December 15, 2008 and early adoption for an existing instrument is not permitted. We are currently evaluating the impact that the adoption of EITF 07-05 will have, if any, on our reported financial results.

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 adopted SFAS 162 in November 2008 and determined that it did not have a material impact on our reported financial results.

Edgar Filing: ALFACELL CORP - Form 10-Q

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 January 31, 2009, we were exposed to market risks, primarily changes in U.S. interest rates. As of January 31, 2009, we held total cash and cash equivalents of approximately \$1.2 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.

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 Acting 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 January 31, 2009, the end of the period covered by this report. Based on this evaluation, the Chief Executive Officer and the Acting 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 has been no changes in our internal control over financial reporting during the quarter ended January 31, 2009 that has materially affected, or is 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

Below are the risk factors that have been revised since the filing of our Annual Report on Form 10-K for the year ended July 31, 2008 (the "2008 Form 10-K") on October 14, 2008. You are urged to read these risk factors in the 2008 Form 10-K in addition to the following revised risk factors set forth below. Each of the risk factors set forth here and in our 2008 Form 10-K could materially adversely affect our business, operating results and financial condition, as well as the value of an investment in our common stock. Additional risks and uncertainties not presently known to us, or those we currently deem immaterial, may also materially harm our business, operating results and financial condition.

Based upon guidance provided by the FDA at a pre-NDA meeting, we decided to put on hold the filing of a new drug application (NDA) for ONCONASE® for unresectable malignant mesothelioma (UMM). We do not currently have the resources to pursue additional clinical trials for ONCONASE®.

As we have previously reported, the results of the preliminary statistical analysis of the data from the confirmatory Phase IIIb clinical trial for ONCONASE® in patients suffering from UMM did not meet statistical significance for the primary endpoint of survival in UMM. Although a statistically significant improvement in survival was seen in the treatment of UMM patients who failed one prior chemotherapy regimen, a pre-defined primary data set for this sub-group of patients in the trial, at a pre-NDA meeting with the FDA held in January 2009, the FDA recommended that an additional clinical trial be conducted in this sub-group of patients prior to our submitting an NDA for ONCONASE®. Our current financial situation does not allow us to pursue additional clinical trials unless and until we are able to effect a strategic transaction or otherwise secure additional capital. We effected a reduction in force in January 2009 and have otherwise reduced our operations to the minimum sustainable level required to pursue strategic alternatives and additional capital. Based upon these actions, we expect that our current cash reserves will enable us to maintain our reduced operations through July 2009. While we intend to continue to pursue strategic transactions and additional capital, we cannot provide any assurance that we will be successful in our efforts, and if we are not successful in these efforts we will be forced to cease operations.

We are highly dependent on achieving success in the clinical testing, regulatory approval, and commercialization of ONCONASE® and our other compounds currently under development. If we fail to obtain the necessary regulatory approvals, we will not be allowed to commercialize ONCONASE® and our business will be harmed.

The FDA in the United States and comparable regulatory agencies in foreign countries impose substantial pre-market approval requirements on the introduction of pharmaceutical products. These requirements involve the completion of lengthy and detailed pre-clinical and clinical testing and other costly and time consuming procedures. Satisfaction of these requirements typically takes several years depending on the level of complexity and novelty of the product. The length of time required to complete a clinical trial depends on several factors including the size of the patient population, the ability of patients to get to the site of the clinical study, and the criteria for determining which patients are eligible

to join the study. A significant portion of our expenditures have been devoted, and if we are able to obtain additional capital, in the future will be devoted, to the clinical trials for our lead product candidate, ONCONASE[®]. A delay in the commercial sale of ONCONASE[®] or sales of ONCONASE[®] which did not result in significant revenue to us, would increase the time frame during which our cash flow would be negative, which, in turn, would require us to seek additional financing. Such financing may not be available, and even if it is available, it may not be available on terms favorable or acceptable to us.

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

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

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

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

- our ability to demonstrate clinically that our products have utility and are safe;
- delays or refusals by regulatory authorities in granting marketing approvals;
- our limited financial resources relative to our competitors;
- our ability to obtain and maintain relationships with current and additional marketing partners;
- the availability and level of reimbursement for our products by third party payors;
- incidents of adverse reactions to our products;
- misuse of our products and unfavorable publicity that could result; and
- the occurrence of manufacturing or distribution disruptions.

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

We estimate that as of January 31, 2009, our cash reserves should be sufficient to support our activities through July 2009, based upon our reduced level of operations. As a result of our continuing losses and lack of capital, the report of our independent registered public accounting firm on our July 31, 2008 financial statements included an explanatory paragraph which states that our recurring losses from operations and negative cash flows from operating activities raise substantial doubt about our ability to continue as a going concern. Our financial statements at July 31, 2008 do not include any adjustments that might result from the outcome of this uncertainty. We will need additional financing to conduct our business after July 2009. Factors that would affect the amount and timing of additional capital required include, but are not limited to, the following:

- the condition of the capital markets in general and the willingness of investors to invest in development stage biotech companies, in particular;
- the progress and cost of research and development and clinical trial activities relating to our drug product candidates;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our patent claims and other intellectual property rights and investigating and defending against infringement claims asserted against us by others;
- the emergence of competing technologies and other adverse market developments;
- changes in or terminations of our existing licensing, marketing and distribution arrangements;
- the amount of milestone payments we may receive from current and future collaborators, if any; and
- the cost of manufacturing scale-up and development of marketing operations, if we undertake those activities.

Additional financing may not be available when we need it or be on terms acceptable to us. If adequate financing is not available or we are unable to conclude a strategic transaction prior to the time our current cash reserves are exhausted we will be required to cease operations. If additional capital is raised through the sale of equity, our stockholders' ownership interest could be diluted and such newly-issued securities may have rights, preferences, or privileges superior to those of our other stockholders. The terms of any debt securities we may sell to raise additional capital may place restrictions on our operating activities.

The trading market for our common stock may be limited since our common stock is no longer listed on the Nasdaq Capital Market.

On January 6, 2009 our common stock was delisted from the Nasdaq Capital Market. Since then our common stock has been quoted on the Pink Sheets and may be thinly traded at times. You may be unable to sell our common stock during times when the trading market is limited.

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).

| <u>Exhibit No.</u> | <u>Item Title</u> |
|------------------------|---|
| <u>31.1</u> | <u>Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u> |
| <u>32.1</u> | <u>Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u> |

* Portions of this exhibit have been redacted and filed separately with the SEC pursuant to a confidential treatment request

- 23 -

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)

March 12, 2009

/s/ Kuslima Shogen

*Chief Executive Officer and Acting
Chief Financial Officer*
(Principal Accounting Officer and
Principal Financial Officer)

- 24 -
