

ALFACELL CORP  
Form 10-Q  
March 07, 2008

**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, 2008

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

The number of shares of Common Stock, \$.001 par value, outstanding as of March 5, 2008 was 47,066,880 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**  
January 31, 2008 and July 31, 2007

	January 31, 2008 (Unaudited)	July 31, 2007 (See Note 1)
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 10,207,924	\$ 6,968,172
Prepaid expenses	291,306	150,207
Loan receivable, related party	185,161	-
Total current assets	10,684,391	7,118,379
Property and equipment, net of accumulated depreciation and amortization of \$314,736 at January 31, 2008 and \$290,581 at July 31, 2007	160,189	136,723
Loan receivable, related party	-	180,397
Other assets	350,000	385,000
Total assets	\$ 11,194,580	\$ 7,820,499
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 892,719	\$ 432,786
Accrued clinical trial expenses	860,125	898,134
Accrued professional service fees	283,980	322,051
Accrued compensation expense	113,154	143,369
Obligations under capital lease	3,095	-
Other accrued expenses	10,143	33,560
Total current liabilities	2,163,216	1,829,900
Other liabilities:		
Obligations under capital lease	18,762	-
Deferred rent	190,262	112,119
Deferred revenue	5,200,000	100,000
Total other liabilities	5,409,024	212,119
Total liabilities	7,572,240	2,042,019
Stockholders' equity:		
Preferred stock, \$.001 par value. Authorized and unissued, 1,000,000 shares	-	-
Common stock \$.001 par value. Authorized 100,000,000 shares at January 31, 2008 and July 31, 2007; issued and outstanding 46,944,880 shares and 46,280,880 shares at January 31, 2008 and July 31, 2007, respectively	46,945	46,281
Capital in excess of par value	100,060,999	97,803,954
Deficit accumulated during development stage	(96,485,604)	(92,071,755)
Total stockholders' equity	3,622,340	5,778,480
Total liabilities and stockholders' equity	\$ 11,194,580	\$ 7,820,499

See accompanying notes to condensed financial statements.

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**ALFACELL CORPORATION**  
(A Development Stage Company)

CONDENSED STATEMENTS OF OPERATIONS

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

(Unaudited)

	Three Months Ended January 31,		Six Months Ended January 31,		August 24, 1981 (Date of Inception) to January 31, 2008
	2008	2007	2008	2007	
Sales	\$ -	\$ -	\$ -	\$ -	\$ 553,489
Operating expenses:					
Cost of sales	-	-	-	-	336,495
Research and development	2,033,500	1,472,578	3,649,291	3,042,763	64,459,713
General and administrative	1,473,736	1,061,743	2,645,252	1,987,781	35,380,665
Total operating expenses	3,507,236	2,534,321	6,294,543	5,030,544	100,176,873
Loss from operations	(3,507,236)	(2,534,321)	(6,294,543)	(5,030,544)	(99,623,384)
Investment income	66,063	98,539	126,570	221,872	2,175,427
Other income	-	-	-	-	99,939
Interest:					
Related parties, net	-	-	-	-	(1,147,547)
Others	(1,256)	-	(1,256)	(46)	(2,875,428)
Loss before state tax benefit	(3,442,429)	(2,435,782)	(6,169,229)	(4,808,718)	(101,370,993)
State tax benefit	1,755,380	510,467	1,755,380	510,467	4,885,389
Net loss	\$ (1,687,049)	\$ (1,925,315)	\$ (4,413,849)	\$ (4,298,251)	\$ (96,485,604)
Loss per basic and diluted common share	\$ (0.04)	\$ (0.04)	\$ (0.10)	\$ (0.10)	
Weighted average number of shares outstanding	46,861,347	44,846,064	46,645,663	44,595,902	

See accompanying notes to condensed financial statements.

**ALFACELL CORPORATION**  
(A Development Stage Company)

CONDENSED STATEMENT OF STOCKHOLDERS' EQUITY

Period from July 31, 2007 to January 31, 2008

(Unaudited)

	Common Stock		Capital In	Deficit	Total
	Number of	Amount	Excess of par	Accumulated	Stockholders'
	Shares		Value	During	Equity
				Development	
				Stage	
Balance at July 31, 2007	46,280,880	\$ 46,281	\$ 97,803,954	\$ (92,071,755)	\$ 5,778,480
Exercise of stock options and warrants	664,000	664	392,256	—	392,920
Share-based compensation	—	—	1,864,789	—	1,864,789
Net loss	—	—	—	(4,413,849)	(4,413,849)
Balance at January 31, 2008	46,944,880	\$ 46,945	\$ 100,060,999	\$ (96,485,604)	\$ 3,622,340

See accompanying notes to condensed financial statements.

**ALFACELL CORPORATION**  
(A Development Stage Company)

CONDENSED STATEMENTS OF CASH FLOWS

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

(Unaudited)

	Six Months Ended January 31,		August 24, 1981 (Date of Inception) to January 31, 2008
	2008	2007	
<b>Cash flows from operating activities:</b>			
Net loss	\$ (4,413,849)	\$ (4,298,251)	\$ (96,485,604)
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	24,155	19,175	1,683,195
Loss on disposal of property and equipment	-	-	18,926
Loss on lease termination	-	-	30,964
Share-based compensation	1,864,789	1,240,718	12,497,330
Amortization of deferred rent	78,143	-	92,298
Amortization of debt discount	-	-	594,219
Amortization of deferred compensation	-	-	11,442,000
Changes in assets and liabilities:			
Increase in prepaid expenses	(141,099)	(170,668)	(351,173)
Increase in loan receivable, related party	(4,764)	(4,763)	(89,110)
Decrease (increase) in other assets	35,000	-	(350,000)
Increase in interest payable-related party	-	-	744,539
Increase (decrease) in accounts payable	459,933	(920,388)	1,399,354
Increase in accrued payroll and expenses, related parties	-	-	2,348,145
(Decrease) increase in accrued expenses	(129,712)	(155,916)	1,986,286
Increase in deferred revenue	5,100,000	-	5,200,000
Net cash provided by (used in) operating activities	2,872,596	(4,290,093)	(59,264,594)
<b>Cash flows from investing activities:</b>			
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)	(25,793)	(1,594,839)
Patent costs	-	-	(97,841)
Net cash used in investing activities	(23,843)	(25,793)	(1,666,717)

(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, 2008 and 2007,  
and the Period from August 24, 1981  
(Date of Inception) to January 31, 2008

(Unaudited)

	Six Months Ended January 31,		August 24, 1981 (Date of Inception) to January 31, 2008
	2008	2007	
<b>Cash flows from financing activities:</b>			
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	(1,921)	-	(1,921)
Proceeds from issuance of common stock, net	-	(31,344)	53,102,893
Proceeds from exercise of stock options and warrants, net	392,920	852,750	13,773,510
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	390,999	821,406	71,139,235
Net increase (decrease) in cash and cash equivalents	3,239,752	(3,494,480)	10,207,924
Cash and cash equivalents at beginning of period	6,968,172	11,518,540	-
Cash and cash equivalents at end of period	\$ 10,207,924	\$ 8,024,060	\$ 10,207,924
<b>Supplemental disclosure of cash flow information -</b>			
interest paid	\$ 1,256	\$ 46	\$ 1,715,482
<b>Noncash financing activities:</b>			
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.

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**ALFACELL CORPORATION**  
(A Development Stage Company)

CONDENSED STATEMENTS OF CASH FLOWS, Continued

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

(Unaudited)

	Six Months Ended January 31,		August 24, 1981 (Date of Inception) to January 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	\$ 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, 2008, the results of its operations for the three and six months ended January 31, 2008 and 2007, and the period from August 24, 1981 (date of inception) to January 31, 2008, the changes in stockholders’ equity for the six months ended January 31, 2008, and its cash flows for the six month periods ended January 31, 2008 and 2007, and the period from August 24, 1981 (date of inception) to January 31, 2008. The results of operations for the three and six months ended January 31, 2008 are not necessarily indicative of operating results for fiscal year 2008 or future interim periods. The July 31, 2007 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, 2007, filed with the Securities and Exchange Commission.

Certain footnote disclosures normally included in financial statements prepared in accordance with GAAP 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, 2007.

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.

Certain reclassifications have been made to prior year amounts to conform to the current year presentations.

The Company has reported net losses of approximately \$1,687,000 and \$4,414,000 for the three and six months ended January 31, 2008, respectively and \$8,755,000, \$7,810,000 and \$6,462,000 for the fiscal years ended July 31, 2007, 2006 and 2005, respectively. The loss from date of inception, August 24, 1981, to January 31, 2008 amounts to approximately \$96,486,000.

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



**1. ORGANIZATION AND BASIS OF PRESENTATION, Continued**

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.

The Company expects that its cash balances as of January 31, 2008, will be sufficient to support its activities through the fourth quarter of its fiscal year 2009 based on its expected level of receipts and expenditures, which assumes timely and successful completion of its Phase IIIb clinical trial, and submission and approval of the related 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 out-licensing agreements with other companies for its technology and its drug candidates. Such additional funds may not become available as the Company may need them or be available on acceptable terms. Insufficient funds could require the Company to delay, scale back, or eliminate one or more of its research and development programs or to license third parties to commercialize drug product candidates or technologies that the Company would otherwise seek to develop without relinquishing its rights thereto. Until and unless the Company's operations generate significant revenues, the Company expects to continue to fund operations from equity financing or from up-front, milestone or other payments received in connection with licensing or strategic partnering agreements. 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 of such exercises or sale or the amount of capital it will receive, if any.

**2. 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,	
	2008	2007	2008	2007
<b>Numerator:</b>				
Net loss	\$ (1,687,049)	\$ (1,925,315)	\$ (4,413,849)	\$ (4,298,251)
<b>Denominator:</b>				
Weighted average number of common shares outstanding	46,861,347	44,846,064	46,645,663	44,595,902
Loss per common share - basic and diluted	\$ (0.04)	\$ (0.04)	\$ (0.10)	\$ (0.10)
<b>Potentially dilutive securities:</b>				
Warrants	15,235,034	16,533,067	15,235,034	16,533,067
Stock options	5,299,067	4,356,350	5,299,067	4,356,350
Total potentially dilutive securities	20,534,101	20,889,417	20,534,101	20,889,417

**2. LOSS PER COMMON SHARE, Continued**

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.

**3. SHARE-BASED COMPENSATION**

Effective August 1, 2005, the Company adopted Statement of Financial Accounting Standards 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 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 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		Six Months Ended	
	January 31,		January 31,	
	2008	2007	2008	2007
Research and development	\$ 485,323	\$ 133,483	\$ 942,398	\$ 349,884
General and administrative	379,368	342,729	922,391	707,009
Total share-based compensation expense	\$ 864,691	\$ 476,212	\$ 1,864,789	\$ 1,056,893
Basic and diluted loss per common share	\$ 0.02	\$ 0.01	\$ 0.04	\$ 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. 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.





**3. SHARE-BASED COMPENSATION, Continued**

	Three Months Ended January 31,		Six Months Ended January 31,	
	2008	2007	2008	2007
Expected dividend yield	0%	0%	0%	0%
Risk-free interest rate	3.08%	4.73%	3.08%	4.69%
Expected stock price volatility	95.90%	109.00%	95.90%	110.59%
Expected term (years)	4.58	5.31	4.58	5.57
Weighted average grant date fair value	\$ 1.24	\$ 1.31	\$ 1.24	\$ 1.24

The following table summarizes the stock option activity for the period August 1, 2007 to January 31, 2008:

	Stock Options Outstanding	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance August 1, 2007	4,867,039	\$ 2.85		
Granted	635,000	1.74		
Exercised	(114,000)	0.43		\$ 175,510
Expired	(63,000)	1.92		
Forfeited	(25,972)	2.00		
Balance January 31, 2008	5,299,067	2.78	6.26	\$ 3,370,534
Exercisable as of January 31, 2008	3,031,066	3.22	4.65	\$ 2,155,275
Unvested as of January 31, 2008	2,268,001	2.19	8.42	\$ 1,215,259

During the fiscal quarter ended January 31, 2008, the Company issued an aggregate of 265,000 stock options to its board members with an exercise price of \$1.72 per share and six-year exercise term. The aggregate grant date fair market value of these options, \$275,865, is being amortized over the one-year vesting period. The Company recognized compensation expense of \$22,989 for the fiscal quarter ended January 31, 2008.

During the fiscal quarter ended January 31, 2008, the Company issued an aggregate of 40,000 stock options to various non-employee consultants for services rendered. The options vested immediately, have an exercise price of \$1.75 per share and a ten-year exercise term. The aggregate grant date fair market value of these options, \$52,840, was recognized as an expense by the Company for the fiscal quarter ended January 31, 2008.

### **3. SHARE-BASED COMPENSATION, Continued**

During the fiscal quarter ended January 31, 2008, the Company issued an aggregate of 330,000 stock options to various non-employee consultants for serving as the Company's scientific advisors and research collaborators and for contributions made on behalf of the Company's pre-clinical and clinical research programs. Of these options, 10,000 vested immediately, 50% of the balance will vest after one year and the remaining 50% of the balance will vest after two years. The options have an exercise price of \$1.75 per share and a ten-year term. Under the variable accounting provisions of EITF 96-18, the aggregate grant date fair market value of these options, \$456,730, is being amortized over the vesting period and the aggregate re-measured fair market value at January 31, 2008 of \$179,507 was recognized as an expense by the Company for the fiscal quarter ended January 31, 2008.

As of January 31, 2008, there was approximately \$2,313,000 of total unrecognized compensation expense related to unvested options granted that is expected to be recognized over a weighted average period of 0.85 years.

### **4. CASH AND CASH EQUIVALENTS**

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. The carrying value of these investments approximates their fair market value due to their short maturity and liquidity.

### **5. LOAN RECEIVABLE, RELATED PARTY**

Amounts due from a loan to the Company's Chief Executive Officer totaling \$185,161 at January 31, 2008 and \$180,397 at July 31, 2007 are classified as a current asset in loan receivable, related party as the loan is due, and payment is expected to be received, on August 1, 2008. In each of the six months ended January 31, 2008 and 2007, the Company accrued 8% interest in the amount of approximately \$4,800 on the unpaid principal balance.

### **6. 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

### **7. REVENUE RECOGNITION**

The Company recognizes revenue in accordance with Staff Accounting Bulletin No. 104, "Revenue Recognition" ("SAB 104") issued by the staff of the SEC. Under SAB 104, revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred and/or services have been rendered, the sales price is fixed or determinable, and collectibility is reasonably assured.

The Company enters into marketing and distribution agreements, which contain multiple deliverables. Under the provisions of Emerging Issues Task Force No. 00-21, "Accounting for Revenue Arrangements with Multiple Deliverables", the Company evaluates whether these deliverables constitute separate units of accounting to which total arrangement consideration is allocated. A deliverable qualifies as a separate unit of accounting when the item delivered to the customer has standalone value, there is objective and reliable evidence of fair value of items that have not been delivered to the customer, and, if



## **7. REVENUE RECOGNITION, Continued**

there is a general right of return for the items delivered to the customer, delivery or performance of the undelivered items is considered probable and substantially in the control of the Company. Arrangement consideration is allocated to units of accounting on a relative fair-value basis or the residual method if the Company is unable to determine the fair value of all deliverables in the arrangement. Consideration allocated to a unit of accounting is limited to the amount that is not contingent upon future performance by the Company. Upon determination of separate units of accounting and allocated consideration, the general criteria for revenue recognition is applied to each unit of accounting.

During the fiscal quarter ended January 31, 2008, the Company entered into a License Agreement for ONCONASE<sup>®</sup> with Par Pharmaceutical, Inc. in the U.S. Under the terms of the License Agreement, on January 14, 2008, Strativa Pharmaceuticals (“Strativa”), the proprietary products division of Par Pharmaceutical, received exclusive marketing, sales and distribution rights to ONCONASE<sup>®</sup> for the treatment of cancer in the United States and its territories. The Company retains all rights and obligations for product manufacturing, clinical development and obtaining regulatory approvals, as well as all rights for those non-U.S. jurisdictions in which it has not currently granted any such rights or obligations to third parties. Joint oversight committees with members from the Company and Strativa will manage the alliance. The Company received a cash payment of \$5 million upon the signing of the License Agreement and will be entitled to an additional cash payment of up to \$30 million upon FDA approval of ONCONASE<sup>®</sup> for unresectable, or inoperable, malignant mesothelioma (“UMM”). The Company will also be entitled to receive up to \$190 million in additional milestone payments in connection with the development of ONCONASE<sup>®</sup> for up to three additional cancer indications and achieving certain net sales levels, in addition to receiving double-digit royalties on net sales of ONCONASE<sup>®</sup>. In the event of approval of ONCONASE<sup>®</sup> for a cancer indication in addition to UMM, the Company will have the option to co-promote ONCONASE<sup>®</sup> in the United States, with support from Strativa. Strativa will provide technical expertise for a future Alfacell oncology sales force, as well as funding for certain associated costs. Under certain circumstances, the Company will have the right to co-promote ONCONASE<sup>®</sup>, at the Company’s cost, prior to the time ONCONASE<sup>®</sup> is approved for any such additional cancer indication. The initial non-refundable cash payment received by the Company was allocated to deferred revenue and will be recognized ratably as revenue once the general criteria for revenue recognition have been met for the unit of accounting to which the payment has been allocated.

## **8. CAPITAL STOCK**

During the fiscal quarter ended October 31, 2007, the Company issued an aggregate of 364,000 shares of its common stock upon the exercise of warrants and stock options by unrelated parties and employees at per share exercise prices ranging from \$0.26 to \$0.85. The Company realized aggregate gross proceeds of \$198,920 from these exercises.

During the fiscal quarter ended January 31, 2008, the Company issued an aggregate of 300,000 shares of its common stock upon the exercise of warrants by unrelated parties at per share exercise prices ranging from \$0.60 to \$1.00. The Company realized aggregate gross proceeds of \$194,000 from these exercises.

**9. SALE OF NET OPERATING LOSS CARRYFORWARDS**

New Jersey has enacted legislation permitting certain corporations located in New Jersey to sell a portion of their state tax loss carryforwards and state research and development credits in order to obtain state tax benefits. For the state fiscal year 2008 (July 1, 2007 to June 30, 2008), the Company had approximately \$2,496,000 of total available state net operating loss carryforwards and state research and development credits that were 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 of state net operating loss carryforwards and state research and development credits that were saleable, which was recognized as state tax benefit for the six months ended January 31, 2008.

For the state fiscal year 2007 (July 1, 2006 to June 30, 2007), the Company had approximately \$2,338,000 of total available state net operating loss carryforwards and state research and development credits that were saleable, of which New Jersey permitted the Company to sell approximately \$574,000. In December 2006, the Company received approximately \$510,000 from the sale of the \$574,000 of state net operating loss carryforwards and state research and development credits, which was recognized as state tax benefit for the six months ended January 31, 2007.

**10. COMMITMENTS AND CONTINGENCIES***License Agreements*

On July 23, 1991, the Board of Directors authorized the Company to pay Kuslima Shogen, the Company's founder and CEO, an amount equal to 15% of any gross royalties which may be paid to the Company from any license(s) with respect to the Company's principal product, ONCONASE®, or any other products derived from amphibian source extract, produced either as a natural, synthesized, and/or genetically engineered drug for which the Company is the owner or co-owner of the patents, or acquires such rights in the future, for a period not to exceed the life of the patents. If the Company manufactures and markets its own drugs, then the Company will pay Ms. Shogen an amount equal to 5% of gross sales from any products sold during the term of the patents. On April 16, 2001, this agreement was amended and clarified to provide that Ms. Shogen would receive the 15% royalty payment relating to licenses or 5% of net sales relating to sales but not both, unless the Company and the licensee both market the licensed product.

*Lease Commitments*

Future minimum lease payments under noncancelable operating and capital leases (with initial or remaining terms in excess of one year) as of January 31, 2008:

	Total	Payments Due in Fiscal Year					2013 and Thereafter
		2008	2009	2010	2011	2012	
Building lease	\$ 3,094,770	\$ 68,640	\$ 275,445	\$ 302,036	\$ 317,446	\$ 317,446	\$ 1,813,757
Equipment operating and capital lease	133,935	16,774	33,548	31,024	25,976	25,976	637
Total contractual cash obligations	\$ 3,228,705	\$ 85,414	\$ 308,993	\$ 333,060	\$ 343,422	\$ 343,422	\$ 1,814,394

**10. COMMITMENTS AND CONTINGENCIES, Continued**

*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.

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

Information herein contains, in addition to historical information, forward-looking statements that involve risks and uncertainties. All statements, other than statements of historical fact, regarding our financial position, potential, business strategy, plans and objectives for future operations are "forward-looking statements." These statements are commonly identified by the use of forward-looking terms and phrases as "anticipates," "believes," "estimates," "expects," "intends," "may," "seeks," "should," or "will" or the negative thereof or other variations thereon or comparable terminology, 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 II Item 1A "Risk Factors" herein and Part I, Item 1A. "Risk Factors" in our most recent annual report on Form 10-K, filed on October 15, 2007, as amended by our subsequent quarterly reports 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, 2008, we had 16 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 Statement of Financial Accounting Standards No. 7, "Accounting and Reporting by Development Stage Enterprises." We are devoting substantially all of our present efforts to establishing a new business and developing new drug products. Our planned principal operations of marketing and/or licensing new drugs have not commenced and, accordingly, we have not derived any significant revenue from these operations.

Since our inception in 1981, we have devoted the vast majority of our resources to the research and development of ONCONASE<sup>®</sup>, 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<sup>®</sup> 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 include the sponsorship of human clinical trials for our drug candidates. Until we are able to consistently generate revenue through the sale of drug or non-drug 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.

During our fiscal quarter ended January 31, 2008, management's efforts were primarily focused on our continued preparation of the ONCONASE<sup>®</sup> rolling NDA and completing the negotiations of a U.S. License Agreement for ONCONASE<sup>®</sup> with Par Pharmaceutical, Inc. Under the terms of the License



Agreement, on January 14, 2008, Strativa Pharmaceuticals (“Strativa”), the proprietary products division of Par Pharmaceutical, received exclusive marketing, sales and distribution rights to ONCONASE<sup>®</sup> for the treatment of cancer in the United States and its territories. We retain all rights and obligations for product manufacturing, clinical development and obtaining regulatory approvals, as well as all rights for those non-U.S. jurisdictions in which we have not currently granted any such rights or obligations to third parties. Joint oversight committees with members from Alfacell and Strativa will manage the alliance. We received a cash payment of \$5 million upon the signing of the License Agreement and will be entitled to an additional cash payment of up to \$30 million upon FDA approval of ONCONASE<sup>®</sup> for UMM. We will also be entitled to receive up to \$190 million in additional milestone payments in connection with the development of ONCONASE<sup>®</sup> for up to three additional cancer indications and achieving certain net sales levels, in addition to receiving double-digit royalties on net sales of ONCONASE<sup>®</sup>. In the event of approval of ONCONASE<sup>®</sup> for a cancer indication in addition to UMM, we will have the option to co-promote ONCONASE<sup>®</sup> in the United States, with support from Strativa. Strativa will provide technical expertise for a future Alfacell oncology sales force, as well as funding for certain associated costs. Under certain circumstances, we will have the right to co-promote ONCONASE<sup>®</sup>, at our cost, prior to the time ONCONASE<sup>®</sup> is approved for any such additional cancer indication. The Company will also supply all of Strativa’s requirements for ONCONASE<sup>®</sup> pursuant to a Supply Agreement with Par Pharmaceutical, Inc. executed on January 14, 2008.

Also during January 2008, we entered into a marketing and distribution agreement with BL&H Co. Ltd. for the commercialization of ONCONASE<sup>®</sup> in Korea, Taiwan and Hong Kong. Under the agreement, we received a \$0.1 million up-front fee and are eligible to receive additional cash milestones and 50% of net sales in the territory. Additionally, we entered into a Purchase and Supply Agreement (the “Supply Agreement”) with Scientific Protein Laboratories LLC (“SPL”), in January 2008. Under the Supply Agreement, SPL will manufacture and be our exclusive supplier for the bulk drug substance used to make ONCONASE<sup>®</sup>. The term of the Supply Agreement shall be ten years and we have the right to terminate the Supply Agreement at any time without cause on two years prior notice to SPL.

Management changes during the quarter ended January 31, 2008, included the appointment of our CFO, Mr. Lawrence A. Kenyon to the additional role of Chief Operating Officer. Mr. Kenyon was also appointed to our board of directors in November 2007. Additionally, in January 2008, Dr. David Sidransky, an independent director, was appointed Chairman of our board of directors, replacing our CEO, Ms. Kuslima Shogen, in that role. Ms. Shogen continues to serve as CEO and as a director. The purpose of these changes is to give Mr. Kenyon control of daily operations and to allow Ms. Shogen to focus her efforts on completion of the ONCONASE<sup>®</sup> Phase IIIb clinical trial and rolling NDA.

Almost all of the \$64.5 million of research and development expenses we have incurred since our inception has gone toward the development of ONCONASE<sup>®</sup> and related drug candidates. For the six months ended January 31, 2008 and for the fiscal years ended July 31, 2007, 2006 and 2005, our research and development expenses were approximately \$3.6 million, \$5.5 million, \$5.2 million, and \$5.1 million, respectively, almost all of which were used for the development of ONCONASE<sup>®</sup> and related drug candidates. ONCONASE<sup>®</sup> is currently in an international, centrally randomized, confirmatory Phase IIIb registration clinical trial. The primary endpoint of the trial is a statistically significant improvement in overall survival. The first interim analysis results based on one third of the required events (deaths) of the study, which evaluates the efficacy, safety and tolerability of the combination of ONCONASE<sup>®</sup> + doxorubicin as compared to doxorubicin alone, have been reported. The median survival time (MST) demonstrated a trend favoring the ONCONASE<sup>®</sup> + doxorubicin treatment group (12 months) over the doxorubicin group (10 months). A two month improvement in median survival had previously been observed in the Treatment Target Group (n=104) analysis from a previously completed Phase III single agent study that favored ONCONASE<sup>®</sup> over doxorubicin treatments (11.6 months vs. 9.6 months). The



Company's Phase IIIb confirmatory registration trial was designed based on the conclusions drawn from the TTG analysis but powered to reach a statistically significant difference in overall survival between the ONCONASE® + doxorubicin treatment group and the doxorubicin treatment group at 316 evaluable events. The interim data, which represented one third of the planned number of evaluable events, was sufficient for us to continue the trial as planned, but was not sufficient for supporting our filing for marketing approval at that time. To date, we have reached 313 evaluable events. Enrollment in the trial was completed in September 2007.

The timing of filing for marketing registrations in the US, European Union and Australia is data driven. Therefore, we cannot predict with certainty what our total cost associated with obtaining marketing approvals in all of these regions will be, or when and if such approvals will be granted, or when actual sales will occur. In the U.S., we have submitted all of the various components of our rolling NDA for ONCONASE® that do not require the statistical analysis of the data from the Phase IIIb trial, in anticipation of potentially achieving favorable results. Estimated costs related to completion of the NDA will total at least approximately \$4 million, of which, we estimate \$2 million will be required to complete the NDA and \$2 million will be allocated to manufacturing sufficient quantities of ONCONASE® to complete the required testing of our manufacturing processes.

ONCONASE® has been granted orphan drug designation for treatment of malignant mesothelioma 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 previously 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 designations from these agencies provide benefits such as marketing exclusivity, reduced filing fees and regulatory guidance.

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 in connection with license and collaboration agreements we have entered into with third parties and through other debt financings, the sale of our tax benefit and research products, interest income and financing received from our Chief Executive Officer. During the three months ended January 31, 2008, we received gross proceeds of approximately \$194,000 from exercises of stock options and warrants. These proceeds will be used primarily to complete our confirmatory Phase IIIb clinical trial and support our anticipated filing of an NDA of ONCONASE® for UMM, assuming satisfactory results from the ongoing clinical trial. We have incurred losses since inception and, to date, we have generated only small amounts of capital from marketing and distribution agreements for ONCONASE®.

## Results of Operations

### Three month periods ended January 31, 2008 and 2007

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

Research and development expense for the three month period ended January 31, 2008 was approximately \$2.0 million compared to approximately \$1.5 million for the same period in 2007, an increase of approximately \$0.5 million, or 38%. The increase was primarily related to increased expenses of approximately \$0.4 million related to our preparations for a potential NDA submission upon reaching the required number of evaluable events in our confirmatory Phase IIIb ONCONASE<sup>®</sup> clinical trial, and increased compensation expense of approximately \$0.1 million related to increased share-based compensation expense.

General and administrative expense for the three month period ended January 31, 2008 was approximately \$1.5 million compared to approximately \$1.1 million for the same period in 2007, an increase of approximately \$0.4 million, or 39%. This increase was due to increased legal expenses of approximately \$0.2 million primarily related to negotiations that resulted in commercial partnerships for ONCONASE<sup>®</sup>, increased fees for professional services of approximately \$0.1 million and increased general office expenses of approximately \$0.1 million.

For the three month periods ended January 31, 2008 and January 31, 2007, our investment income was approximately \$0.1 million.

The State of New Jersey has enacted legislation permitting certain corporations located in New Jersey to sell a portion of their state tax loss carryforwards and state research and development credits, or state net operating loss carryforwards, in order to obtain state tax benefit. For the state fiscal year 2008 (July 1, 2007 to June 30, 2008), we had approximately \$2,496,000 of total available state net operating loss carryforwards and state research and development credits that qualified for sale, 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 of state net operating loss carryforwards and state research and development credits, which was recognized as state tax benefit for the three months ended January 31, 2008.

For the state fiscal year 2007 (July 1, 2006 to June 30, 2007), we had approximately \$2,338,000 of total available state net operating loss carryforwards that qualified for sale, of which New Jersey permitted us to sell approximately \$574,000. In December 2006, we received approximately \$510,000 from the sale of the \$574,000 of state net operating loss carryforwards, which was recognized as state tax benefit for the three months ended January 31, 2007.

The net loss for the three month period ended January 31, 2008 was approximately \$1.7 million as compared to \$1.9 million for the same period last year, a decrease of approximately \$0.2 million.

Six month periods ended January 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 six month periods ended January 31, 2008 and 2007.

Research and development expense for the six month period ended January 31, 2008 was approximately \$3.6 million compared to approximately \$3.0 million for the same period in 2007, an increase of approximately \$0.6 million, or 20%. The increase was primarily due to increased compensation expense of approximately \$0.4 million, mostly related to share-based compensation, and increased expenses of approximately \$0.2 million related to our preparations for a potential NDA submission upon reaching the required number of evaluable events in our confirmatory Phase IIIb ONCONASE® clinical trial.

General and administrative expense for the six month period ended January 31, 2008 was approximately \$2.6 million compared to \$2.0 million for the same period in 2007, an increase of \$0.6, or 30%. This increase was due to increased legal expenses of approximately \$0.3 million which primarily related to negotiations that resulted in commercial partnerships for ONCONASE® and increased compensation expense of approximately \$0.3 million, mostly due to increased share-based compensation expense.

For the six month period ended January 31, 2008, our investment income was approximately \$0.1 million compared to approximately \$0.2 million for the same period in 2007, a decrease of \$0.1 million. This decrease was due to lower balances of cash and cash equivalents on hand for the six month period ended January 31, 2008 as compared to the same period in 2007.

The State of New Jersey has enacted legislation permitting certain corporations located in New Jersey to sell a portion of their state tax loss carryforwards and state research and development credits, or state net operating loss carryforwards, in order to obtain state tax benefit. For the state fiscal year 2008 (July 1, 2007 to June 30, 2008), we had approximately \$2,496,000 of total available state net operating loss carryforwards and state research and development credits that qualified for sale, 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 of state net operating loss carryforwards and state research and development credits, which was recognized as state tax benefit for the six months ended January 31, 2008.

For the state fiscal year 2007 (July 1, 2006 to June 30, 2007), we had approximately \$2,338,000 of total available state net operating loss carryforwards that qualified for sale, of which New Jersey permitted us to sell approximately \$574,000. In December 2006, we received approximately \$510,000 from the sale of the \$574,000 of state net operating loss carryforwards, which was recognized as state tax benefit for the six months ended January 31, 2007.

The net loss for the six month period ended January 31, 2008 was approximately \$4.4 million as compared to \$4.3 million for the same period last year, an increase of \$0.1 million. The cumulative loss from the date of inception, August 24, 1981 to January 31, 2008, amounted to \$96.5 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.

## Liquidity and Capital Resources

We have reported cumulative net losses of approximately \$23 million for the three most recent fiscal years ended July 31, 2007. The net losses from date of inception, August 24, 1981 to January 31, 2008 amounts to approximately \$96.5 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 in connection with license and collaboration agreements we have entered into with third parties and through other debt financings, the sale of our state tax benefits and research products, and investment income and financing received from our Chief Executive Officer. During the six months ended January 31, 2008, we received a cash payment of \$5.0 million as a non-refundable up-front fee for entering into a licensing agreement for ONCONASE<sup>®</sup> with Par Pharmaceutical, Inc., approximately \$1.8 million in the sale of our New Jersey state tax benefit, and approximately \$0.4 million in proceeds from exercise of stock options and warrants. As of January 31, 2008, we had approximately \$10.2 million in cash and cash equivalents. We currently believe that our cash and cash equivalents on hand at January 31, 2008 can support our activities through the fourth quarter of our fiscal year 2009 based on our expected level of receipts and expenditures, which assumes timely and successful completion of our Phase IIIb clinical trial, and submission and approval of the related NDA.

The primary use of cash over the next 12 months will be to fund our regulatory and commercial efforts for ONCONASE<sup>®</sup> 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 our rolling NDA submission and completion of the ONCONASE<sup>®</sup> Phase IIIb clinical trial. Additional expenses are also expected to be incurred as we continue to move our drug product candidates towards the next phase of clinical and pre-clinical development.

If still available under New Jersey law, we will attempt to sell the remaining \$1,764,000 of our state net operating loss carryforwards between July 1, 2007 and June 30, 2008 (state fiscal year 2008). This amount, which is a carryover of our remaining state net operating loss carryforwards from state fiscal year 2007, may increase if we incur additional net losses and research and development credits during state fiscal year 2008. We cannot estimate, however, what percentage of our state net operating loss carryforwards that qualify for sale New Jersey will permit us to sell, how much money we will receive in connection with the sale, if any, if we will be able to find a buyer for our state net operating loss carryforwards or if such funds will be available in a timely manner.

We may seek to satisfy future funding requirements through public or private offerings of securities or with collaborative or other arrangements with corporate partners. Additional financing may not be available when needed or on terms acceptable to us. If adequate financing is not available, we may be required to delay, scale back, or eliminate certain of our research and development programs, relinquish rights to certain of our technologies, drugs or products, or license third parties to commercialize products or technologies that we would otherwise seek to develop ourselves.

### *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, 2008.

*Contractual Obligations and Commercial Commitments*

Future minimum lease payments under non-cancelable operating and capital leases (with initial or remaining terms in excess of one year) as of January 31, 2008:

	Payments Due in Fiscal Year						
	Total	2008	2009	2010	2011	2012	2013 and Thereafter
Building lease	\$ 3,094,770	\$ 68,640	\$ 275,445	\$ 302,036	\$ 317,446	\$ 317,446	\$ 1,813,757
Equipment operating and capital lease	133,935	16,774	33,548	31,024	25,976	25,976	637
Total contractual cash obligations	\$ 3,228,705	\$ 85,414	\$ 308,993	\$ 333,060	\$ 343,422	\$ 343,422	\$ 1,814,394

*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 Consolidated Financial Statements" in our Annual Report on Form 10-K for the year ended July 31, 2007.

*Recently Issued Accounting Standards*

In December 2007, the Financial Accounting Standards Board ("FASB") issued Statement No. 141(R) "Business Combinations". This Statement 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. The Statement 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.

On December 21, 2007, the Securities and Exchange Commission ("SEC") issued Staff Accounting Bulletin ("SAB") No. 110 ("SAB 110") to permit entities, under certain circumstances to continue to use the "simplified" method, in developing estimates of expected term of "plain-vanilla" share options in accordance with Statement No. 123R, "Share-Based Payment". SAB 110 amended SAB 107 to permit the use of the "simplified" method beyond December 31, 2007. We believe that the adoption of SAB 110 will not have a material impact on our consolidated financial statements.

In June 2007, the FASB issued Emerging Issues Task Force ("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 are currently evaluating the impact that the adoption of EITF 07-03 will have, if any, on our financial statements.

In February 2007, the FASB issued Statement of Financial Accounting Standards (“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. SFAS 159 will be effective for our company on August 1, 2008. We are currently evaluating the impact of the adoption of SFAS 159 will have, if any, on our financial statements.

In December 2006, the FASB issued a FASB Staff Position (“FSP”) EITF Issue No. 00-19-2 "Accounting for Registration Payment Arrangements" ("FSP 00-19-2") which addresses an issuer's accounting for registration payment arrangements. FSP 00-19-2 specifies that the contingent obligation to make future payments or otherwise transfer consideration under a registration payment arrangement, whether issued as a separate agreement or included as a provision of a financial instrument or other agreement, should be separately recognized and measured in accordance with SFAS No.5 "Accounting for Contingencies." The guidance in FSP 00-19-2 amends SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities," and No.150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity", and FASB Interpretation No.45, "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others" to include scope exceptions for registration payment arrangements. FSP 00-19-2 is effective immediately for registration payment arrangements and the financial instruments subject to those arrangements that are entered into or modified subsequent to the date of issue of FSP 00-19-2. For registration payment arrangements and financial instruments subject to those arrangements that were entered into prior to the issuance of FSP 00-19-2, this is effective for financial statements issued for fiscal years beginning after December 15, 2006, and interim periods within those fiscal years. We have analyzed the provisions of FSP 00-19-2 and determined that it will not have an effect on our financial statements.

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 are required to adopt SFAS 157 as of August 1, 2008, and are currently evaluating the impact that the adoption of SFAS 157 will have, if any, on our reported financial results.

In September 2006, the SEC issued SAB No. 108 “Quantifying Misstatements in Financial Statements” (“SAB 108”). Under SAB 108, we are required to use a combination of the two previously-acceptable approaches for quantifying misstatements, and to adjust our financial statements if this combined approach results in a conclusion that an error is material. We adopted SAB 108 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. On August 1, 2007, 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, 2008, we were exposed to market risks, primarily changes in U.S. interest rates. As of January 31, 2008, we held total cash and cash equivalents of approximately \$10.2 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. Based upon our balance of cash and cash equivalents as of January 31, 2008, a decrease in interest rates of 1.0% would cause a corresponding decrease in our annual interest income of approximately \$102,000.

**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 ("the Exchange Act") as of January 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 has been no changes in our internal control over financial reporting during the quarter ended January 31, 2008 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, 2007 (the "2007 Form 10-K") on October 15, 2007. You are urged to read these risk factors in the 2007 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 2007 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.

**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 in the future will be devoted, to the clinical trials for our lead product candidate, ONCONASE® and activities related to the preparation and filing of the NDA for ONCONASE for the treatment of malignant mesothelioma. Although we believe we could modify some of our expenditures to reduce our cash outlays in relation to our clinical trials and other NDA related expenditures, we cannot quantify the amount by which such expenditures might be modified. 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, might 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.

We are approaching the scheduled completion of our confirmatory Phase IIIb clinical trial of ONCONASE® as a treatment for malignant mesothelioma. Data from an interim analysis based on the first 105 events (deaths) showed a two-month survival advantage of ONCONASE® + doxorubicin (12 months) vs. doxorubicin (10 months). These results were consistent with data from the previous Phase III clinical trial and were the basis for our decision to continue the trial. The primary endpoint of the Phase IIIb clinical trial is survival, which tracks the length of time patients enrolled in the study live. According to the protocol, 316 evaluable patient deaths must occur in order to perform the required statistical analyses to determine the efficacy of ONCONASE® in patients with unresectable (inoperable) malignant mesothelioma. As of March 7, 2008, we had confirmed that 313 evaluable patient deaths had occurred. While we expect to be able to confirm that the required 316 evaluable patient deaths have occurred in the relatively near future, it is impossible to predict when that will occur and we cannot apply for FDA,



EMA or TGA approval to market ONCONASE<sup>®</sup> until the clinical trials and all other registration requirements have been met.

Several factors could prevent the successful completion or cause significant delays of these trials including an inability to enroll a sufficient number of patients and a failure to demonstrate that the product is safe and effective in humans. Also if safety concerns develop, the FDA, EMA and TGA could stop our trials before their completion. Drugs in late stages of clinical development may fail to show the desired safety and efficacy results despite having progressed through initial clinical testing. While previous limited clinical trials with ONCONASE<sup>®</sup> have produced certain favorable results in the treatment of unresectable malignant mesothelioma, we cannot be certain that the final results of the current Phase IIIb clinical trial will support the filing of an NDA with the FDA or the approval of an NDA by the FDA. We or the FDA may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

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 long-term viability would be threatened. If we fail to achieve regulatory approval or foreign marketing authorizations for ONCONASE<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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 seek to generate revenue through licensing, marketing and development arrangements prior to receiving revenue from the sale of our products. To date we have entered into one US license agreement and three non-US regional marketing and distribution agreements and we may not be able to successfully negotiate any additional agreements. In the past, we have entered into several development arrangements which have resulted in limited revenues for us. We cannot assure investors that these arrangements or future arrangements, if any, will result in significant amounts of revenue for us in the future. We, therefore, are unable to predict the extent of any future losses or the time required to achieve profitability, if at all.

**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, 2008, our then existing cash reserves should be sufficient to support our activities through the fourth quarter of our fiscal year 2009 based on our expected level of expenditures, which assumes timely and successful completion of our Phase IIIb clinical trial, and submission and approval of the related NDA. Regardless of the results from our current clinical trial, we will need additional financing to conduct our business after July 31, 2009. If the outcome of our Phase IIIb clinical trial results in a marketing approval of ONCONASE by the FDA, we will be eligible to receive significant cash milestone payments from our US marketing partner. If the results of our Phase IIIb clinical trial do not demonstrate the efficacy and safety of ONCONASE® for malignant mesothelioma, or if we are delayed in submitting the related NDA, the receipt of milestone payments may be delayed or may not occur at all and our ability to raise additional capital could be adversely affected. Factors that would affect the amount and timing of additional capital required include, but are not limited to, the following:

- the progress and cost of completing and filing marketing registrations for ONCONASE® with the FDA in the United States, with the EMEA in Europe and with the TGA in Australia;
- our degree of success in commercializing our drug product candidates, including entering into additional marketing and distribution agreements;
- 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, we may be required to delay, scale-back, or eliminate certain of our research and development programs, to relinquish rights to some of our technologies or products, or to grant licenses to third parties to commercialize products or technologies that we would otherwise seek to develop ourselves. We could also 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. Failure to secure additional financing may cause us to delay or abandon some or all of our development programs.

**We are and will be dependent upon third parties for manufacturing our products. If these third parties do not devote sufficient time and resources to our products our revenues and profits may be adversely affected.**

We do not have the required manufacturing facilities to manufacture our product. We presently rely on third parties to produce ONCONASE® for use in clinical trials. We have entered into a ten year purchase and supply agreement with Scientific Protein Laboratories, LLC, or SPL, for the manufacturing of ranpirnase (protein drug substance) from the oocytes, or the unfertilized eggs, of the *Rana pipiens* frog, which is found in the Northwest United States and is commonly called the leopard frog.

Additionally, we contract with Ben Venue Corporation for the manufacturing of ONCONASE® and with Catalent and Aptuit for the labeling, storage and shipping of ONCONASE® for clinical trial use. We utilize the services of these third party manufacturers solely on an as needed basis with terms and prices customary for our industry.

We use FDA GMP licensed manufacturers for ranpirnase and ONCONASE®. We have identified several alternative service providers for the manufacturing services for which we may contract. In order to replace an existing service provider we must amend our IND to notify the FDA of the new manufacturer. Although the FDA generally will not suspend or delay a clinical trial as a result of replacing an existing manufacturer, the FDA has the authority to suspend or delay a clinical trial if, among other grounds, human subjects are or would be exposed to an unreasonable and significant risk of illness or injury as a result of the replacement manufacturer.

We intend to rely on third parties to manufacture our products if they are approved for sale by the appropriate regulatory agencies and are commercialized. Third party manufacturers may not be able to meet our needs with respect to the timing, quantity or quality of our products or to supply products on acceptable terms.

**Because we do not have in-house marketing, sales or distribution capabilities, we have contracted with third parties and expect to contract with third parties in the future for these functions and we will therefore be dependent upon such third parties to market, sell and distribute our products in an effort to generate revenues.**

We currently have no in-house sales, marketing or distribution capabilities. In order to commercialize any product candidates for which we receive FDA or non-US approval, we expect to rely on established third parties who have strategic partnerships with us to perform these functions. To date, we have entered into a license agreement with Par Pharmaceutical, Inc. in the US and three marketing and distribution agreements for ONCONASE® in regions outside the US. We cannot assure you we will be able to maintain these relationships or establish new relationships with biopharmaceutical or other marketing companies with existing distribution systems and direct sales forces to market any or all of our product candidates on acceptable terms, if at all.

In addition, we expect to begin to incur significant expenses in determining our commercialization strategy with respect to one or more of our product candidates for regions outside the US. The determination of our commercialization strategy with respect to a product candidate will depend on a number of factors, including:

- the extent to which we are successful in securing third parties to collaborate with us to offset some or all of the funding obligations with respect to product candidates;
- the extent to which our agreement with our collaborators permits us to exercise marketing or promotion rights with respect to the product candidate;
- how our product candidates compare to competitive products with respect to labeling, pricing, therapeutic effect, and method of delivery; and
- whether we are able to establish agreements with third party collaborators, including large biopharmaceutical or other marketing companies, with respect to any of our product candidates on terms that are acceptable to us.

**If we lose key management personnel or are unable to attract and retain the talent required for our business, our business could be materially harmed.**

We are highly dependent on the principal members of our management team, including, but not limited to, Kuslima Shogen, our founder and Chief Executive Officer, and Lawrence A. Kenyon, our Chief Operating Officer, Chief Financial Officer and Corporate Secretary. None of the members of our management team have employment contracts with us. We do not have key man insurance on any of our management. If we were to lose the services of Ms. Shogen, Mr. Kenyon, or other members of our management team, and were unable to replace them, our product development and the achievement of our strategic objectives could be delayed.

In addition, our success will depend on our ability to attract and retain qualified commercial, scientific, technical, and managerial personnel. While we have not experienced unusual difficulties to date in recruiting and retaining personnel, there is intense competition for qualified staff and there is no assurance that we will be able to retain existing personnel or attract and retain qualified staff in the future.

**Material weaknesses or deficiencies in our internal control over financial reporting could harm stockholders' and business partners' confidence in our financial reporting, our ability to obtain financing, and other aspects of our business.**

Internal control over financial reporting can provide only reasonable and not absolute assurance that deficiencies or weaknesses are identified. Additionally, potential control deficiencies that are not yet identified could emerge and internal controls that are currently deemed to be in place and operating effectively are subject to the risk that those controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Identification and corrections of these types of potential control deficiencies could have a material impact on our business, financial position, results of operations and disclosures and impact our ability to raise funds.

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

(a) Recent Sales of Unregistered Securities

During the quarter ended January 31, 2008, we issued 200,000, 65,000 and 35,000 shares to McCash Family Limited Partnership, Donna McCash Irrevocable Trust and an unrelated private party,





respectively, upon the exercise of warrants at an exercise price ranging from \$0.60 to \$1.00 per share, which resulted in gross proceeds of \$194,000. We have previously registered the resale of these shares by the stockholders on a Form S-3 registration statement.

The above transactions with the McCash Family Limited Partnership and Donna McCash Irrevocable Trust, who are accredited investors as such term is defined under Regulation D of the Securities Act of 1933, as amended (the “Securities Act”), were exempt from registrations under Section 4(2) of the Securities Act. The above transaction with the unrelated private party, who we reasonably believed had such knowledge and experience in financial and business matters that she was capable of evaluating the merits and risks of the prospective investment, was exempt from registration under Section 4(2) of the Securities Act. We did not engage in any public advertising or general solicitation in connection with the either the issuance or exercise of the above warrants. The net proceeds from these transactions will be used for general corporate purposes.

(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**

(a) An annual meeting of stockholders was held on January 30, 2008.

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

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

(i) For the election of directors

Director	Number of Shares of Common Stock Voted For	Number of Shares of Common Stock Withheld	Number of Broker Non-Votes
Kuslima Shogen	36,379,016	1,849,663	0
John P. Brancaccio	34,133,803	4,094,876	0
Stephen K. Carter	34,133,557	4,095,122	0
Donald R. Conklin	34,138,458	4,095,221	0
Lawrence A. Kenyon	34,139,154	4,089,525	0
James J. Loughlin	34,133,557	4,095,122	0
David Sidransky	33,972,863	4,255,816	0
Paul M. Weiss	34,133,158	4,095,521	0

(ii) Proposal to ratify the appointment of J.H. Cohn LLP as our independent registered public accounting firm for the year ending July 31, 2008.

Number of Shares of Common Stock Voted For	Number of Shares of Common Stock Voted Against	Number of Shares of Common which Abstained from Voting	Number of Broker Non- Votes
37,726,874	290,008	211,798	0

**Item 5. Other Information**

None.

**Item 6. Exhibits**

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

Exhibit No.	Item Title
10.41	License Agreement, dated January 14, 2008, between the Company and Par Pharmaceutical, Inc.*
10.42	Supply Agreement, dated January 14, 2008, between the Company and Par Pharmaceutical, Inc.
10.43	Purchase and Supply Agreement, dated January 14, 2008, between the Company and Scientific Protein Laboratories LLC
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

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

**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 7, 2008

/s/ Lawrence A. Kenyon  
*Chief Financial Officer*  
(Principal Accounting Officer and  
Principal Financial Officer)

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