Altus Pharmaceuticals Inc.
Form 10-Q
August 04, 2009

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-Q

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

For the quarterly period ended June 30, 2009

OR

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

For the transition period from to

Commission File No. 000-51711

ALTUS PHARMACEUTICALS INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**04-3573277**
(State or Other Jurisdiction of Incorporation or Organization)	*(I.R.S. Employer Identification No.)*
610 Lincoln Street, Waltham, Massachusetts	**02451**
(Address of Principal Executive Offices)	*(Zip Code)*

Registrant s telephone number, including area code: (781) 373-6000

Indicate by check mark whether the registrant (1) has 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 þ NO o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).
YES o NO o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o	Accelerated filer þ	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

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

The number of shares outstanding of the registrant s common stock as of July 31, 2009 was 31,131,056.

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Part I
Item 1. Financial Statements
ALTUS PHARMACEUTICALS INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)
(In thousands, except share and per share amounts)

	June 30, 2009	December 31, 2008
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 8,050	$ 22,308
Marketable securities available-for-sale		26,292
Current portion of restricted cash	3,709	
Prepaid expenses and other current assets	1,645	2,350
Total current assets	13,404	50,950
PROPERTY AND EQUIPMENT, Net	7,944	9,601
RESTRICTED CASH NET OF CURRENT PORTION	5,173	3,700
TOTAL ASSETS	$ 26,521	$ 64,251
LIABILITIES, REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$ 8,011	$ 12,568
Current portion of Dr. Falk Pharma GmbH obligation		2,300
Current portion of long-term debt		1,313
Current portion of deferred rent and lease incentive obligation	2,873	340
Total current liabilities	10,884	16,521
Dr. Falk Pharma GmbH obligation, net of current portion		4,049
Long-term debt, net of current portion		1,432
Deferred rent and lease incentive obligation, net of current portion	2,968	5,645
TOTAL LIABILITIES	13,852	27,647
COMMITMENTS AND CONTINGENCIES		

REDEEMABLE PREFERRED STOCK:		
Redeemable Preferred Stock, par value $0.01 per share; 450,000 shares authorized, issued and outstanding at June 30, 2009 and December 31, 2008 at accreted redemption value	6,844	6,731
STOCKHOLDERS EQUITY:		
Common stock, par value $0.01 per share; 100,000,000 shares authorized; 31,131,056 shares issued and outstanding at June 30, 2009 and December 31, 2008	311	311
Additional paid-in capital	366,662	365,033
Accumulated deficit	(361,148)	(335,668)
Accumulated other comprehensive income		197
Total stockholders equity	5,825	29,873
TOTAL LIABILITIES, REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS EQUITY	$ 26,521	$ 64,251

See notes to unaudited condensed consolidated financial statements.

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ALTUS PHARMACEUTICALS INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)
(In thousands, except per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
CONTRACT REVENUE, NET	$	$	$	$ 2,622
COSTS AND EXPENSES:				
Research and development	4,888	20,967	18,869	42,534
General and administrative	2,110	4,700	5,541	10,476
Restructuring charges	1,461		5,090	
Total costs and expenses	8,459	25,667	29,500	53,010
LOSS FROM OPERATIONS	(8,459)	(25,667)	(29,500)	(50,388)
OTHER INCOME (EXPENSE):				
Interest income	105	750	270	2,149
Interest expense	(81)	(377)	(353)	(729)
Foreign currency exchange gain (loss)	(441)	34	89	(791)
Gain on debt restructuring	3,925		3,925	
Other income	89		89	
Other income (expense) net	3,597	407	4,020	629
NET LOSS	(4,862)	(25,260)	(25,480)	(49,759)
PREFERRED STOCK DIVIDENDS	(56)	(56)	(113)	(113)
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	$ (4,918)	$ (25,316)	$ (25,593)	$ (49,872)
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER SHARE BASIC AND DILUTED	$ (0.16)	$ (0.82)	$ (0.82)	$ (1.62)
	31,131	30,843	31,131	30,834

WEIGHTED AVERAGE SHARES
OUTSTANDING BASIC AND DILUTED

See notes to unaudited condensed consolidated financial statements.

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ALTUS PHARMACEUTICALS INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)
(In thousands)

	Six Months Ended June 30,	
	2009	**2008**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (25,480)	$ (49,759)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on debt restructuring	(3,925)	
Depreciation and amortization	996	1,847
Impairment of property and equipment due to restructuring	910	
Stock-based compensation expense related to the issuance of stock options	1,742	3,535
Noncash interest expense	248	537
Foreign currency exchange (gain) loss	(89)	791
Changes in assets and liabilities:		
Accounts receivable		3,454
Prepaid expenses and other assets	705	(581)
Restricted cash	(5,182)	
Deferred rent and lease incentive obligation	(144)	2,128
Accounts payable, accrued expenses and other long-term liabilities	(5,083)	(2,375)
Deferred revenue recognized		(2,087)
Net cash used in operating activities	(35,302)	(42,510)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of marketable securities	(8,902)	(26,995)
Sales of marketable securities	18,997	
Maturities of marketable securities	16,000	18,714
Purchases of property and equipment	(168)	(1,151)
Sales of property and equipment	324	
Net cash provided by (used in) investing activities	26,251	(9,432)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of stock options and warrants		312
Payment of Dr. Falk Pharma GmbH obligation	(2,462)	(3,136)
Proceeds from issuance of long-term debt		2,476
Repayment of long-term debt	(2,745)	(1,185)
Net cash used in financing activities	(5,207)	(1,533)

NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(14,258)	(53,475)
CASH AND CASH EQUIVALENTS Beginning of period	22,308	113,607
CASH AND CASH EQUIVALENTS End of period	$ 8,050	$ 60,132

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ALTUS PHARMACEUTICALS INC. AND SUBSIDIARY
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2009 AND 2008
(IN THOUSANDS, EXCEPT SHARE AND PER SHARE AMOUNTS)

1. BASIS OF PRESENTATION

The accompanying condensed consolidated financial statements are unaudited and have been prepared in accordance with accounting principles generally accepted in the United States of America for interim reporting. Certain information and footnote disclosures normally included in our annual consolidated financial statements have been condensed or omitted. Accordingly, the interim consolidated financial statements do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. The interim financial statements have been prepared on the same basis as the annual consolidated financial statements and, in the opinion of management, reflect all adjustments (including normal recurring adjustments) considered necessary to present fairly our financial position and results of operations and cash flows for the interim periods presented. The results of operations for the interim periods are not necessarily indicative of the results that may be expected for any future period or the year ending December 31, 2009. The condensed consolidated financial statements reflect the operations of us and our wholly owned subsidiary. All intercompany accounts and transactions have been eliminated.

Our condensed consolidated financial statements have been prepared assuming that we will continue as a going concern. As of June 30, 2009, we had $8,050 of cash and cash equivalents and an accumulated deficit of $361,148. We do not have sufficient cash to meet our funding requirements through December 31, 2009. This projection is based on our anticipated cost structure after implementation of the realignment plan that was announced on January 26, 2009, as discussed in Note 2, and expectations regarding expenses and potential cash inflows. We will require significant additional funding to remain a going concern and to fund operations until such time, if ever, as we become profitable. We intend to pursue additional equity or debt financing and/or collaboration arrangements to support the continued development of our product candidates. There can be no assurances as to the availability of additional financing or the terms upon which additional financing may be available in the future. These events raise substantial doubt about our ability to continue as a going concern. The condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

These unaudited condensed consolidated financial statements and related disclosures should be read in conjunction with the audited financial statements for the year ended December 31, 2008, which are included in our Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission, or the SEC.

2. REALIGNMENT PLAN

On January 26, 2009, we announced a strategic realignment to focus on the advancement of our long-acting, recombinant human growth hormone candidate, ALTU-238, as a once-per-week treatment for adult and pediatric patients with growth hormone deficiency. To conserve capital resources, we discontinued our activities in support of Trizytek™ [liprotamase], an enzyme replacement therapy for patients suffering from malabsorption due to exocrine pancreatic insufficiency. In connection with the realignment plan, we recorded restructuring charges of $3,629 and $1,461 in the first and second quarters of 2009, respectively.

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Provisions associated with the restructuring are included in operating expenses in the condensed consolidated statements of operations. Activities against our restructuring accrual, which is included in accounts payable and accrued liabilities in the condensed consolidated balance sheets, were as follows in 2009:

	Balance at December 31, 2008	Provisions	Payments	Asset Impairment	Balance at June 30, 2009
Termination benefits	$	$ 3,488	$ (2,289)	$	$ 1,199
Facilities related		395	(158)		237
Asset impairment		910		(910)	
Other charges		297	(228)		69
Total	$	$ 5,090	$ (2,675)	$ (910)	$ 1,505

We account for restructuring charges in accordance with Statement of Financial Accounting Standard, or SFAS, No. 146, Accounting for Costs Associated with Exit or Disposal Activities, or SFAS 146. SFAS 146 requires that a liability for a cost associated with an exit or disposal activity be recognized and measured initially at its fair value in the period in which the liability is incurred, except for one-time termination benefits that meet specific requirements.

Termination benefits relate to severance and benefit costs associated with our decision to implement a workforce reduction of approximately 70%, primarily in functions related to the Trizytek program as well as certain general and administrative positions. The employees were informed of the decision on January 26, 2009 and, after a statutory waiting period, 93 employees were terminated on March 27, 2009, resulting in a restructuring charge of $3,447 in the first quarter of 2009. An additional three employees were terminated in the second quarter of 2009, resulting in a restructuring charge of $41. Virtually all of the severance benefits will be paid out by the end of 2009.

In the second quarter of 2009, we abandoned the 83,405 square foot office facility we lease at 333 Wyman Street in Waltham, MA, or 333 Wyman, and consolidated our operations into 39,797 square feet of office and laboratory space under a lease for 63,880 square feet at 610 Lincoln Street in Waltham, or 610 Lincoln. On July 1, 2009, we entered into amendments effective June 30, 2009 related to the two facilities. Both leases had original terms that expired in 2018. Under the terms of the amendment to the 333 Wyman lease, we made a $1,025 payment to the landlord in July for the payment of rent due under the lease through October 31, 2009. The landlord has agreed to terminate the 333 Wyman lease provided it receives an additional payment of $475 on the earliest of the date we receive capital funding in excess of $25,000, we are acquired or merge, or November 2, 2009. In addition, within ninety days after the termination of the lease, the landlord can require us to remove certain improvements from 333 Wyman which we estimate would cost approximately $405 which we have recorded as an asset retirement obligation included in accrued liabilities. We will charge amounts paid to the landlord against the deferred rent and incentive liability, and reverse any excess to income upon the lease termination.

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Pursuant to the amendment of the 610 Lincoln lease, the amount of space leased by us was reduced on June 30, 2009 by approximately 24,083 square feet and the rent payable under the 610 Lincoln lease was reduced accordingly. For 610 Lincoln, we will reduce the deferred rent and lease incentive liability by $1,268 in the third quarter of 2009 corresponding to the portion of the 610 Lincoln space that was reduced by the lease amendment on July 1, 2009, offset by the write-off of the net book value of leasehold improvements of $897.

During the second quarter of 2009, we recorded a restructuring charge related to moving and facility related costs of $395 which we incurred as part of consolidating operations. In addition, we concluded that the 333 Wyman leasehold improvements and certain furniture and fixtures together with the related asset retirement cost were impaired and accordingly recorded an impairment charge of $910 in the second quarter of 2009.

Other charges relate primarily to legal fees associated with terminating our strategic alliance agreement with Cystic Fibrosis Foundation Therapeutics, Inc., or CFFTI, for the development of Trizytek entering into a new licensing arrangement with CFFTI for the Trizytek program, and terminating our manufacturing agreement with Lonza, Ltd., or Lonza.

The strategic realignment was deemed to be an impairment indicator under SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets. Therefore, we performed an undiscounted cash flow analysis to determine if our assets were recoverable. As the estimated undiscounted cash flows exceed the net book value of our assets, we concluded an impairment did not exist.

3. CYSTIC FIBROSIS FOUNDATION THERAPEUTICS, INC. AGREEMENT

In connection with the realignment plan discussed above, on February 20, 2009, CFFTI and we entered into a letter agreement, or the Letter Agreement, and a license agreement, or the License Agreement, terminating our strategic alliance agreement. Under the terms of the License Agreement, we assigned the Trizytek trademark and certain patent rights to CFFTI and granted CFFTI an exclusive, worldwide, royalty-bearing license to use certain other intellectual property owned or controlled by us to develop, manufacture and commercialize any product using, in any combination, the three active pharmaceutical ingredients, or APIs, which comprise Trizytek. In these agreements, we also agreed to assist CFFTI with a transition of our on-going development and regulatory activities and clinical trials through March 27, 2009, after which CFFTI became responsible for future development activities. In connection with this transition, we agreed to deposit $1,859 into an escrow account, which was bilaterally controlled by CFFTI and us, to cover the cost of specified batches of APIs for Trizytek that were transferred to CFFTI. In exchange, CFFTI agreed to release us from all obligations and liabilities resulting from the original strategic alliance agreement, and to pay us a percentage of any proceeds CFFTI realizes with respect to any rights licensed or assigned to CFFTI under the License Agreement. We have fulfilled our requirements to assist CFFTI with a transition of our on-going development and regulatory activities and clinical trials and do not anticipate incurring any further costs related to Trizytek.

On July 2, 2009, we entered into a three-way agreement with CFFTI and Alnara Pharmaceuticals, Inc., or Alnara. Alnara has sublicensed the development rights to Trizytek from CFFTI. Under the terms of that agreement, we agreed to waive our right to participate in the decision to release the escrow funds and that CFFTI could release the funds at its sole discretion without waiving our right to assert that the batches of APIs made by Lonza fail to satisfy Lonza s contractual obligations under Lonza s Manufacturing and Supply Agreement with us. The parties agreed that Alnara would settle certain claims by Lonza and a supplier against us for monies due related to the manufacture of batches of APIs which amounted to $2,213. The parties agreed that CFFTI shall reduce by $500 any amounts payable to Altus under the License Agreement from proceeds CFFTI realizes associated with licensing or assigning Trizytek to Alnara.

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4. LONZA LTD. CONTRACT TERMINATION

On March 27, 2009, we informed Lonza of our intent to terminate the Manufacturing and Supply Agreement, or the Manufacturing Agreement, dated November 16, 2006, as amended, between us and Lonza due to Lonza s material breach of the Manufacturing Agreement. On June 29, 2009, we terminated the Manufacturing Agreement due to Lonza s failure to cure the material breach within the 90 day cure period provided in the Manufacturing Agreement. The Manufacturing Agreement is a six-year agreement between us and Lonza providing for the manufacturing and supply of commercial quantities of APIs for Trizytek. Under the Manufacturing Agreement, Lonza agreed to manufacture the APIs in accordance with defined specifications and applicable current good manufacturing practice regulations and international regulatory requirements. We specified the material breach as Lonza s failure to meet the requirements of the Manufacturing Agreement with respect to the production of validation batches of the APIs for Trizytek.

Before we delivered the notice of our intent to terminate the Manufacturing Agreement due to Lonza s breach, Lonza asserted that we had unilaterally terminated the Manufacturing Agreement, without notice. The Manufacturing Agreement provides that we may terminate the Manufacturing Agreement for convenience with 12 months prior written notice if we stop development of Trizytek and obligates us to make a termination payment of a specified amount to Lonza after the 12 month notice period less the cost of APIs we purchase from Lonza over a certain period of time. The specified payment is 8,293 Swiss francs, or $7,641 based on exchange rates at June 30, 2009. We responded to Lonza asserting that we have not terminated the Manufacturing Agreement for convenience. Lonza has also asserted under the terms of the Manufacturing Agreement that we owe them interest of approximately $50 per month starting on January 1, 2009 based on us not taking delivery of a specified value of APIs.

On May 15, 2009, Lonza filed a lawsuit against us in the United States District Court for the Southern District of New York. Lonza seeks to have the court (1) declare a proper forum for arbitrating the disputes under the Manufacturing Agreement, (2) reform the Manufacturing Agreement to prohibit Altus from enforcing confidentiality and non-competition provisions, and (3) award Lonza reasonable attorneys fees and costs. On June 29, 2009, Altus filed an answer to Lonza s complaint indicating its belief that Lonza s claims were meritless and simultaneously filed a counterclaim seeking damages due to Lonza s material breach of the Manufacturing Agreement, without waiving its rights that the allegations of the counterclaims are exclusively arbitrable. The parties subsequently agreed to arbitrate the breach dispute before the American Arbitration Association, and on July 23, 2009, with the consent of the parties, the court dismissed without prejudice Lonza s claim for declaratory relief concerning the arbitrable forum.

We believe that as a result of Lonza s material breach, no termination fees or interest charges are due to Lonza under the terms of the Manufacturing Agreement. We have assessed the potential contingent liability associated with Lonza s assertions and our contention that the contract has been terminated due to Lonza s material breach. Based on our assessment, we do not believe that any one individual potential outcome is more likely than any other potential outcome and, accordingly, no provision as been made for a contingent liability at June 30, 2009.

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5. COMPREHENSIVE LOSS

Comprehensive loss was as follows for the three and six months ended June 30:

	Three Months		Six Months	
	2009	2008	2009	2008
Net loss	$ (4,862)	$ (25,260)	$ (25,480)	$ (49,759)
Unrealized loss on available-for-sale marketable securities	(66)	(164)	(197)	(336)
Comprehensive loss	$ (4,928)	$ (25,424)	$ (25,677)	$ (50,095)

6. NET LOSS PER SHARE

Basic and diluted net loss per common share is calculated by dividing net loss attributable to common stockholders by the weighted average number of common shares outstanding during the period. Diluted net loss per common share is the same as basic net loss per common share, since the effects of potentially dilutive securities are antidilutive for all periods presented.

Outstanding dilutive securities not included in the calculation of diluted net loss attributable to common stockholders per share were as follows for the three and six months ended June 30:

(In thousands)	2009	2008
Options to purchase common stock	3,795	5,138
Warrants to purchase common stock	1,207	3,593
Total	5,002	8,731

7. FAIR VALUE MEASUREMENT

We measure cash equivalents and marketable securities available for sale at fair value on a recurring basis using valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs. At June 30, 2009 and December 31, 2008, our balance of cash, cash equivalents and marketable securities were valued using observable inputs such as quoted prices for identical assets in active markets. We held no marketable securities at June 30, 2009. The carrying amounts of accounts payable and accrued expenses approximate fair value because of their short-term nature.

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8. RESTRICTED CASH

Restricted cash consists of amounts held in escrow accounts to support potential future cash obligations as follows:

	June 30, 2009	December 31, 2008
Support for letters of credits related to lease obligations	$ 3,700	$ 3,700
Severance benefits for current employees	3,323	
Amounts held in escrow under CFFTI Agreement	1,859	
Total restricted cash	8,882	3,700
Less: current portion	(3,709)	
Long-term portion	$ 5,173	$ 3,700

In connection with entering into the 333 Lease and the 610 Lease in October 2007, we were required to provide letters of credit to the respective landlords in the amount of $1,850 each. In connection with the issuance of the letters of credit, we were required to place a total of $3,700 into an interest bearing certificate of deposit as collateral. As part of the amendment to the 333 Lease entered into on July 1, 2009, the landlord agreed to return the letter of credit for that facility to us on March 31, 2010 assuming we were not in default of either the amended 333 Lease or amended 610 Lease. As a result, the portion of the escrow balance supporting the letter of credit for the 333 Lease has been classified as a current asset in the condensed consolidated balance sheet at June 30, 2009.

In connection with our severance policies for executives and non-executive employees we placed a total of $3,323 into non-interest bearing escrow accounts for the potential payment of severance benefits.

As discussed in Note 3, on April 6, 2009 in connection with the License Agreement with CFFTI we placed $1,859 into a non-interest bearing escrow account to cover the cost of specified batches of APIs for Trizytek that were transferred by us to CFFTI. Under the terms of the original escrow arrangement, disbursements from the escrow account required bilateral approval by CFFTI and us. In connection with the three-way agreement with CFFTI and Alnara entered into on July 2, 2009, we agreed to waive our right to participate in the release of the escrow funds, but without waiving our right to assert that the batches of APIs made by Lonza fail to satisfy Lonza s contractual obligations under the Manufacturing Agreement. On July 6, 2009, CFFTI unilaterally decided to release the amount held in escrow to cover the cost of the specified batches of APIs. Consequently, the escrow balance is classified as a current asset in the condensed consolidated balance sheet at June 30, 2009.

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9. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consisted of the following:

	June 30, 2009	December 31, 2008
Accounts payable	$ 798	$ 1,678
Accrued compensation	681	700
Accrued professional fees	224	346
Accrued research and development	3,833	8,500
Accrued restructuring costs	1,505	
Other accrued expenses	970	1,344
Total	$ 8,011	$ 12,568

10. INDEBTEDNESS

On March 26, 2009, we prepaid the remaining balance on our existing secured equipment loan with Oxford Finance Corporation, or Oxford, of $2,406. In connection with the prepayment, the parties agreed to terminate the Master Security Agreement dated as of August 19, 2004 between us and Oxford, as amended or supplemented, as well as other debt documents (collectively, the Credit Documents). Under the Credit Documents, we borrowed funds from Oxford from time to time which were repayable over 36 to 48 months, depending on the type of equipment that secured the loans. Borrowings were secured by liens on substantially all of the Company s tangible assets, and all such liens have been released in connection with the termination of the Credit Documents.

On May 7, 2009, Dr. Falk Pharma GmbH, or Dr. Falk, and we entered into an agreement to settle our remaining financial obligation to Dr. Falk. Under the terms of a termination agreement dated June 7, 2007, we agreed to reacquire from Dr. Falk the European marketing rights to Trizytek in exchange for total cash payments of 12,000, payable in installments through June 2010. At March 31, 2009, our total remaining obligation to Dr. Falk was 5,000; 2,000 payable on June 6, 2009 and 3,000 payable on June 6, 2010. Under the terms of the May 7, 2009 amended termination agreement, we made a cash payment of 1,800 in full settlement of our remaining obligation. As a result of the settlement, we recorded a gain of $3,925 in the second quarter of 2009, which is included in the other income (expense) section of the condensed consolidated statements of operations.

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11. STOCK-BASED COMPENSATION

The following table represents stock-based compensation expense included in our Condensed Consolidated Statements of Operations for the three and six months ended June 30:

	Three Months		Six Months	
	2009	2008	2009	2008
Research and development	$ 85	$ 899	$ 639	$ 1,360
General and administrative	455	1,112	1,103	2,175
Total	$ 540	$ 2,011	$ 1,742	$ 3,535

The fair value of the stock options granted was estimated on the date of grant using all relevant information, including application of the Black-Scholes option-pricing model. We did not grant any stock options during the three months ended June 30, 2009. When applying the Black-Scholes option-pricing model to compute stock-based compensation, we assumed the following for the six months ended June 30:

	2009	2008
Risk-free interest rate	1.8% to 2.2%	2.8% to 3.6%
Expected average option life	6.25 years	5.75 to 6.25 years
Dividends	None	None
Volatility	102% to 104%	68% to 75%

The expected average option life assumption is based upon the simplified or plain-vanilla method, provided under SAB 107 which averages the contractual term of the our options (10 years) with the vesting term (4 years) taking into consideration multiple vesting tranches. Expected volatility for the period ended June 30, 2009 is based upon the historical volatility data of our common stock. Expected volatility for the period ended June 30, 2008 is based upon the historical volatility data of our common stock and the historical volatility of comparable companies over the expected option term.

We operate the 2002 Employee, Director, and Consultant Stock Option Plan, or the 2002 Plan, which replaced the 1993 Stock Option Plan, or the 1993 Plan, on February 7, 2002. Under the 1993 and 2002 Plans and an inducement grant to Georges Gemayel, Ph.D., our Chief Executive Officer, granted in June 2008, the total number of shares issuable upon exercise of outstanding stock options and available for future grant to employees, directors and consultants at June 30, 2009 was 6,710,391 shares.

All option grants are nonstatutory (nonqualified) stock options except option grants to employees (including officers and directors) intended to qualify as incentive stock options under the Internal Revenue Code. Incentive stock options may not be granted at less than the fair market value of our common stock on the date of grant. Nonqualified stock options may be granted at an exercise price established by the Board of Directors at its sole discretion. Vesting periods are generally quarterly over a four year period and are determined by the Board of Directors or a delegated subcommittee or officer. Options granted under the 1993 and 2002 Plans expire no more than 10 years from the date of grant.

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A summary of the stock option activity under the 1993 Plan, 2002 Plan and the inducement grant given to our CEO for the six months ended June 30, 2009 is as follows:

	Shares	Weighted Average Exercise Price	Weighed Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Balance January 1, 2009 (1,794,968 options vested)	4,053,276	$ 8.12		
Granted	2,316,000	0.22		
Forfeited	(1,377,913)	6.09		
Expired	(1,196,050)	9.97		
Options outstanding June 30, 2009	3,795,313	$ 3.37	8.4	$ 341
Options exercisable June 30, 2009 (1)	1,137,904	$ 6.23	6.5	$ 48
Options vested and expected to vest June 30, 2009	3,353,480	$ 3.37	8.4	$ 341

(1) Options and awards granted prior to January 25, 2006 are generally exercisable immediately, but the shares purchased are subject to restriction on transfer until vested.

The aggregate intrinsic value in the table above represents the value (the difference between our closing common stock price on the last trading day of the three months ended June 30, 2009, which was $0.41 on June 30, 2009, and the exercise price of the options, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on June 30, 2009. As of June 30, 2009, total unrecognized stock-based compensation expense relating to unvested employee stock awards, adjusted for estimated forfeitures, was $12,555. This amount is expected to be recognized over a weighted-average period of 3.1 years. The weighted average fair value of options granted during the six months ended June 30, 2009 and 2008 was $0.18 and $3.15 per share, respectively.

12. RECENT ACCOUNTING PRONOUNCEMENTS

In May 2009, the Financial Accounting Standards Board issued SFAS No. 165, Subsequent Events , or SFAS 165. The SFAS 165 does not require significant changes regarding recognition or disclosure of subsequent events, but does require disclosure of the date through which subsequent events have been evaluated for disclosure and recognition. SFAS 165 is effective for financial statements issued after June 15, 2009. The implementation of SFAS 165 did not have a significant impact on our financial statements. Subsequent events through the filing date of this Form 10-Q have been evaluated for disclosure and recognition.

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ITEM 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Overview

We are a biopharmaceutical company focused on the development and commercialization of oral and injectable protein therapeutics using our proprietary protein crystallization technology, which we believe will have significant advantages over existing products and will address unmet medical needs. Our lead product candidate is ALTU-238, a long-acting, crystallized formulation of recombinant human growth hormone, for which we have completed a Phase II clinical trial in adults for growth hormone deficiency and have begun a Phase II clinical trial for growth hormone deficiency in pediatric patients. Our next most advanced product candidate is ALTU-237, for which we have completed a Phase I clinical trial for the treatment of hyperoxalurias. We also have a pipeline of other product candidates in preclinical research and development which are currently on hold until such time, if any, that we are able to obtain additional financing.

On January 26, 2009, we announced a strategic realignment to focus on the advancement ALTU-238. To conserve capital resources, we have discontinued our activities in support of Trizytek™ [liprotamase], an enzyme replacement therapy for patients suffering from malabsorption due to exocrine pancreatic insufficiency. In connection with the realignment, we implemented a workforce reduction of approximately 70%, primarily in functions related to the Trizytek program as well as certain general and administrative positions. As a result of these activities, we recognized a charge of $3.6 million in the first quarter of 2009, primarily for severance and related expenses, and $1.5 million in the second quarter of 2009 primarily for facility related charges and asset impairments in connection with our consolidation of operations into one building. We expect that virtually all of the remaining cash payments associated with these activities will be paid out by the end of 2009.

On February 20, 2009, Cystic Fibrosis Foundation Therapeutics, Inc., or CFFTI, and we entered into a letter agreement, or the Letter Agreement, and a license agreement, or the License Agreement, terminating our strategic alliance agreement. Under the terms of the License Agreement, we assigned the Trizytek trademark and certain patent rights to CFFTI and granted CFFTI an exclusive, worldwide, royalty-bearing license to use certain other intellectual property owned or controlled by us to develop, manufacture and commercialize any product using, in any combination, the three active pharmaceutical ingredients, or APIs, which comprise Trizytek. In these agreements, we also agreed to assist CFFTI with a transition of our on-going development and regulatory activities and clinical trials through March 27, 2009, after which CFFTI became responsible for future development activities. In exchange, CFFTI agreed to release us from all obligations and liabilities resulting from the original strategic alliance agreement, and to pay us a percentage of any proceeds CFFTI realizes associated with any rights licensed or assigned to CFFTI under the License Agreement.

Our future operating results will largely depend on the progress of ALTU-238 in the clinical development process and our ability to raise sufficient capital to fund operations.

We have generated significant losses as we have advanced our product candidates into clinical development and expect to continue to generate losses as we continue development of ALTU-238 and finalize our realignment of operations. As of June 30, 2009, we had $8.1 million of cash and cash equivalents and an accumulated deficit of $361.1 million. We believe we have sufficient cash to meet our funding requirements into September 2009. We will require significant additional

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funding to remain a going concern and to fund operations through December 31, 2009 and until such time, if ever, we become profitable. However, adequate additional financing may not be available to us on acceptable terms.

Financial Operations Overview

Contract Revenue. Our contract revenue in 2008 consisted of amounts earned under former collaborative research and development agreements with CFFTI relating to Trizytek and with Genentech, Inc., or Genentech, related to ALTU-238. We do not anticipate recognizing any contract revenue in 2009 unless we enter into a new collaborative agreement for one of our research and development programs. We do not expect to generate any revenue from the commercial sale of products in the foreseeable future.

Research and Development Expense. Research and development expense consists primarily of expenses incurred in developing and testing product candidates, including:

- salaries and related expenses for personnel, including stock-based compensation expenses;
- fees paid to professional service providers in conjunction with independently monitoring our clinical trials and evaluating data in conjunction with our clinical trials;
- costs of contract manufacturing services;
- costs of materials used in clinical and non-clinical trials;
- performance of non-clinical trials, including toxicity studies in animals; and
- depreciation of equipment used to develop our products and costs of facilities.

We expense research and development costs as incurred.

We completed a Phase III efficacy clinical trial of the capsule form of Trizytek in August 2008, and were conducting two long-term safety studies and preparing for the filing of a New Drug Application, or NDA, when we decided to terminate development. As of June 30, 2009, we had incurred approximately $169.6 million for the development of Trizytek. We have fulfilled our requirements to assist CFFTI with a transition of our on-going development and regulatory activities and clinical trials and do not anticipate incurring any further development costs related to Trizytek.

We completed a Phase II clinical trial of ALTU-238 in adults in 2006 and began a Phase II clinical trial for pediatric patients in March 2009. From January 1, 2003, the date on which we began separately tracking development costs for ALTU-238, through June 30, 2009, we incurred approximately $61.6 million in total development costs for this product candidate.

We completed a Phase I clinical trial for ALTU-237 in June 2008. From January 1, 2006, the date on which we began separately tracking development costs for ALTU-237, through June 30, 2009, we have incurred approximately $21.0 million in total development costs for this product candidate. Further development of ALTU-237 is on hold until sufficient additional funding can be secured.

The amount and timing of resources we devote to our clinical and preclinical product candidates in the future will be influenced by our ability to fund further development activities, or the potential to enter into one or more strategic collaborations that would provide full or partial funding for the development of our product candidates.

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The successful development of our product candidates is highly uncertain. At this time, we cannot precisely estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the remainder of the development of ALTU-238 or any of our clinical or preclinical product candidates, or the period, if any, in which material net cash inflows will commence. This is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- the availability of sufficient capital resources to fund development activities.
- the scope, rate of progress and expense of our clinical trials and other research and development activities;
- the potential benefits of our product candidates over other therapies;
- our ability, either by ourselves or with potential collaborators, to manufacture, market, commercialize and achieve market acceptance for any of our product candidates that we are developing or may develop in the future;
- future clinical trial results;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the expense and timing of regulatory approvals;
- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate, including a decision to discontinue the development of that product candidate. For example, if the U.S. Food and Drug Association, or FDA, or other regulatory authority were to require us to conduct clinical trials beyond those which we currently anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant delays in enrollment in any of our clinical trials, we would be required to expend significant additional financial resources and time on the completion of clinical development. There is no guarantee that such additional resources will be available to us. Notwithstanding the above, we expect research and development expenses to decrease significantly in 2009, as compared to 2008, as a result of our discontinuance of the Trizytek program and the realignment plan.

General and Administrative Expense. General and administrative expense consists primarily of salaries and other related costs for personnel, including stock-based compensation expenses, in our executive, finance, information technology and human resource functions. Other costs primarily include facility costs not otherwise included in research and development expense, corporate insurance, and professional fees for accounting and legal services, including patent-related expenses.

We expect general and administrative expenses to decrease significantly in 2009, as compared to 2008, as a result of the realignment, primarily due to a significant reduction in general and administrative headcount and the rationalization of facilities-related and other variable infrastructure expenses consistent with an organization of approximately 33 employees.

Interest and Other Income (Expense), Net. Interest income consists of interest earned on our cash and cash equivalents and marketable securities. Interest expense consists of interest incurred

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on equipment loans, which were fully paid off in March 2009, and amortization of the discount associated with our obligation to Dr. Falk Pharma GmbH, or Dr. Falk, with whom we formerly had a collaborative agreement regarding the development of Trizytek in certain countries outside the United States. We settled our obligation to Dr. Falk in May 2009, and as a result will cease amortization of the discount. We do not anticipate recording additional interest expense until such time that enter into a new financing arrangement.

Preferred Stock Dividends. Preferred stock dividends consist of cumulative but undeclared dividends payable on our redeemable preferred stock.

Critical Accounting Policies and Significant Judgments and Estimates

A critical accounting policy is one which is both important to the portrayal of our financial condition and results and requires management s most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. See the discussion of our significant accounting policies in Note 3 to the Consolidated Financial Statements included in our Annual Report on Form 10-K for fiscal year 2008 for additional information regarding our critical accounting policies.

Restructuring charges. We account for restructuring charges in accordance with Statement of Financial Accounting Standard, or SFAS, No. 146, Accounting for Costs Associated with Exit or Disposal Activities. Facilities related expenses and liabilities are based on estimates of the remaining obligations associated with a facility which we vacated in the second quarter of 2009. These estimates, which include an estimate of costs associated with our agreement with our landlord to terminate the lease early, will be reviewed on a regular basis until the outcome is finalized, and we will make any modifications to our estimates we believe necessary, based on our judgment, to reflect any changed circumstances. It is possible that such estimates could change in the future resulting in additional adjustments, and the effect of any such adjustments could be material.

Results of Operations

Three and Six Months Ended June 30, 2009 Compared to Three and Six Months Ended June 30, 2008

Contract revenue, net

			Increase (Decrease)	
	2009	**2008**	**$**	**%**
		(dollars in thousands)		
Three months ended June 30,				
Contract revenue, net	$	$	$	N/A
Six months ended June 30,				
Contract revenue, net	$	$ 2,622	$(2,622)	(100%)

We will not recognize any contract revenue in 2009 unless we enter into a new collaborative arrangement for one of our research or development programs.

We recognized $1.9 million related to the CFFTI collaborative agreement during the six months ended June 30, 2008, including no revenue in the three months then ended, representing our total remaining deferred revenue balance. We terminated our collaborative agreement with CFFTI on February 20, 2009. During the three months ended March 31, 2008, we also recognized $0.7 million of revenue related to our terminated collaboration and license agreement with Genentech.

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This revenue was related to an additional amount that Genentech agreed to pay us for services we performed on Genentech s behalf in the fourth quarter of 2007.

Research and development

	Three Months Ended June 30,		Increase (Decrease)	
	2009	2008	$	%
	(dollars in thousands)			
Trizytek	$ 229	$ 10,732	$ (10,503)	(98%)
ALTU-238	3,309	5,438	(2,129)	(39%)
ALTU-237		1,669	(1,669)	(100%)
Other research and development	737	1,324	(587)	(44%)
Depreciation	528	905	(377)	(42%)
Stock-based compensation	85	899	(814)	(91%)
Total research and development	$ 4,888	$ 20,967	$ (16,079)	(77%)

	Six Months Ended June 30,		Increase (Decrease)	
	2009	2008	$	%
	(dollars in thousands)			
Trizytek	$ 7,693	$25,573	$(17,880)	(70%)
ALTU-238	7,728	7,904	(176)	(2%)
ALTU-237	200	3,606	(3,406)	(94%)
Other research and development	1,524	2,390	(866)	(36%)
Depreciation	1,085	1,701	(616)	(36%)
Stock-based compensation	639	1,360	(721)	(53%)
Total research and development	$18,869	$42,534	$(23,665)	(56%)

Research and development expense for the three and six months ended June 30, 2009 decreased due primarily to us discontinuing our activities in support of Trizytek in the first quarter of 2009. In connection with the Letter Agreement and License Agreement we entered into with CFFTI, we agreed to assist CFFTI with a transition of our on-going development, manufacturing and regulatory activities and clinical trials through March 27, 2009, after which CFFTI became responsible for future development activities. During the first six months of 2008, we were conducting a Phase III efficacy trial and two long-term safety studies of Trizytek, one in cystic fibrosis patients and one in chronic pancreatitis patients with pancreatic insufficiency. ALTU-238 costs during the second quarter of 2009 decreased as compared to the same period in 2008. The decrease is primarily due to decreased manufacturing related costs for ALTU-238, primarily due to the timing of human growth hormone purchased from Sandoz GmbH, or Sandoz, and the manufacture of clinical material at Althea Technologies, Inc., or Althea. During the second quarter of 2009, we purchased $1.5 million of human growth hormone from Sandoz as compared to $3.8 million during the second quarter of 2008. The decrease in costs was partially offset by increased clinical costs relating to our Phase II pediatric trial, which we began in March 2009. ALTU-238 costs for the six months ended June 30, 2009 and 2008 were relatively unchanged as the decrease relating to the purchase of human growth hormone was offset by increased clinical costs preparing and initiating the Phase II pediatric trial. ALTU-237 costs decreased significantly from the same periods last

year as we have suspended further development activities on this program until sufficient funding is available. Other research and development spending reflects our continued efforts to exploit our core crystallization capabilities. Depreciation for the three and six months

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ended June 30, 2009 decreased as compared to the same periods in 2008 primarily due to the accelerated depreciation of certain leasehold improvements and furniture and fixtures in 2008 associated with our former facilities located in Cambridge, MA. Upon our decision to relocate our facilities to Waltham, MA, we shortened the useful lives of certain assets related to the Cambridge facilities to correspond with the term we were expecting to remain in those facilities. Stock-based compensation decreased for both the three and six months ended June 30, 2009 as compared to the same periods last year primarily due to true-up adjustments recognized on forfeited stock options due to the significantly reduced workforce on March 27, 2009.

General and administrative

	Three Months Ended June 30,		Increase (Decrease)	
	2009	2008	$	%
	(dollars in thousands)			
Personnel	$ 391	$ 1,897	$ (1,506)	(79%)
Legal services	393	150	243	162%
General insurance	206	216	(10)	(5%)
Market research and related costs	14	47	(33)	(70%)
Consulting and professional services	310	371	(61)	(16%)
Stock-based compensation	455	1,112	(657)	(59%)
Other general and administrative	341	907	(566)	(62%)
Total general and administrative	$ 2,110	$ 4,700	$ (2,590)	(55%)

	Six Months Ended June 30,		Increase (Decrease)	
	2009	2008	$	%
	(dollars in thousands)			
Personnel	$ 1,633	$ 4,545	$ (2,912)	(64%)
Legal services	858	420	438	104%
General insurance	410	476	(66)	(14%)
Market research and related costs	55	159	(104)	(65%)
Consulting and professional services	606	947	(341)	(36%)
Stock-based compensation	1,103	2,175	(1,072)	(49%)
Other general and administrative	876	1,754	(878)	(50%)
Total general and administrative	$ 5,541	$ 10,476	$ (4,935)	(47%)

General and administrative costs for the three and six months ended June 30, 2009 decreased in total as compared to the same period in 2008, commensurate with the downsizing of our corporate infrastructure. Personnel costs dropped significantly in the three and six month period ended June 30, 2009 as a result of our reduction in workforce which reduced administrative headcount from 32 at June 30, 2008 to six at June 30, 2009. Also included in personnel costs for the six months ended June 30, 2008 is a one-time charge of $0.6 million associated with a separation agreement with Sheldon Berkle, our former Chief Executive Officer, or CEO, who resigned in February 2008, and increased recruiting costs related to the search for a new CEO. Stock-based compensation also decreased during the three and six months ended June 30, 2009 as compared to the same period in 2008 due primarily to the decrease in

headcount. Consulting and professional fees also decreased during 2009 as compared to 2008. Included in consulting and professional services during the first quarter of 2008 was $0.2 million of costs relating to a tax study, for which we had no comparable costs in 2009. Partially offsetting the decrease in general and administrative costs was an increase in outside legal costs during the three

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and six months ended June 30, 2009 as compared to the same period of 2008 primarily due to increased reliance on outside legal counsel.

Restructuring charges

	Three Months Ended June 30,	
	2009	2008
	(dollars in thousands)	
Termination benefits	$ 41	$
Facilities related	395	
Asset impairment	910	
Other charges	115	
Total restructuring charges	$ 1,461	$

	Six Months Ended June 30,	
	2009	2008
	(dollars in thousands)	
Termination benefits	$ 3,488	$
Facilities related	395	
Asset impairment	910	
Other charges	297	
Total restructuring charges	$ 5,090	$

Termination benefits relate to severance and benefit costs associated with our decision to implement a reduction of approximately 70% of our workforce, primarily in functions related to the Trizytek program as well as certain general and administrative positions. The employees were informed of the decision on January 26, 2009 and, after a statutory waiting period, 93 employees were terminated on March 27, 2009. We recorded a restructuring charge of $3.4 million in the first quarter of 2009 related to severance and related benefits, and an additional charge of $41,000 in the second quarter of 2009 when three remaining employees were terminated. The majority of the severance benefits will be paid out by the end of 2009.

In the second quarter of 2009, we abandoned the 83,405 square foot office facility we lease at 333 Wyman Street in Waltham, MA, or 333 Wyman, and consolidated our operations into 39,797 square feet of office and laboratory space under a lease for 63,880 square feet at 610 Lincoln Street in Waltham, or 610 Lincoln. On July 1, 2009, we entered into amendments effective June 30, 2009 related to the two facilities. Both leases had original terms that expired in 2018. Under the terms of the amendment to the 333 Wyman lease, we made a $1.0 million payment to the landlord for the payment of rent due under the lease through October 31, 2009. The landlord has agreed to terminate the 333 Wyman lease provided it receives an additional payment of $0.5 million on the earliest of the date we receive capital funding in excess of $25 million, we are acquired or merge, or November 2, 2009. In addition, within ninety days after the termination of the lease, the landlord can require us to remove certain improvements from 333 Wyman which we estimate would cost approximately $0.4 million which we have recorded as an asset retirement obligation included in accrued liabilities.

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We will charge amounts paid to the landlord against the deferred rent and incentive liability, and reverse any excess to income upon the lease termination.

Pursuant to the amendment of the 610 Lincoln lease, the amount of space leased by us was reduced on June 30, 2009 by approximately 24,083 square feet and the rent payable under the 610 Lincoln lease was reduced accordingly. For 610 Lincoln, we will reduce the deferred rent and lease incentive liability by $1.3 million in the third quarter of 2009 corresponding to the portion of the 610 Lincoln space that was reduced by the lease amendment on July 1, 2009, offset by the write-off of the net book value of leasehold improvements of $0.9 million.

During the second quarter of 2009, we recorded a restructuring charge related to moving and facility related costs of approximately $0.4 million which we incurred as part of consolidating operations. In addition, we concluded that the 333 Wyman leasehold improvements and certain furniture and fixtures together with the releated asset retirement cost were impaired, and accordingly recorded an impairment charge of $0.9 million in the second quarter of 2009.

Other charges relate primarily to legal associated with terminating our strategic alliance agreement with CFFTI for the development of Trizytek entering into a new licensing arrangement with Cystic Fibrosis Foundation Therupeutics, Inc., or CFFTI, for the Trizytek program, and terminating our manufacturing agreement with Lonza.

Other income (expense) net

	Three Months Ended June 30,		Increase (Decrease)	
	2009	2008	$	%
	(dollars in thousands)			
Interest income	$ 105	$ 750	$ (645)	(86%)
Interest expense	(81)	(377)	(296)	(79%)
Foreign currency exchange gain (loss)	(441)	34	(475)	(1397%)
Gain on debt restructuring	3,925		3,925	N/A
Other	89		89	N/A
Total other income (expense) net	$ 3,597	$ 407	$ 3,190	784%

	Six Months Ended June 30,		Increase (Decrease)	
	2009	2008	$	%
	(dollars in thousands)			
Interest income	$ 270	$ 2,149	$ (1,879)	(87%)
Interest expense	(353)	(729)	(376)	(52%)
Foreign currency exchange gain (loss)	89	(791)	880	111%
Gain on debt restructuring	3,925		3,925	N/A
Other	89		89	N/A
Total other income (expense) net	$ 4,020	$ 629	$ 3,391	539%

Interest income for the three and six months ended June 30, 2009 decreased as compared to the same period in 2008. Our average cash balances for the periods ended June 30, 2008 were higher than our average cash balances for the periods ended June 30, 2009, resulting in higher interest income during 2008. In addition, a decrease in prevailing interest rates in the overall market also contributed to lower interest income for the three and six months ended June 30, 2009. Interest expense for both periods consists of interest on our secured equipment loan with Oxford

Finance Corporation, or Oxford, and accretion of non-cash interest expense on our former obligation to Dr. Falk. On March 26, 2009, we prepaid the remaining balance of $2.4 million of our secured

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equipment loan with Oxford. Foreign currency exchange gains (losses) primarily reflect foreign currency adjustments relating to our former obligation to Dr. Falk, which was denominated in Euros, and amounts due to Lonza, which are denominated in Swiss Francs.

On May 7, 2009, Dr. Falk and we entered into an agreement to settle our remaining financial obligation to Dr. Falk. Under the terms of the agreement, we made a payment of 1.8 million, or approximately $2.5 million, in May 2009 in full settlement of our remaining obligation. As a result of the settlement, we recorded a gain on debt restructuring of $3.9 million in the second quarter of 2009

Preferred stock dividends

The preferred stock dividends for the three and six months ended June 30, 2009 and 2008 relate entirely to dividends on our redeemable preferred stock, which remained outstanding at June 30, 2009.

Liquidity and Capital Resources

Overview

We have financed our operations since inception primarily through the sale of equity securities, payments from our collaborators, borrowings and capital lease financings and, prior to the middle of 2004, revenue from product sales.

Since our inception, we have generated significant losses while we have advanced our product candidates into preclinical and clinical trials. As we continue to advance ALTU-238 and any of our other product candidates through development, we expect to incur additional operating losses until such time, if any, as our efforts result in commercially viable and profitable drug products. In January 2009, we announced a realignment plan to discontinue our activities in support of Trizytek in order to conserve our financial resources for the development of ALTU-238 and any other products we may develop. We anticipate that after the impact of our restructuring our current cash and cash equivalents will be sufficient to fund our operations into September 2009. We will require significant additional funding to remain a going concern and to fund operations until such time, if ever, we become profitable. Raising sufficient capital in the current financial environment may be particularly difficult, and there can be no assurance that additional financing will be available on acceptable terms when needed, if at all. In addition to equity financing, we continue to evaluate and aggressively pursue other forms of capital infusion including collaborations with organizations that have capabilities that are complementary to our own, as well as program structured financing arrangements, in order to continue the development of our product candidates.

We believe the key factors that will affect our internal and external sources of cash are:

- our ability to fund operations for a sufficient period to develop additional data or exercise a transaction;
- the receptivity of the capital markets to financings of biotechnology companies;
- the success of clinical trials for ALTU-238;
- our ability to successfully develop, manufacture and obtain regulatory approval for ALTU-238;
- our ability to enter into strategic collaborations with corporate collaborators and the success of such collaborations; and
- the final outcome of our disagreement with Lonza concerning the termination of our manufacturing agreement.

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We may raise funds from time to time through public or private sales of equity or from borrowings. Financing may not be available on acceptable terms, or at all, and our failure to raise capital when needed could materially adversely impact our ability to continue as a going concern. Additional equity financing may be dilutive to the holders of our common stock and debt financing, if available, may involve significant cash payment obligations and covenants that restrict our ability to operate our business. For example, warrants issued in connection with our Series C financings contain price protection provisions that reduce the exercise price of the warrants in the event we issue equity securities at a lower price than the original exercise price, thus furthering dilution. At June 30, 2009, 1,133,112 such warrants with an exercise price of $9.80 per warrant were outstanding. We do not engage in off-balance sheet financing arrangements, other than operating leases.

On January 26, 2009, we announced a strategic realignment to focus on the advancement of ALTU-238 and to discontinue our activities in support of Trizytek. In connection with the realignment plan, we recognized a charge of $3.6 million in the first quarter of 2009, primarily for severance and related expenses, and $1.5 million in the second quarter of 2009, primarily for facility related charges in connection our consolidation of operations into one building. We expect that the majority of the remaining cash payments associated with these activities will be paid out by the end of 2009.

As described in Note 4 to the Condensed Consolidated Financial Statements included in this report, on March 27, 2009, we informed Lonza of our intent to terminate the Manufacturing Agreement between us and Lonza due to Lonza s material breach of the Manufacturing Agreement. On June 29, 2009, we terminated the Manufacturing Agreement due to Lonza s failure to cure the material breach within the 90 day cure period provided in the Manufacturing Agreement. The parties subsequently agreed to arbitrate the breach dispute before the American Arbitration Association. We believe that as a result of Lonza s material breach, no termination fees or interest charges are due to Lonza under the terms of the Manufacturing Agreement and, accordingly, no provisions have been made for such payments at June 30, 2009.

Summary Cash Flow Information

	June 30, 2009	December 31, 2008	Increase (Decrease) $	Increase (Decrease) %
	(dollars in thousands)			
Cash, cash equivalents and marketable securities	$ 8,050	$ 48,600	$ (40,550)	(83%)
Working capital	2,520	34,429	(31,909)	(93%)

	Six Months Ended June 30,	
	2009	2008
	(dollars in thousands)	
Cash flows from:		
Operating activities	$ (35,302)	$ (42,510)
Investing activities	26,251	(9,432)
Financing activities	(5,207)	(1,533)

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At June 30, 2009, we had $8.1 million in cash and cash equivalents, and held no marketable securities. Our balance of cash and cash equivalents at June 30, 2009 does not include $8.9 million held as restricted cash. The composition and mix of cash, cash equivalents and marketable securities may change frequently as a result of our evaluation of conditions in the financial markets, the maturity of specific investments, and our near term liquidity needs. Our funds at June 30, 2009 were invested in government and agency money market funds.

Cash flows from operating activities. Since our inception, we have generated significant losses while we have advanced our product candidates into preclinical and clinical trials. Accordingly, we have historically used cash in our operating activities. During the six months ended June 30, 2009 and June 30, 2008, our operating activities used $35.3 million and $42.5 million, respectively. The use of cash in each period was primarily a result of expenditures associated with our research and development activities and amounts incurred to develop and maintain our administrative infrastructure. During the six months ended June 30, 2009, we placed $3.3 million into escrow accounts for potential severance benefits for current employees, in connection with our severance policies. In addition, as part of our Letter Agreement and License Agreement with CFFTI, we placed $1.9 million into an escrow account to cover the cost of specified batches of APIs for Trizytek that were transferred to CFFTI. These amounts are classified as restricted cash at June 30, 2009.

Cash flows from investing activities. Net cash provided by investing activities was $26.3 million for the six months ended June 30, 2009, reflecting $35.0 million of proceeds from sales and maturities of marketable securities and $0.3 million of proceeds from the sale of equipment, partially offset by $8.9 million to purchase marketable securities and $0.2 million for capital expenditures. During the same period in 2008, net cash used by investing activities was $9.4 million, reflecting $27.0 million to purchase marketable securities and $1.2 million for capital expenditures, partially offset by $18.7 million of proceeds from maturities of marketable securities. We expect capital expenditures to be negligible for the remainder of 2009.

Cash flows from financing activities. For the six months ended June 30, 2009, our financing activities consumed $5.2 million due to our payment of $2.5 million to Dr. Falk in connection with our termination agreement as well as debt principal repayments of $2.7 million which reflects the full repayment of all outstanding long-term debt. For the six months ended June 30, 2008, our financing activities used $1.5 million, reflecting a $3.1 million payment to Dr. Falk and $1.2 million in repayments of long-term debt principal, partially offset by $2.5 million of proceeds form the issuance of long-term debt under our equipment financing agreement and $0.3 million in proceeds from the exercise of common stock options.

The following table summarizes our contractual obligations at June 30, 2009 and the effects such obligations are expected to have on our liquidity and cash flows in future periods:

Payments Due by Period
(dollars in thousands)

	Total	Remainder of 2009	2010 through 2011	2012 through 2013	After 2013
Contractual Obligations (1):					
Operating lease obligations (2)	$ 14,830	$ 1,996	$ 2,706	$ 2,756	$ 7,372
Purchase obligations (3) (4)	7,942	5,571	2,371		
Total contractual cash obligations	$ 22,772	$ 7,567	$ 5,077	$ 2,756	$ 7,372

(1) Excludes estimated payment of $7.2 million to Vertex

Pharmaceuticals, Inc., or Vertex, in connection with its optional redemption of shares of redeemable preferred stock on or after

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December 31, 2010, plus dividends accruing after that date and royalties to Genentech on product sales of ALTU-238.

(2) Includes payments of $1.5 million due our landlord in consideration of the agreement to terminate the 333 Lease early, and our negotiated amendment to the 610 Lease to reduce the amount of square footage.

(3) Represents amounts due to Sandoz based on the foreign currency exchange rate at June 30, 2009, under the terms of our supply agreement with Sandoz pursuant to which we are obligated to purchase all of the recombinant human growth hormone, or hGH, forecasted for 2009 and 50% of the hGH forecasted for 2010.

(4) Excludes an approximate $7.6 million termination fee that Lonza contends we owe related to Lonza s claim that we unilaterally terminated our Manufacturing Agreement for convenience. We refute this contention and believe that as a result of Lonza s material breach, no termination fee is owed under the terms of the agreement.

Forward-Looking Statements and Risk Factors

This report contains forward-looking statements. The forward-looking statements include statements about the time period during which existing cash resources can support our operations, our ability to raise additional capital, the possibility of future revenues, the impact of our realignment activities on future use of cash, the financial impact of changes in interest rates, and other statements regarding our plans, estimates and beliefs. These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. Because of these risks and uncertainties, the forward-looking events and circumstances discussed in this report may not transpire. We discuss many of these risks in Part II Item 1A of this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 2008 under the heading Risk Factors. In some cases, you can identify forward-looking statements by terms such as anticipate, believe, could, estimate, expect, intend, may, plan, potential, predict, project, should, will, expressions intended to identify forward-looking statements.

Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements speak only as of the date of this Quarterly Report. You should read this Quarterly Report with the understanding that our actual future results may be materially different. Except as required by law, we do not undertake any obligation to update or revise any forward-looking statements contained in this Quarterly Report, whether as a result of new information, future events or otherwise.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

At June 30, 2009 we only held cash and cash equivalents, which were invested in government and agency money market funds, which are not subject to significant market risk. To minimize the risk associated with changing interest rates, we invest primarily in money market funds, bank certificates of deposit, United States government securities and investment-grade commercial paper and corporate notes that can be held to their maturity date.

Our assets are principally located in the United States and a majority of our historical revenues and operating expenses are denominated in United States dollars. In addition, some purchases of raw materials and contract manufacturing services are also denominated in foreign currencies. Accordingly, we are subject to market risk with respect to foreign currency-denominated

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expenses. We recognized foreign currency exchange gains of $0.1 million in the six months ended June 30, 2009. We may engage in additional collaborations with international partners. If we enter into additional collaborations with international partners providing for foreign currency-denominated revenues and expenses, we may be subject to significant foreign currency and market risk.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer, or CEO, and Principal Financial Officer, or PFO, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934) as of June 30, 2009. In designing and evaluating our disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and our management necessarily applied its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation by our management, our CEO and PFO concluded that, as of June 30, 2009, our disclosure controls and procedures were: (1) designed to ensure that material information relating to us is made known to our CEO and PFO by others within the Company, particularly during the period in which this report was being prepared and (2) effective, in that they provide reasonable assurance that information required to be disclosed by us in reports that we file or submit under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is recorded, processed, summarized, and reported within the time periods specified in the Securities and Exchange Commission s rules and forms and that such information is accumulated and communicated to management as appropriate to allow timely decisions regarding required disclosures.

Changes in Internal Control

Based on an evaluation by management, no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended June 30, 2009 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On May 15, 2009, Lonza filed a lawsuit against us in the United States District Court for the Southern District of New York. The lawsuit relates to the disputes between Lonza and us with respect to the Manufacturing Agreement. Lonza seeks to have the court (1) declare a proper forum for arbitrating the disputes under the Manufacturing Agreement, (2) reform the Manufacturing Agreement to prohibit us from enforcing confidentiality and non-competition provisions, and (3) award Lonza reasonable attorneys fees and costs. Background regarding the contractual disputes can be found in Note 4 on this Form 10-Q. On June 29, 2009, we filed an answer to Lonza s complaint indicating our belief that Lonza s claims are meritless. We simultaneously filed a counterclaim seeking damages due to Lonza s material breach of the Manufacturing Agreement, without waiving our rights that the allegations of the counterclaims are exclusively arbitrable. The parties subsequently agreed to arbitrate the breach dispute before the American Arbitration Association, and on July 23, 2009, with the consent of the parties, the court dismissed without prejudice Lonza s claim for declaratory relief concerning the arbitrable forum.

ITEM 1A. RISK FACTORS

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Our business is subject to numerous risks. We cannot assure investors that our assumptions and expectations about our business will prove to have been correct. Important factors could cause our actual results to differ materially from those indicated or implied by forward-looking statements. Such factors that could cause or contribute to such differences include those factors discussed below.

Our existing and potential stockholders should consider carefully the risks described below and the other information in this Quarterly Report, including under the heading Forward-Looking Statements and Risk Factors , our Management s Discussion and Analysis of Financial Condition and Results of Operations and our condensed consolidated financial statements and the related notes. We may be unable, for many reasons, including those that are beyond our control, to implement our current business strategy. The following risks may result in material harm to our business, our financial condition and our results of operations. In that event, the market price of our common stock could decline.

Except as required by law, we do not undertake any obligation to update or revise any forward-looking statements contained in this Quarterly Report, whether as a result of new information, future events, or otherwise.

Risks Related to Our Business and Strategy

If we fail to obtain the capital necessary to fund our operations we may need to cease operations or liquidate.

Any capital raising transaction we are able to complete may substantially dilute the ownership of existing equity holders or may provide rights to our intellectual property or contemplate rights in liquidation that are superior to those of existing investors. Any such financing, and any sale of assets or business combination transaction, may imply a company valuation below the market price of our common stock and may result in minimal proceeds to stockholders or creditors. We have ongoing discussions regarding transactions that imply low valuations for the company s assets. Depending on our financial position, we may pursue such a transaction. If we are unable to raise capital or execute a sale or business combination transaction, we may need to cease operations or liquidate. In such a scenario, our creditors would be entitled to payment ahead of our equity holders, and there may not be sufficient assets to pay our creditors.

We will need additional capital in order to fund our operations, develop and commercialize our product candidates, or to finance the discovery and development of our next generation of product candidates.

Due to financial constraints, we discontinued our activities in support of Trizytek, a late-stage clinical candidate. We will require substantial additional future capital in order to complete the development and commercialization of our remaining clinical-stage product candidates, ALTU-238 and ALTU-237, and to conduct the research and development and clinical and regulatory activities necessary to bring our early stage research products and product candidates into clinical development. At this time, we have made a decision to allocate our financial, capital and human resources to ALTU-238, are evaluating the feasibility of moving forward our early-stage clinical and pre-clinical programs and will make future decisions on these programs depending upon the availability of resources. Our future capital requirements will depend on many factors, including:

- the timing, progress and results of ongoing manufacturing development work for ALTU-238;
- the actual expenses of discontinuing the Trizytek program, including any contractual termination payments we are required to make and the cost and outcome of related litigation;
- any further non-clinical or clinical studies we may initiate based on the results of our Phase I

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clinical trial for ALTU-237 or discussions with regulatory authorities;

the results of our Phase II pediatric clinical trial for ALTU-238 that we initiated in March 2009 and the results and costs of future clinical trials for ALTU-238 that we may initiate;

the results of our preclinical studies and testing for our early stage research products and product candidates, and any decisions to initiate clinical trials;

the costs, timing and outcome of regulatory review of our product candidates in clinical development, and any of our preclinical product candidates that progress to clinical trials;

the cost of obtaining clinical and commercial supplies of active pharmaceutical ingredients, or APIs, and finished drug product in sufficient quantities for clinical development and any commercial launch;

the costs of establishing commercial operations, including commercial manufacturing and distribution arrangements and sales, marketing and medical affairs functions, should any of our product candidates be approved and we participate in the launch;

the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our issued patents, seeking freedom to operate under any third party intellectual property rights, and defending intellectual property-related claims;

our ability to establish and maintain collaborative or financing arrangements and obtain milestone, royalty and other payments from collaborators or third parties;

the costs associated with our realignment plan, including termination of contractual obligations and facility-related costs; and

the extent to which we acquire or invest in new businesses, products or technologies.

Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, or we decide it is necessary to preserve existing resources, we will likely find it appropriate or necessary to stage, delay or terminate preclinical studies, clinical trials or other development activities for one or more of our product candidates. We are funding all costs related to the development ALTU-238 and cannot defer or avoid such expenses without delaying or curtailing the program unless we can enter into a new collaboration agreement or secure alternative funding to support the development of ALTU-238. The failure to obtain additional financing or enter into a new collaboration could lead to a delay in or discontinuation of further development of ALTU-238.

The inclusion of a going concern explanatory paragraph in the audit report of our registered public accounting firm for fiscal 2008 may materially and adversely affect our ability to raise new capital.

Our independent registered public accounting firm modified their report for the fiscal year ended December 31, 2008 with respect to our ability to continue as a going concern. This type of modification typically would indicate that our recurring losses from operations and current lack of sufficient funds to sustain operations through the end of the following fiscal year raise substantial doubt about our ability to continue as a going concern. Our consolidated financial statements have been prepared on the basis of a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. If we became unable to continue as a going concern, we would have to liquidate our assets and might receive significantly less than the values at which they are carried on our consolidated financial statements. Any shortfall in the proceeds from the liquidation of our assets would directly reduce the amounts, if any, that holders of our securities could receive in liquidation.

To remain a going concern, we will require significant funding. Our available funds will not be sufficient to fund the completion of the development and commercialization of any of our

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product candidates, including ALTU-238. We currently expect that our existing capital resources will be sufficient to maintain our current and planned operations into September 2009. In addition, our operating plan may change as a result of many factors, including factors currently unknown to us, and we may need additional funds sooner than we anticipate.

The terms of our redeemable preferred stock held by Vertex Pharmaceuticals Incorporated contemplate a significant payment under certain circumstances. We may not have sufficient resources to make such a payment.

If Vertex Pharmaceuticals Incorporated, or Vertex, the holder of our redeemable preferred stock, elects to exercise its redemption rights with respect to those shares on or after December 31, 2010, we may be obligated to pay an aggregate of $7.2 million plus dividends accrued after that date. We would require additional funding to make this payment. Funds for this purpose may not be available to us on favorable terms, or at all. In addition, the terms of the preferred stock contemplate an acceleration of this redemption right in the event of certain deemed liquidation events, which would include many types of business combination transactions. In such a circumstance, the payment of the redemption amounts would be due prior to distributions to common stockholders.

We may have contractual liabilities in connection with our discontinuation of the Trizytek program.

We had significant contractual obligations that we entered into with third parties for the Trizytek program. In connection with our discontinuation of Trizytek program activities and a new license agreement with CFFTI, CFFTI assumed certain, but not all, of these obligations, and we remain responsible for the unassumed obligations. We have disagreements with CFFTI with respect to the parties rights and obligations under the agreements providing for CFFTI to assume these obligations. These disputes occupy management time and attention, may lead to out-of-pocket costs, and could result in litigation or claims for damages.

On March 27, 2009, we informed Lonza of our intent to terminate the Manufacturing Agreement, dated November 16, 2006, as amended, between us and Lonza due to Lonza s material breach of the Manufacturing Agreement. On June 29, 2009, we terminated the Manufacturing Agreement due to Lonza s failure to cure the material breach within the 90 day cure period provided in the Manufacturing Agreement. Before we delivered the notice of our intent to terminate the Manufacturing Agreement due to Lonza s breach, Lonza asserted that we had unilaterally terminated the Manufacturing Agreement, without notice. Lonza maintains that we owe 8.3 million Swiss francs, or $7.6 million, based on exchange rates at June 30, 2009, under these provisions. The Manufacturing Agreement is currently the subject of a lawsuit that Lonza filed against us in the United States District Court for the Southern District of New York on May 15, 2009. On June 29, 2009, we filed an answer to Lonza s complaint indicating our belief that Lonza s claims are meritless and asserted a counterclaim for breach of contract, without waiving our rights that the allegations of the counterclaim are exclusively arbitrable. The parties subsequently agreed to arbitrate the breach dispute before the American Arbitration Association. The parties have engaged in settlement discussions, but have yet to reach, and may not reach, an acceptable settlement. This dispute consumes management time and attention, as well as out-of-pocket legal fees, and could result in us being required to make a substantial payment to Lonza.

We have a history of net losses, which we expect to continue for at least several years and, as a result, we are unable to predict the extent of any future losses or when, if ever, we will achieve, or be able to maintain, profitability.

We have incurred significant losses since 1999, when we were reorganized as a company independent from Vertex. At June 30, 2009, our accumulated deficit was $361.1 million, and we expect to continue to incur losses for at least the next several years. We have only been able to generate limited amounts of revenue from license and milestone payments under collaboration agreements and payments for funded research and development, as well as revenue from products

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we no longer sell. Although our realignment of operations to focus on the development of ALTU-238 will result in a reduction in our annual research and development spending, we expect to continue to incur net operating losses for the next several years.

We must generate significant revenue to achieve and maintain profitability. All of our product candidates are still in development. Even if we succeed in developing and commercializing one or more of our product candidates, we may not be able to generate sufficient revenue to achieve or maintain profitability. Our failure to become and remain profitable would further depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations.

Raising additional capital by issuing securities or through collaboration and licensing arrangements may cause dilution to existing stockholders, restrict our operations or require us to relinquish proprietary rights.

We may seek the additional capital necessary to fund our operations through public or private equity offerings, debt financings, or collaboration and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, existing stock ownership interests will be diluted, such dilution will in all likelihood be substantial, and the terms of such securities may include liquidation or other preferences that adversely affect the rights of our existing stockholders. In addition, certain warrants that we have issued contain price protection provisions that reduce the exercise price of the warrants in the event we issue equity securities at a lower price than the original exercise price, thus furthering dilution. At June 30, 2009, we had 1,133,112 such warrants. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take actions such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration and licensing arrangements with third parties, we may have to relinquish valuable development and commercialization rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us.

The NASDAQ Marketplace Rules contemplate stockholder approval of certain financings, which may limit our ability to raise sufficient capital.

The NASDAQ Marketplace Rules contemplate that we will obtain stockholder approval under certain circumstances if we issue outstanding equity securities that would comprise more than 20% of our total shares of common stock outstanding before the issuance of the securities. In order to comply with these rules, we may need to obtain stockholder approval, and we may fail to obtain any such stockholder approval. If we failed to obtain such an approval prior to a financing, our funding options would be limited, which would adversely affect our ability to successfully develop and commercialize our product candidates or to finance the discovery and development of our next generation of product candidates. If we engage in a financing without obtaining the stockholder approval contemplated by the NASDAQ rules, we may be delisted. We might seek an exemption from the stockholder approval rules for a particular transaction, or we may determine to engage in a financing that may be deemed to violate these rules.

Our competitors may develop products that are less expensive, safer or more effective, which may diminish or prevent the commercial success of any product candidate that we bring to market.

Competition in the pharmaceutical and biotechnology industries is intense. We face competition from pharmaceutical and biotechnology companies, as well as numerous academic and research institutions and governmental agencies engaged in drug discovery activities, both in the United States and abroad. Most of these competitors have greater financial resources than we do and greater experience in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing than we do, and some have products or are pursuing the development of product candidates that target the same diseases and conditions that are the focus of our drug development programs, including those set forth below.

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ALTU-238. If approved, ALTU-238, the product candidate we are developing as a once-weekly treatment for human growth hormone, or hGH, deficiency and related disorders, will compete with existing approved hGH therapies from companies such as BioPartners, Eli Lilly, Genentech, Merck Serono, Novo Nordisk, Pfizer, Sandoz, and Teva Pharmaceutical Industries. In addition, we understand that ALTU-238 may compete with product candidates in clinical development from some of these companies and others, including LG Life Sciences, which is developing a long-acting hGH therapy based on an encapsulated microparticle technology, and Merck Serono and Novo Nordisk, which are also developing long-acting hGH therapies.

*ALTU-*237. If approved, ALTU-237, the product candidate we may further develop for the treatment of hyperoxalurias, depending on the availability of funding, may compete with product candidates in development at companies such as Amsterdam Molecular Therapeutics, Medix, NephroGenex, and OxThera.

We may not be successful in establishing and maintaining collaborations on acceptable terms, which could adversely affect our ability to develop and commercialize our products.

An element of our business strategy is to establish collaborative arrangements with third parties with regard to development, regulatory approval, sales, marketing and distribution of our products. We may collaborate with other companies to accelerate the development of some of our early-stage product candidates, to develop and commercialize or co-commercialize our more mature product candidates or to advance other business objectives. The process of establishing new collaborative relationships is difficult, time-consuming and involves significant uncertainty. We face, and will continue to face, significant competition in seeking appropriate collaborators. Moreover, if we do establish collaborative relationships, our collaborators may fail to fulfill their responsibilities or seek to renegotiate or terminate their relationships with us due to unsatisfactory clinical results, a change in business strategy, a change of control or other reasons. In the event of a termination, we may incur termination payments or other expenses in connection with any reacquisition of rights. For example, in connection with the termination of our collaboration with Genentech for ALTU-238, we became solely responsible for all expenses in connection with the ALTU-238 program. If we are unable to establish and maintain collaborative relationships on acceptable terms, we may have to delay or discontinue further development of one or more of our product candidates, undertake development and commercialization activities at our own expense or find alternative sources of funding.

If we enter into new collaborative agreements, our collaborators and we may not achieve our projected research and development goals in the time frames we announce and expect, which could have an adverse impact on our business and could cause our stock price to decline.

If we enter into new collaborative agreements for our product candidates, we expect to set goals for and make public statements regarding the timing of activities, such as the commencement and completion of preclinical studies and clinical trials, anticipated regulatory approval dates and developments and milestones under those collaboration agreements. The actual timing of such events can vary dramatically due to a number of factors such as delays or failures in our or our collaborators preclinical studies or clinical trials, delays or failures in manufacturing process development activities or in manufacturing product candidates, the amount of time, effort and resources to be committed to our programs by our future collaborators, delays in filing for regulatory approval, and the uncertainties inherent in the regulatory approval process, including delays in obtaining regulatory approval. We cannot be certain that our or our collaborators preclinical studies and clinical trials will advance or be completed in the time frames we announce or expect, that our collaborators or we will make regulatory submissions or receive regulatory approvals as planned or that our collaborators or we will be able to adhere to our current schedule for the achievement of key milestones under any of our internal or collaborative programs. If our collaborators or we fail to achieve one or more of these milestones as planned, our business would be materially adversely affected and the price of our common stock could decline.

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Risks Related to Development of Our Product Candidates

If we, or if we enter into future collaborative agreements, our collaborators, are unable to commercialize our lead product candidates, or experience significant delays in doing so, our business will be materially harmed.

We have invested a significant portion of our time and financial resources to date in the development of oral and injectable crystallized protein therapies, including Trizytek, for which we have discontinued development activities, ALTU-238 and ALTU-237 (the development of which is on hold until sufficient additional funding can be secured), for the treatment of gastrointestinal and metabolic disorders. Our ability and the ability of a collaborative partner to develop and commercialize our current product candidates successfully, and therefore our ability to generate revenues, will depend on numerous factors, including:

- successfully scaling up the manufacturing processes for our product candidates, successfully completing stability testing and release of our product candidates, and obtaining sufficient supplies of, our product candidates, in order to complete our clinical trials and toxicology studies on a timely basis;
- receiving marketing approvals from the FDA and foreign regulatory authorities;
- arranging for commercial-scale supplies of our product candidates with contract manufacturers whose manufacturing facilities operate in compliance with current good manufacturing practice regulations, or cGMPs, including the need to scale up the manufacturing process for commercial scale supplies;
- establishing sales, marketing and distribution capabilities on our own, through collaborative agreements or through third parties;
- obtaining commercial acceptance of our product candidates, if approved, in the medical community and by third-party payors and government pricing authorities; and
- establishing favorable pricing from foreign regulatory authorities.

If we are not successful in commercializing ALTU-238 or are significantly delayed in doing so, our business will be materially harmed.

Because our product candidates are in clinical development, there is a significant risk of failure.

Of the large number of drugs in development, only a small percentage result in the submission of an NDA to the FDA, and even fewer are approved for commercialization. We will only receive regulatory approval to commercialize a product candidate if we can demonstrate to the satisfaction of the FDA or the applicable foreign regulatory authority, in well-designed and controlled clinical trials, that the product candidate is safe and effective and otherwise meets the appropriate standards required for approval for a particular indication. Clinical trials are lengthy, complex and extremely expensive programs with uncertain results. A failure of one or more of our clinical trials may occur at any stage of testing. We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA.

A number of events or factors, including any of the following, could delay the completion of our ongoing and planned clinical trials and negatively impact our ability to submit an NDA and obtain regulatory approval for, and to market and sell, a particular product candidate, including our clinical-stage product candidates:

- unavailability of funds;
- conditions imposed by us or imposed on us by the FDA or any foreign regulatory authority regarding the scope or design of our clinical trials;
- delays in obtaining, or our inability to obtain or maintain, required approvals from institutional review boards, or IRBs, or other reviewing entities at clinical sites selected for

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participation in our clinical trials;

negative or inconclusive results from clinical trials, or results that are inconsistent with earlier results, that necessitate additional clinical studies;

delays in the completion of manufacturing development work for our product candidates, and in collecting the necessary manufacturing information for submission of our marketing approval applications for our product candidates;

any dispute that arises under our current or future collaborative agreements or our agreements with third parties;

insufficient supply or deficient quality of our product candidates or other materials necessary to conduct our clinical trials;

difficulties enrolling subjects in our clinical trials, including, for example, finding pediatric subjects with hGH deficiency who have not previously received hGH therapy for our pediatric trials of ALTU-238;

serious or unexpected side effects experienced by subjects in clinical trials; or

failure of our third-party contractors or our investigators to comply with regulatory requirements or otherwise meet their contractual obligations to us in a timely manner.

Delays in or inconclusive results from our clinical trials may result in increased development costs for our product candidates and corresponding delays in the filing of an NDA for product candidates and the receipt of marketing approval for the product candidate or discontinuation of a program, which could cause our stock price to decline and could limit our ability to obtain additional financing. For example, our stock price declined significantly following the announcement of the results of our Phase III clinical trial for Trizytek. In addition, we were unable to secure a corporate partnership for Trizytek following the announcement of such results and consequently decided to discontinue the Trizytek program which is now exclusively licensed to CFFTI. In addition, if one or more of our product candidates are delayed, our competitors may be able to bring products to market before we do, and the commercial advantage, profitability or viability of our product candidates, including our clinical-stage product candidates, could be significantly reduced.

We have not yet completed a full Phase III program for any of our product candidates in clinical development, other than for the Trizytek program, for which we discontinued development activities, and we have not advanced, and may never advance, our product candidates that are currently in preclinical testing into clinical trials. Even if our trials are successful, we may still be required or may determine it is desirable to perform additional studies for approval or in order to achieve a broad indication for the labeling of the drug.

For the ALTU-238 program, we have completed Phase I clinical trials in healthy adults and a Phase II clinical trial in adults with hGH deficiency and have commenced a Phase II clinical trial in children with hGH deficiency. The efficacy of ALTU-238 has not yet been tested in a human clinical trial, and ALTU-238 may prove not to be clinically effective as an extended-release formulation of hGH. In addition, it is possible that patients receiving ALTU-238 will suffer additional or more severe side effects than we observed in our earlier Phase I and Phase II clinical trials, which could delay or preclude regulatory approval of ALTU-238 or limit its commercial use.

If we observe serious or other adverse events during the time our product candidates are in development or after our products are approved and on the market, we may be required to perform lengthy additional clinical trials, may be denied regulatory approval of such products, may be forced to change the labeling of such products or may be required to withdraw any such products from the market, any of which would hinder or preclude our ability to generate revenues.

As our clinical trials progress or increase in size or the medical conditions of the population in which we are testing our products vary, the potential for serious or other adverse events related or

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unrelated to our product candidates could vary and possibly increase. If the incidence of these events increases in number or severity, if a regulatory authority believes that these events constitute an adverse effect caused by the drug, or if other effects are identified either during future clinical trials or after any of our drug candidates are approved and on the market:

- we may be required to conduct additional preclinical or clinical trials, make changes in clinical trial brochures or, if a product is approved, make changes to the labeling of any such products, reformulate any such products, or implement changes to or obtain new approvals of our or our contractors or collaborators manufacturing facilities or processes;
- regulatory authorities may be unwilling to approve our product candidates or may withdraw approval of our products;
- we may experience a significant drop in the sales of the affected products;
- our reputation in the marketplace may suffer; and
- we may become the target of lawsuits, including class action suits.

Any of these events could prevent approval or harm sales of the affected products or could substantially increase the costs and expenses of commercializing and marketing any such products.

We may fail to select or capitalize on the most scientifically, clinically or commercially promising or profitable indications or therapeutic areas for our product candidates.

We have limited technical, managerial and financial resources to determine the indications on which we should focus the development efforts related to our product candidates. We may make incorrect determinations. Our decisions to allocate our research, management and financial resources toward particular indications or therapeutic areas for our product candidates may not lead to the development of viable commercial products and may divert resources from better opportunities. Similarly, our decisions to delay or terminate drug development programs may also be incorrect and could cause us to miss valuable opportunities. For example, we have made a decision to allocate substantially all of our existing financial, capital and human resources to ALTU-238, and are evaluating the feasibility of moving forward our early-stage clinical and pre-clinical programs and will make future decisions on these programs depending upon the availability of resources. If we invest in the advancement of a candidate that proves not to be viable, we will have fewer resources available for potentially more promising candidates.

Risks Related to Regulatory Approval of Our Product Candidates and Other Government Regulations

If we or our future collaborators do not obtain required regulatory approvals, we will be unable to commercialize our product candidates, and our ability to generate revenue will be materially impaired.

ALTU-238, ALTU-237 and any other product candidates we may discover or acquire and seek to commercialize, either alone or in conjunction with a collaborator, are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries relating to the testing, manufacture, safety, efficacy, recordkeeping, labeling, packaging, storage, approval, advertising, promotion, sale and distribution of drugs. In the United States and in many foreign jurisdictions, we must successfully complete rigorous preclinical testing and clinical trials and an extensive regulatory review process before a new drug can be sold. We have not obtained regulatory approval for any product. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays.

The time required to obtain approval by the FDA is unpredictable but typically takes many years following the commencement of clinical trials, depending upon numerous factors, including the complexity of the product candidate and the disease to be treated. Our product candidates may fail to receive regulatory approval for many reasons, including:

- a failure to demonstrate to the satisfaction of the FDA or comparable foreign regulatory

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authorities that a product candidate is safe and effective for a particular indication;

the results of clinical trials may not meet the level of statistical significance required by the FDA or other regulatory authorities for approval;

an inability to demonstrate that a product candidate s benefits outweigh its risks;

an inability to demonstrate that the product candidate presents an advantage over existing therapies;

the FDA s or comparable foreign regulatory authorities disagreement with the manner in which our collaborators or we interpret the data from preclinical studies or clinical trials;

the FDA s or comparable foreign regulatory authorities failure to approve the manufacturing processes or facilities of third-party contract manufacturers of clinical and commercial supplies; and

a change in the approval policies or regulations of, or the specific advice provided to us by, the FDA or comparable foreign regulatory authorities or a change in the laws governing the approval process.

The FDA or comparable foreign regulatory authorities might decide that the data are insufficient for approval and require additional clinical trials or other studies. Furthermore, even if we do receive regulatory approval to market a commercial product, any such approval may be subject to limitations on the indicated uses for which our collaborative partner or we may market the product or may be subject to post-approval commitments to conduct Phase IV studies, patient monitoring or other risk management measures that could require significant financial resources. It is possible that none of our existing or future product candidates will ever obtain the appropriate regulatory approvals necessary for us or our collaborators to begin selling them.

Failure to obtain regulatory approvals or to comply with regulatory requirements in foreign jurisdictions would prevent us or any collaborator from marketing our products internationally.

We intend to have our product candidates marketed outside the United States. In order to market products in the European Union and many other non-United States jurisdictions, our collaborators or we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. We have no experience in obtaining foreign regulatory approvals for our product candidates. The approval procedures vary among countries and can involve additional and costly preclinical and clinical testing and data review. The time required to obtain approval in other countries may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. We also face challenges arising from the different regulatory requirements imposed by United States and foreign regulators with respect to clinical trials. The European Medicines Agency, or EMEA, often imposes different requirements than the FDA with respect to the design of a pivotal Phase III clinical trial. Our future collaborators or we may not receive necessary approvals to commercialize our products in any market. The failure to obtain these approvals could harm our business and result in decreased revenues from the sale of products or from milestones or royalties associated with any collaboration agreements we may enter into in the future.

Our product candidates will remain subject to ongoing regulatory requirements even if they receive marketing approval, and if we fail to comply with these requirements, we could lose these approvals, and the sales of any approved commercial products could be suspended.

Even if we receive regulatory approval to market a particular product candidate, the product will remain subject to extensive regulatory requirements, including requirements relating to manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, distribution and record keeping. In addition, the approval may be subject to limitations on the uses

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for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product, which could reduce our revenues, increase our expenses and render the approved product candidate not commercially viable.

In addition, as clinical experience with a drug increases after approval because it is typically used by a larger and more diverse group of patients after approval than during clinical trials, side effects and other problems may be observed after approval that were not seen or anticipated during pre-approval clinical trials or other studies. Any adverse effects observed after the approval and marketing of a product candidate could result in limitations on the use of or withdrawal of any approved products from the marketplace. Absence of long-term safety data may also limit the approved uses of our products, if any. If we fail to comply with the regulatory requirements of the FDA and other applicable United States and foreign regulatory authorities, or previously unknown problems with any approved commercial products, manufacturers or manufacturing processes are discovered, we could be subject to administrative or judicially imposed sanctions or other setbacks, including:

- restrictions on the products, manufacturers or manufacturing processes;
- warning letters;
- civil or criminal penalties;
- fines;
- injunctions;
- product seizures or detentions;
- import or export bans or restrictions;
- voluntary or mandatory product recalls and related publicity requirements;
- suspension or withdrawal of regulatory approvals;
- total or partial suspension of production; and
- refusal to approve pending applications for marketing approval of new products or supplements to approved applications.

If we are slow to adapt, or are unable to adapt, to changes in existing regulatory requirements or adoption of new regulatory requirements or policies, we may lose marketing approval for our products when and if any of them are approved, resulting in decreased revenue from milestones, product sales or royalties. Moreover, even when a manufacturer has fully complied with applicable regulatory standards, products manufactured and distributed may ultimately fail to comply with applicable specifications, leading to product withdrawals or recalls.

We deal with hazardous materials and must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our activities and those of our third-party manufacturers on our behalf involve the controlled storage, use and disposal of hazardous materials, including microbial agents, corrosive, explosive and flammable chemicals and other hazardous compounds. Our manufacturers and we are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. Although we believe that the safety procedures for handling and disposing of these materials comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental contamination or injury from these materials.

In the event of an accident, state or federal authorities may curtail our use of these materials and interrupt our business operations. In addition, we could be liable for any resulting civil damages which may exceed our financial

resources and may seriously harm our business. While we believe that the amount of insurance we currently carry, providing coverage of $1.0 million, should be sufficient for typical risks regarding our handling of these materials, it may not be sufficient to cover

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pollution conditions or other extraordinary or unanticipated events. Furthermore, an accident could damage, or force us to shut down, our operations. In addition, if we develop manufacturing capability, we may incur substantial costs to comply with environmental regulations and would be subject to the risk of accidental contamination or injury from the use of hazardous materials in our manufacturing process.

Risks Related to Our Dependence on Third Parties

We have no manufacturing capacity, and we have relied and expect to continue to rely on third-party manufacturers to produce our product candidates.

We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of our product candidates or any of the compounds that we are testing in our preclinical programs, and we lack the internal resources and the capabilities to do so. As a result, we currently rely, and we expect to rely in the future, on third-party manufacturers to supply the APIs for our product candidates and to produce and package final drug products, if and when they are approved for marketing. Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates or products ourselves, including:

- reliance on the third party for manufacturing process development, sourcing of key raw materials and specialized manufacturing equipment, regulatory compliance and quality assurance;
- limitations on supply availability resulting from capacity and scheduling constraints of the third party;
- the possible breach of the manufacturing agreement by the third party because of factors beyond our control; and
- the possible termination or non-renewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us.

Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our future profit margins and our ability to develop our product candidates and commercialize any products that receive regulatory approval on a timely basis.

We currently rely on a limited number of manufacturers for the clinical and commercial supply of each of our product candidates, which could delay or prevent the clinical development and commercialization of our product candidates.

We currently depend on single source suppliers for ALTU-238. Any disruption in production, inability of a supplier to produce adequate quantities of clinical and other material to meet our needs or other impediments could adversely affect our ability to successfully complete the clinical trials and other studies of our product candidates, delay submissions of our regulatory applications or adversely affect our ability to commercialize our product candidates in a timely manner, or at all.

We have purchased the hGH, the active pharmaceutical ingredient in ALTU-238, for our prior and ongoing clinical trials from Sandoz. We have also produced ALTU-238 for these trials and believe that the current scale of manufacturing is sufficient to support the planned Phase III program for ALTU-238 in both adult and pediatric growth hormone deficient patients. In July 2008, Sandoz and we entered into a long term supply agreement, which has an initial term expiring in 2012, with an optional two year extension period. Because we do not have another long term supplier of hGH in place, any disruption in Sandoz ability to supply us with hGH as needed would adversely affect the ALTU-238 program.

We have an agreement with Althea for Althea to use the hGH supplied to it to produce the clinical supplies for our planned clinical trials of ALTU-238. Any delay in the production, testing and release of ALTU-238 could delay our planned clinical trials and result in additional unforeseen expenses.

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Our agreement with Althea covers only the manufacture of ALTU-238 for the planned clinical trials of ALTU-238. We will need to negotiate an additional agreement under which Althea would provide the commercial supply of ALTU-238 or find an alternative commercial manufacturer. Switching manufacturers would require cooperation from Althea, technology transfers, training, and validation of the alternative manufacturer s processes, and, under some circumstances, will require us to make a specified payment to Althea. Changes in manufacturing processes or procedures, including a change in the location where the drug is manufactured or a change of a third-party manufacturer, may require prior review and approval from the FDA and satisfaction of comparable foreign requirements. This review may be costly and time-consuming and could delay or prevent the launch of a product. If we are unable to secure another contract manufacturer for ALTU-238 at an acceptable cost, the commercialization of ALTU-238 could be delayed, prevented or impaired, and the costs related to ALTU-238 may increase. Any dispute over the terms of, or decisions regarding, our collaboration with Althea or other adverse developments in our relationship would materially harm our business and might accelerate our need for additional capital.

Our contract manufacturers may encounter difficulties or unforeseen expenses in connection with the commercial scale-up of manufacturing activities for our product candidates

We do not have any agreements in place to manufacture our product candidates on a commercial scale, other than the supply agreement for API for ALTU-238. In order to commercialize ALTU-238, we, in conjunction with Althea, will need to scale up the manufacturing of ALTU-238 drug product. We may be required to fund capital improvements to support scale-up of manufacturing and related activities. Althea may not be able to increase its manufacturing capacity and we may need to find an alternative supplier. In addition, Sandoz may discontinue its manufacturing of hGH, in which case we would need to find an alternative source. It may be difficult for us to enter into additional supply arrangements on a timely basis or on acceptable terms, which could delay or prevent our ability to commercialize ALTU-238.

Any performance failure on the part of a contract manufacturer could delay clinical development or regulatory approval of our product candidates or commercialization of any approved products.

The failure of a contract manufacturer to achieve and maintain high manufacturing standards could result in patient injury or death, product liability claims, product recalls, product seizures or withdrawals, delays or failures in testing or delivery, cost overruns, failure of regulatory authorities to grant marketing approvals, delays, suspensions or withdrawals of approvals, injunctions, fines, civil or criminal penalties, or other problems that could seriously harm our business. Contract manufacturers may encounter difficulties involving production yields, quality control and quality assurance. These manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state and foreign agencies which audit strict compliance with cGMP and other applicable government regulations and corresponding foreign standards. However, we or a future collaborator may have limited control over third-party manufacturers compliance with these regulations and standards. Present or future manufacturers might not be able to comply with cGMP and other FDA or international regulatory requirements.

We rely on third parties to conduct, supervise and monitor our clinical trials, and those third parties may not perform satisfactorily, including failing to meet established deadlines for the completion of such trials.

We rely on third parties such as contract research organizations, medical institutions and clinical investigators to enroll qualified patients and conduct, supervise and monitor our clinical trials. Our reliance on these third parties for clinical development activities reduces our control over these activities. Our reliance on these third parties, however, does not relieve us of our regulatory responsibilities, including ensuring that our clinical trials are conducted in accordance with good clinical practice regulations and the investigational plan and protocols contained in the IND. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. In addition, they may not complete activities on schedule, or may not conduct

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our preclinical studies or clinical trials in accordance with regulatory requirements or our trial design. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, our efforts to obtain regulatory approvals for, and commercialize, our product candidates may be delayed or prevented.

Because we may in the future enter into sales or collaboration transactions, we may be dependent upon our collaborators, and we may be unable to prevent them from taking actions that may be harmful to our business or inconsistent with our business strategy.

Any future licensing and collaboration agreements that we may enter into with respect to our product development candidates may reduce or eliminate the control we have over the development and commercialization of our product candidates. Our future collaborators may decide to terminate a development program under circumstances where we might have continued such a program, or may be unable or unwilling to pursue ongoing development and commercialization activities as quickly as we would prefer. A collaborator may follow a different strategy for product development and commercialization that could delay or alter development and commercial timelines and likelihood of success. A collaborator may also be unwilling or unable to fulfill its obligations to us, including its development and commercialization responsibilities. Any future collaborators will likely have significant discretion in determining the efforts and level of resources that they dedicate to the development and commercialization of our product candidates. In addition, although we seek to structure our agreements with potential collaborators to prevent the collaborator from developing and commercializing a competitive product, we are not always able to negotiate such terms and the possibility exists that our collaborators may develop and commercialize, either alone, or with others or through an in-license or acquisition, products that are similar to or competitive with the products that are the subject of the collaboration with us. If any collaborator terminates its collaboration with us or fails to perform or satisfy its obligations to us, the development, regulatory approval or commercialization of our product candidate would be delayed or may not occur and our business and prospects could be materially and adversely affected. Likewise, if we fail to fulfill our obligations under a collaboration and license agreement, our collaborator may be entitled to damages, to terminate the agreement, or terminate or reduce its financial payment obligations to us under our collaborative agreement.

Our collaborations with outside scientists and consultants may be subject to restriction and change.

We work with chemists, biologists and other scientists at academic and other institutions, and consultants who assist us in our research, development, regulatory and commercial efforts. These scientists and consultants have provided, and we expect that they will continue to provide, valuable advice on our programs. These scientists and consultants are not our employees, may have other commitments that would limit their future availability to us and typically will not enter into non-compete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. In addition, we will be unable to prevent them from establishing competing businesses or developing competing products. For example, if a key principal investigator identifies a potential product or compound that is more scientifically interesting to his or her professional interests, his or her availability could be restricted or eliminated.

Risks Related to Commercialization of Our Product Candidates

If physicians and patients do not accept our future products, we may be unable to generate significant revenue, if any.

Even if we or a future collaborator receives regulatory approval for our product candidates, these product candidates may not gain market acceptance among physicians, healthcare payors, government pricing agencies, patients or the medical community. Physicians may elect not to recommend or patients may elect not to use these products for a variety of reasons, including:

prevalence and severity of adverse side effects;

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ineffective marketing and distribution support;

timing of market introduction of competitive products;

lack of availability of, or inadequate reimbursement from managed care plans and other third-party or government payors;

lower demonstrated clinical safety and efficacy compared to other products;

other potential advantages of alternative treatment methods; and

lack of cost-effectiveness or less competitive pricing.

If our approved drugs fail to achieve market acceptance, we will not be able to generate significant revenue, if any.

If the government and third-party payors fail to provide coverage and adequate payment rates for our future products, if any, our revenue and prospects for profitability will be harmed.

In both domestic and foreign markets, our sales of any future products will depend in part upon the availability of reimbursement from third-party payors. Such third-party payors include government health programs such as Medicare and Medicaid, managed care providers, private health insurers and other organizations. These third-party payors are increasingly attempting to contain healthcare costs by demanding price discounts or rebates and limiting both coverage on which drugs they will pay for and the amounts that they will pay for new drugs. As a result, they may not cover or provide adequate payment for our drugs.

In the United States there have been, and we expect that there will continue to be, a number of federal and state proposals to implement governmental pricing reimbursement controls. The Medicare Prescription Drug and Modernization Act of 2003 imposed new requirements for the distribution and pricing of prescription drugs that may affect the marketing of our products, if we obtain FDA approval for those products. Under this law, Medicare was extended to cover a wide range of prescription drugs other than those directly administered by physicians in a hospital or medical office. Competitive regional private drug plans were authorized to establish lists of approved drugs, or formularies, and to negotiate rebates and other price control arrangements with drug companies. Proposals to allow the government to negotiate Medicare drug prices with drug companies directly, if enacted, might further constrain drug prices, leading to reduced revenues and profitability. While we cannot predict whether any future legislative or regulatory proposals will be adopted, the adoption of such proposals could have a material adverse effect on our business, financial condition and profitability.

Foreign governments tend to impose strict price controls on pharmaceutical products, which may adversely affect our revenues, if any.

In some foreign countries, particularly the countries of the European Union, Canada and Japan, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In some countries, the pricing is limited by the pricing of existing or comparable therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our ability to enter into collaborative development and commercialization agreements and our revenues from these agreements could be adversely affected.

There is a substantial risk of product liability claims in our business. If we are unable to obtain sufficient insurance, a product liability claim against us could adversely affect our business.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face even greater risks upon any commercialization by

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us of our product candidates. We have product liability insurance covering our clinical trials in the amount of $10 million, which we believe is adequate to cover any current product liability exposure we may have. However, liabilities may exceed the extent of our coverage, resulting in material losses. Clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance or increase our existing coverage at a reasonable cost to protect us against losses that could have a material adverse effect on our business. An individual may bring a product liability claim against us if one of our products or product candidates causes, or is claimed to have caused, an injury or is found to be unsuitable for consumer use. Any product liability claim brought against us, with or without merit, could result in:

liabilities that substantially exceed our product liability insurance, which we would then be required to pay from other sources, if available;

an increase of our product liability insurance rates or the inability to maintain insurance coverage in the future on acceptable terms, or at all;

withdrawal of clinical trial volunteers or patients;

damage to our reputation and the reputation of our products, resulting in lower sales;

regulatory investigations that could require costly recalls or product modifications;

litigation costs; and

the diversion of management s attention from managing our business.

Risks Related to Our Intellectual Property

If the combination of patents, trade secrets and contractual provisions that we rely on to protect our intellectual property is inadequate to provide us with market exclusivity, our ability to successfully commercialize our product candidates will be harmed and we may not be able to operate our business profitably.

Our success depends, in part, on our ability to obtain, maintain and enforce our intellectual property rights both domestically and abroad. The patent position of biotechnology companies is generally highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. The validity, enforceability and commercial value of our rights, therefore, are highly uncertain.

Our patents may not protect us against our competitors. The issuance of a patent is not conclusive as to its scope, validity or enforceability. The scope, validity or enforceability of our patents can be challenged in litigation. Such litigation is often complex, can involve substantial costs and distraction and the outcome of patent litigation is often uncertain. If the outcome is adverse to us, third parties may be able to use our patented inventions and compete directly with us, without payment to us. Third parties may also be able to circumvent our patents by design innovations. We may not receive any additional patents based on the applications that we have filed and are currently pending.

Because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing or, in some cases, not at all, and because publications of discoveries in the scientific literature often lag behind actual discoveries, neither we nor our licensors or collaborators can be certain that they or we were the first to make the inventions claimed in patents or pending patent applications, or that they or we were the first to file for protection of the inventions set forth in these patent applications. Assuming the other requirements for patentability are met, in the United States, the first to make the claimed invention is entitled to the patent, and outside the United States, the first to file is entitled to the patent.

Many of the proteins that are the APIs in our product candidates are off-patent. Therefore, we have obtained and are seeking to obtain patents directed to novel compositions of matter, formulations, methods of manufacturing and methods of treatment to protect some of our products.

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Such patents may not, however, prevent our competitors from developing products using the same APIs but different manufacturing methods or formulation technologies that are not covered by our patents.

If third parties successfully assert that we have infringed their patents and proprietary rights or challenge the validity of our patents and proprietary rights, we may become involved in intellectual property disputes and litigation that would be costly, time consuming, and could delay or prevent the development or commercialization of our product candidates.

Our ability to commercialize our product candidates depends on our ability to develop, manufacture, market and sell our product candidates without infringing the proprietary rights of third parties. Third parties may allege our product candidates infringe their intellectual property rights. Numerous United States and foreign patents and pending patent applications that are owned by third parties exist in fields that relate to our product candidates and our underlying technology, including patents and patent applications claiming compositions of matter of, methods of manufacturing, and methods of treatment using, specific proteins, combinations of proteins, and protein crystals. For example, we are aware of some issued United States and/or foreign patents that may be relevant to the development and commercialization of our product candidates. However, we believe that, if these patents were asserted against us, it is likely that we would not be found to infringe any valid claim of the patents relevant to our development and commercialization of these products. If any of these patents were asserted against us and determined to be valid and construed to cover any of our product candidates, including, without limitation, ALTU-238 and ALTU-237, our development and commercialization of these products could be materially adversely affected.

Although we believe it is unlikely that we would be found to infringe any valid claim of these patents, we may not succeed in any action in which the patents are asserted against us. In order to successfully challenge the validity of any United States patent, we would need to overcome a presumption of validity. This burden is a high one requiring clear and convincing evidence. If any of these patents were found to be valid and we were found to infringe any of them, or any other patent rights of third parties, we would be required to pay damages, stop the infringing activity or obtain licenses in order to use, manufacture or sell our product candidates. Any required license might not be available to us on acceptable terms, or at all. If we succeeded in obtaining these licenses, payments under these licenses would reduce any earnings from our products. In addition, some licenses might be non-exclusive and, accordingly, our competitors might gain access to the same technology as that which was licensed to us. If we failed to obtain a required license or were unable to alter the design of our product candidates to make the licenses unnecessary, we might be unable to commercialize one or more of our product candidates, which could significantly affect our ability to establish and grow our commercial business.

In order to protect or enforce our patent rights, defend our activities against claims of infringement of third-party patents, or to satisfy contractual obligations to licensees of our own intellectual property, we might be required to initiate patent litigation against third parties, such as infringement suits or nullity, opposition or interference proceedings. Our collaborators or we may enforce our patent rights under the terms of our major collaboration and license agreements, but neither we nor our collaborators is required to do so. In addition, others may sue us for infringing their patent rights or file nullity, opposition or interference proceedings against our patents, even if such claims are without merit.

Intellectual property litigation is relatively common in our industry and can be costly. Even if we prevail, the cost of such litigation could deplete our financial resources. Litigation is also time consuming and could divert management s attention and resources away from our business. Furthermore, during the course of litigation, confidential information may be disclosed in the form of documents or testimony in connection with discovery requests, depositions or trial testimony. Disclosure of our confidential information and our involvement in intellectual property litigation could materially adversely affect our business. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially

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greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could significantly limit our ability to continue our operations.

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. While we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have inadvertently or otherwise used or disclosed intellectual property, trade secrets or other proprietary information of any such employee s former employer. Litigation may be necessary to defend against these claims and, even if we are successful in defending ourselves, could result in substantial costs or be distracting to management. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel.

If we are unable to protect our trade secrets, we may be unable to protect our interests in proprietary technology, processes and know-how that is not patentable or for which we have elected not to seek patent protection.

In addition to patented technology, we rely upon unpatented proprietary technology, processes and know-how, including particularly our manufacturing know-how relating to the production of the crystallized proteins used in the formulation of our product candidates. In an effort to protect our unpatented proprietary technology, processes and know-how, we require our employees, consultants, collaborators, contract manufacturers and advisors to execute confidentiality agreements. These agreements, however, may not provide us with adequate protection against improper use or disclosure of confidential information, in particular as we are required to make such information available to a larger pool of people as we seek to increase production of our product candidates and their component proteins. These agreements may be breached, and we may not become aware of, or have adequate remedies in the event of, any such breach. In addition, in some situations, these agreements may conflict with, or be subject to, the rights of third parties with whom our employees, consultants, collaborators, contract manufacturers or advisors have previous employment or consulting relationships. Also, others may independently develop substantially equivalent technology, processes and know-how or otherwise gain access to our trade secrets. If we are unable to protect the confidentiality of our proprietary technology, processes and know-how, competitors may be able to use this information to develop products that compete with our products, which could adversely impact our business.

If we fail to comply with our obligations in the agreements under which we licensed development, commercialization or other technology rights to products or technology from third parties, we could lose license rights that are important to our business or incur financial obligations based on our exercise of such license rights.

Some of our license agreements provide for licenses to us of technology that is important to our business, and we may enter into additional agreements in the future that provide licenses to us of valuable technology. These licenses impose, and future licenses may impose, various commercialization, milestone and other obligations on us. If we fail to comply with these obligations, the licensor may have the right to terminate the license even where we are able to achieve a milestone or cure a default after a date specified in an agreement, in which event we would lose valuable rights and our ability to develop our product candidates.

Risks Related to Our Employees and Growth

Our future success depends on our ability to attract, retain and motivate key executives and personnel and to attract, retain and motivate qualified personnel.

We are a small company with 33 employees as of July 31, 2009. We recently underwent a strategic realignment, which resulted in an approximate 70% headcount reduction. Our success depends on our ability to attract, retain and motivate highly qualified management, development and scientific personnel, which may be made more difficult as a result of the realignment. In particular,

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we are highly dependant on our new President and Chief Executive Officer, Dr. Georges Gemayel, and the other principal members of our executive, development and scientific teams.

All of the arrangements we have with the key members of our executive, development and scientific teams may be terminated by us or the employee at any time without notice. The loss of the services of any of these persons might impede the achievement of our research, development and commercialization objectives.

Recruiting and retaining qualified development and scientific personnel and sales and marketing personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of development and scientific personnel from universities and research institutions. We do not maintain key person insurance on any of our employees.

As we evolve from a company primarily involved in drug research and development into one that may become involved in the commercialization of drug products, we may have difficulty managing our growth, which could disrupt our operations.

As we advance our drug candidates through the development process, we will need to expand our development, regulatory, manufacturing, sales and marketing capabilities or contract with other organizations to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various contract manufacturers, collaborative partners, suppliers and other organizations. Our ability to manage our operations and growth requires us to continue to improve our operational, financial and management controls, reporting systems and procedures. Such growth could place a strain on our management, administrative and operational infrastructure. We may not be able to make improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls. In addition, the physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Risks Related to Our Common Stock and Public Company Compliance Requirements

Our stock price has been and is likely to continue to be volatile.

Investors should consider an investment in our common stock as risky and subject to significant loss and wide fluctuations in market value. Our common stock has only been publicly traded since January 26, 2006, and accordingly there is a limited history on which to gauge the volatility of our stock price. Our stock price has, however, been volatile since we began to be publicly traded. For example, our stock price declined approximately 50% following our announcement that our collaboration with Genentech had been terminated in December 2007. Our stock price also declined sharply following our announcement of the top line data of our Phase III efficacy trial of Trizytek in August 2008 and in connection with the announcement of our strategic realignment in January 2009. The stock market as a whole has experienced significant volatility, particularly with respect to pharmaceutical, biotechnology and other life sciences company stocks. The volatility of pharmaceutical, biotechnology and other life sciences company stocks may not relate to the operating performance of the companies represented by the stock. In addition, we are currently not in compliance with the applicable rules to qualify for continued listing on The NASDAQ Global Market. To maintain listing, we are required, among other things, to maintain a daily closing bid price of $1.00 and a minimum market value of publicly held shares of $5.0 million.

The market price of our common stock has been between $0.14 and $19.79 per share from January 1, 2007 until July 31, 2009. Some of the factors that may cause the market price of our common stock to continue to fluctuate include:

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delays in or results from our clinical trials or studies;

our entry into or the loss of a significant collaboration or the expansion or contraction of a significant collaboration, disputes with a collaborator, or delays in the progress of a collaborative development program;

competitive product information such as results of clinical trials conducted by others on drugs that would compete with our product candidates or the regulatory filing or approval of such competitive products;

litigation or threatened litigation, including the litigation we are subject to or arbitration we may become subject to in connection with our Manufacturing Agreement with Lonza;

delays or other problems with manufacturing our product candidates or approved products;

failure or delays in advancing product candidates from our preclinical programs, or other product candidates we may discover or acquire in the future, into clinical trials;

failure or discontinuation of any of our research programs;

regulatory review delays, changes in regulatory requirements, new regulatory developments or enforcement policies in the United States and foreign countries;

developments or disputes concerning patents or other proprietary rights;

introduction of technological innovations or new commercial products by us or our competitors;

changes in estimates or recommendations by securities analysts, if any, who cover our common stock;

failure to meet estimates or recommendations by securities analysts, if any, who cover our common stock;

positive or negative publicity regarding our product candidates or any approved products;

sales, future sales or anticipated sales of our common stock by us or our stockholders;

changes in the structure of health care payment systems;

failure of any of our product candidates, if approved, to achieve commercial success;

economic and other external factors or other disasters or crises;

period-to-period fluctuations in our financial results; and

general market conditions.

These and other external factors may cause the market price and demand for our common stock to fluctuate substantially, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. In addition, in the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit regardless of the validity of the claims or the ultimate outcome. Such a lawsuit could also divert the time and attention of our management and create additional volatility in our common stock price.

A significant portion of our total outstanding shares may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. We had 31,131,056 shares

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of common stock outstanding as of July 31, 2009. Holders of up to approximately 7.8 million shares of our common stock, assuming the exercise of warrants to purchase shares of our common stock, have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have registered all shares of common stock issuable under our equity compensation plans and they can now be freely sold in the public market upon issuance. A decline in the price of shares of our common stock might impede our ability to raise capital through the issuance of additional shares of our common stock or other equity securities, and may cause our stockholders to lose part or all of their investments in our shares of common stock.

Provisions of our charter, bylaws, and Delaware law may make an acquisition of us or a change in our management more difficult.

Certain provisions of our certificate of incorporation and bylaws could discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions could limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. Stockholders who wish to participate in these transactions may not have the opportunity to do so. Furthermore, these provisions could prevent or frustrate attempts by our stockholders to replace or remove our management. These provisions:

allow the authorized number of directors to be changed only by resolution of our board of directors;

establish a classified board of directors, such that not all members of the board are elected at one time;

authorize our board of directors to issue without stockholder approval blank check preferred stock that, if issued, could operate as a poison pill to dilute the stock ownership of a potential hostile acquirer to prevent an acquisition that is not approved by our board of directors;

require that stockholder actions must be effected at a duly called stockholder meeting and prohibit stockholder action by written consent;

establish advance notice requirements for stockholder nominations to our board of directors or for stockholder proposals that can be acted on at stockholder meetings;

limit who may call stockholder meetings; and

require the approval of the holders of 80% of the outstanding shares of our capital stock entitled to vote in order to amend certain provisions of our restated certificate of incorporation and restated bylaws.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which may, unless certain criteria are met, prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a prescribed period of time.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

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ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

See the Exhibit Index for a list of the exhibits filed as a part of this Quarterly Report, which Exhibit Index is incorporated by reference.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on August 4, 2009.

ALTUS PHARMACEUTICALS INC.

By /s/ Thomas J. Phair, Jr.
Thomas J. Phair, Jr.
Vice President, Finance and Treasurer
(duly authorized officer)

Exhibit Index

Exhibit Number	Description of Exhibit
3.1	Restated Certificate of Incorporation of the Registrant*
3.2	Restated By-laws of the Registrant**
31.1	Certification of Principal Executive Officer Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
31.2	Certification of Principal Financial Officer Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
32	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

* Filed as Exhibit 3.1 to the Registrant s Annual Report on Form 10-K (000-51711) filed on March 12, 2007.

** Filed as Exhibit 3.4 to the Registrant s Registration Statement on Form S-1A (333-129037) filed on January 11, 2006.