Altus Pharmaceuticals Inc.
Form 10-Q
November 14, 2006

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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 September 30, 2006

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.)*
125 Sidney Street, Cambridge, Massachusetts	**02139**
(Address of Principal Executive Offices)	*(Zip Code)*

Registrant s telephone number, including area code: (617) 299-2900

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 is a large accelerated filer, an accelerated filer, or a non-accelerated filer. 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 o Non-accelerated filer þ

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, $0.01 par value per share, as of November 3, 2006 was 22,948,986.

ALTUS PHARMACEUTICALS INC.
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FOR THE QUARTER ENDED SEPTEMBER 30, 2006

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PART I FINANCIAL INFORMATION

ITEM 1. Unaudited Condensed Consolidated Financial Statements

ALTUS PHARMACEUTICALS INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)
(In thousands, except share and per share amounts)

	September 30, 2006	December 31, 2005
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 44,230	$ 12,872
Investments	53,439	17,189
Prepaid expenses and other current assets	1,922	2,406
Total current assets	99,591	32,467
PROPERTY AND EQUIPMENT, Net	6,242	6,763
OTHER ASSETS, Net	1,312	1,354
TOTAL ASSETS	$ 107,145	$ 40,584
LIABILITIES, REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT)		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$ 5,766	$ 6,535
Current portion of long-term debt	1,873	2,271
Current portion of deferred revenue	8,984	9,412
Total current liabilities	16,623	18,218
Long-term debt	2,956	3,708
Long-term portion of deferred revenue	563	4,232
TOTAL LIABILITIES	20,142	26,158
CONTINGENCIES (Note 8)		
REDEEMABLE PREFERRED STOCK:		
Redeemable Preferred Stock, par value $.01 per share; 450,000 shares authorized, issued and outstanding at September 30, 2006 and December 31, 2005 (liquidation value of $6,195 at September 30, 2006 and $6,056 at December 31, 2005) at accreted redemption value	6,181	5,879
		62,159

Series B Convertible Preferred Stock, par value $.01 per share; no shares authorized, issued or outstanding at September 30, 2006; 12,928,155 shares authorized, 11,773,609 shares issued and outstanding at December 31, 2005 (liquidation value of $63,614 at December 31, 2005) at accreted redemption value		
Series C Convertible Preferred Stock, par value $.01 per share; no shares authorized, issued or outstanding at September 30, 2006; 14,420,359 shares authorized, 11,819,959 shares issued and outstanding at December 31, 2005 (liquidation value of $58,407 at December 31, 2005) at accreted redemption value		51,335
STOCKHOLDERS EQUITY (DEFICIT):		
Series A Convertible Preferred Stock, par value $.01 per share; no shares authorized, issued or outstanding at September 30, 2006; 87,500 shares authorized, issued and outstanding at December 31, 2005 (liquidation value of $4)		897
Common Stock, par value $.01 per share; 100,000,000 shares authorized, 22,674,735 shares issued and outstanding at September 30, 2006; 47,113,986 shares authorized, 1,842,809 shares issued and outstanding at December 31, 2005	227	18
Additional paid-in capital	242,027	14,272
Accumulated deficit	(161,432)	(120,134)
TOTAL STOCKHOLDERS EQUITY (DEFICIT)	80,822	(104,947)
TOTAL LIABILITIES, REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT)	$ 107,145	$ 40,584

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 September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
CONTRACT REVENUE	$ (1,955)	$ 4,125	$ 3,967	$ 6,727
COSTS AND EXPENSES:				
Research and development	10,898	6,112	38,001	19,792
General, sales and administrative	4,171	2,203	10,608	6,003
Total costs and expenses	15,069	8,315	48,609	25,795
LOSS FROM OPERATIONS	(17,024)	(4,190)	(44,642)	(19,068)
OTHER INCOME (EXPENSE):				
Interest income	1,337	217	3,877	701
Interest expense	(165)	(220)	(533)	(617)
Foreign currency loss				(125)
Other income (expense) net	1,172	(3)	3,344	(41)
NET LOSS	(15,852)	(4,193)	(41,298)	(19,109)
PREFERRED STOCK DIVIDENDS AND ACCRETION	(100)	(2,740)	(1,186)	(8,169)
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	$ (15,952)	$ (6,933)	$ (42,484)	$ (27,278)
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER SHARE BASIC AND DILUTED	$ (0.71)	$ (4.01)	$ (2.13)	$ (15.84)
WEIGHTED AVERAGE SHARES OUTSTANDING BASIC AND DILUTED	22,431	1,727	19,952	1,722

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)

	Nine Months Ended September 30,	
	2006	**2005**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (41,298)	$ (19,109)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,261	2,116
Stock-based compensation expense related to the issuance of stock options	2,174	571
Noncash interest expense related to advance against a future milestone	169	169
Loss on disposal of equipment	35	
Noncash interest expense related to Common Stock warrants		6
Changes in assets and liabilities:		
Prepaid expenses and other current assets	484	(279)
Other non-current assets	(89)	
Accounts payable and accrued expenses	(298)	(661)
Milestones received as deferred revenue		3,974
Deferred revenue recognized	(4,097)	(6,664)
Net cash used in operating activities	(40,659)	(19,877)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of investments	(202,464)	(31,844)
Maturities of investments	166,214	50,204
Purchases of property and equipment	(1,664)	(1,930)
Net cash (used in) provided by investing activities	(37,914)	16,430
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from initial public offering of Common Stock	110,164	
Proceeds from exercise of stock options and warrants	1,536	296
Proceeds from long-term debt		2,569
Repayment of long-term debt	(1,769)	(1,687)
Net cash provided by financing activities	109,931	1,178
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	31,358	(2,269)
CASH AND CASH EQUIVALENTS Beginning of period	12,872	9,489

CASH AND CASH EQUIVALENTS End of period	$ 44,230	$ 7,220
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Cash paid for interest	$ 364	$ 491
SUPPLEMENTAL DISCLOSURE OF NONCASH INVESTING AND FINANCING ACTIVITIES:		
First month s payments withheld from long-term debt proceeds	$	$ 70
Dividends accrued for Series B Convertible Preferred Stock and Series C Convertible Preferred Stock converted to Common Stock	$ (20,877)	$

See notes to unaudited condensed consolidated financial statements.

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ALTUS PHARMACEUTICALS INC. AND SUBSIDIARY
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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 (GAAP) for interim reporting. Certain information and footnote disclosures included in the Altus Pharmaceuticals Inc. (the Company) 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 the Company s 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, 2006. These condensed consolidated financial statements should be read in conjunction with the audited financial statements as of and for the year ended December 31, 2005, which are included in the Company s Annual Report on Form 10-K, as filed with the Securities and Exchange Commission (SEC).

The condensed consolidated financial statements reflect the operations of the Company and its wholly-owned subsidiary. All intercompany accounts and transactions have been eliminated.

2. INITIAL PUBLIC OFFERING

In January 2006, the Company completed an initial public offering of 8,050,000 shares of its common stock at a public offering price of $15.00 per share. Net proceeds to the Company were approximately $110.2 million, after deducting underwriting discounts and commissions and offering expenses totaling approximately $10.6 million. Also in January 2006, prior to the initial public offering, the Company effected a 1-for-2.293 reverse stock split of its common stock. All share and per share amounts in the condensed consolidated financial statements have been retroactively adjusted for all periods presented to give effect to the reverse stock split, including reclassifying an amount equal to the reduction in par value to additional paid-in-capital.

In connection with the initial public offering, all shares of Series B Convertible Preferred Stock (Series B Preferred Stock) were converted into 5,182,651 shares of common stock, all shares of Series C Convertible Preferred Stock (Series C Preferred Stock) were converted into 5,203,059 shares of common stock and all shares of Series A Convertible Preferred Stock were converted into 381,596 shares of common stock. As a result, the Company no longer recognizes dividend and accretion expense for these classes of preferred stock. Furthermore, the Company issued an additional 872,054 shares of common stock in satisfaction of $13.1 million of accrued but unpaid dividends on the Series B Preferred Stock, and 519,774 shares of common stock were issued in satisfaction of $7.1 million of accrued but unpaid dividends on the Series C Preferred Stock. All warrants to purchase Series B Preferred Stock were automatically converted into warrants to purchase 508,214 shares of the Company s common stock at an exercise price of $9.80 per share, and all warrants to purchase Series C Preferred Stock were automatically converted into warrants to purchase 1,144,670 shares of the Company s common stock at an exercise price of $9.80 per share. All of these converted warrants became exercisable immediately upon conversion.

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3. REVENUE RECOGNITION

Contract revenue consists of non-refundable research and development funding under collaborative agreements with corporate collaborators and grants from various United States government and non-government institutions. Research and development funding generally compensates the Company for a portion or all of the costs associated with the development and testing related to the collaborative research programs or grants.

Revenue under collaboration agreements with collaborators and non-government institutions is generally recognized using the proportional performance method and is based on the percentage of costs incurred relative to the total costs estimated to be incurred to complete the research program, to the extent such amount is not greater than the cash received. The Company uses an input based measure, specifically direct costs, to determine proportional performance because, for its current agreements, the Company believes that the use of an input based measure is a more accurate representation of proportional performance than an output based measure, such as milestones. The Company believes that the direct cost method also most closely reflects the level of effort related to the Company s research and development collaborations. The impact of fluctuation in exchange rates under collaborative agreements that are denominated in a foreign currency is reflected in deferred revenue at the time cash is received and in revenue at each reporting period. The Company periodically reviews the estimated development costs and, to the extent such estimates change, the cumulative impact of such change is recorded in operations at that time. As a result, the possibility exists that revenue may increase or decrease in future periods as estimated costs increase or decrease, without additional cash inflows from the collaborative partner or non-government institution.

Specifically, with respect to its product candidate ALTU-135, the Company recognizes revenue earned under collaboration agreements using the proportional performance method of revenue recognition. During the three months ended September 30, 2006, the Company reviewed and increased the total estimated development costs relating to ALTU-135 from $118.0 million to $137.5 million. The effect of increasing total estimated development costs, using the proportional performance method of revenue recognition, resulted in a cumulative negative revenue adjustment through September 30, 2006 of $3.7 million which resulted in negative revenue of $2.0 million and revenue of $4.0 million for the three and nine-months ended September 30, 2006, respectively.

Payments received in advance of revenue recognized under collaborative agreements are recorded as deferred revenue. Since the payments received under the collaborative agreements are non-refundable, the termination of a collaborative agreement prior to its completion could result in an immediate recognition of deferred revenue relating to payments already received from the collaborative partner but not previously recognized as revenue.

Research and development funding under grants from the United States government and its agencies is recognized as revenue as development costs are incurred and billed in accordance with the terms of the grant.

4. STOCK-BASED COMPENSATION

In December 2004, the Financial Accounting Standards Board (FASB) issued SFAS No. 123(R), *Share-Based Payment* (SFAS 123(R)). On January 1, 2006, the Company adopted SFAS 123(R), as required, using the modified prospective application method. The Company will continue to determine the fair value of equity instruments using the Black-Scholes option-pricing model and to recognize compensation cost ratably over the appropriate vesting period.

Prior to January 1, 2006, the Company had accounted for stock-based compensation in accordance with the fair value recognition provisions of SFAS 123, *Accounting for Stock-Based Compensation* , which are similar to those in SFAS 123(R), except that SFAS 123 allowed forfeitures to be accounted for as they occur. Under the modified prospective application method, the compensation expense relating to the unvested portion of previously granted

awards at the adoption date is adjusted for estimated forfeitures, and the adjusted compensation expense is recognized ratably over the remaining vesting period. Pre-vesting forfeitures for all grants awarded after January 1, 2006 and for the unvested portion of previously granted

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awards that were outstanding at the date of adoption of SFAS 123(R) were estimated to be approximately 2.5% per annum based on historical experience.

The following table represents stock-based compensation expense included in the Company s Condensed Consolidated Statements of Operations:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands)	2006	2005	2006	2005
Research and development	$ 531	$ 105	$ 1,217	$ 235
General, sales and administrative	439	117	957	336
Total	$ 970	$ 222	$ 2,174	$ 571

Because the Company had utilized the fair value method prescribed by SFAS 123 prior to January 1, 2006, the impact of the adoption of SFAS 123(R) did not have a material impact on the Company s comparative results.

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. When applying the Black-Scholes option-pricing model to compute stock-based compensation, the Company assumed the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Range of risk-free interest rates	4.7% - 5.1%	4.0% - 4.1%	4.4% - 5.1%	3.7% - 4.2%
Expected average option life (in years)	6.25	5.00	6.25	5.00
Volatility	75%	None	75%	None
Dividends	None	None	None	None

The expected term assumption is based upon the simplified or plain-vanilla method, provided under SAB 107 which averages the contractual term of the Company s options (10 years) with the vesting term (4 years) taking into consideration multiple vesting tranches. The Company is allowed to use the plain-vanilla method for all options granted prior to or on December 31, 2007. Upon the Company s initial filing of its Form S-1 Registration Statement on October 17, 2005, the Company began utilizing a volatility factor in valuing options granted to employees. To determine an appropriate volatility factor, the Company reviewed volatility factors being used by a group of peer companies, and selected a volatility factor consistent with those used by this group of peers. Prior to October 17, 2005, the Company had excluded a volatility factor, as permitted for private companies under the provisions of SFAS 123(R). The Company has continued to utilize this methodology for the three and nine month periods ended September 30, 2006 due to the short length of time the Company s common stock has been publicly traded.

The Company operates the 2002 Employee, Director, and Consultant Stock Option Plan (the 2002 Plan), which replaced the 1993 Stock Option Plan (the 1993 Plan) on February 7, 2002. In January 2006, the Board of Directors authorized an additional 1,200,000 shares for future grant under the 2002 Plan. Under the 1993 and 2002 Plans, the total number of shares issuable upon exercise of outstanding stock options or available for future grant to employees, directors and consultants at September 30, 2006 was 4,281,596 shares.

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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 the Company s 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 based on a service period of four years and are determined by the Board of Directors or a delegated subcommittee or officer. 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. At September 30, 2006, the Company had no such shares outstanding. In the event of termination of an employee or the business relationship with a non-employee, the Company must repurchase all unvested shares from the optionee at the original issue price. Options granted under the 1993 and 2002 Plans expire no more than 10 years from the date of grant.

A summary of the stock option activity under the 1993 Plan and 2002 Plan is as follows:

	Shares	Weighted Average Exercise Price	Weighed Average Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Options outstanding January 1, 2006 (1,247,805 options vested)	3,056,795	$ 4.27		
Granted	1,226,034	16.29		
Exercised	(272,243)	4.33		
Canceled	(267,142)	6.28		
Options outstanding September 30, 2006	3,743,444	$ 8.06	8.2	$ 32,174*
Options exercisable September 30, 2006	2,849,751	$ 5.07	7.8	$ 31,251*
Options vested September 30, 2006	1,574,186	$ 4.71	7.2	$ 17,910*

* The intrinsic value of a stock option is the amount by which the market value of the underlying stock exceeds the exercise price of the option. The closing price of the Company s common stock was $15.97 at

September 30, 2006.

During the nine months ended September 30, 2006 and 2005, a total of 272,243 and 102,335 options were exercised, respectively. The intrinsic value of these options was $2,576,000 and $150,000, respectively. Cash received upon the exercise of stock options during these periods was $1,178,000 and $296,000, respectively, and no tax benefit was recognized from the exercises due to the Company s net operating losses. The Company issues shares for the exercise of stock options from unissued reserved shares.

The weighted-average fair value of employee options granted at exercise prices equal to fair market value during the nine months ended September 30, 2006 and 2005 was $11.81 and $1.57, respectively.

As of September 30, 2006, total unrecognized stock-based compensation expense relating to unvested employee stock awards, adjusted for estimated forfeitures, was $15,140,000. This amount is expected to be recognized over a weighted-average period of 2.9 years. If actual forfeitures differ from current estimates, total unrecognized stock-based compensation expense will be adjusted for future changes in estimated forfeitures.

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In November 2005, the FASB issued FASB Staff Position (FSP) No. FAS123(R)-3 *Transition Election Related to Accounting for Tax Effects of Share-Based Payment Awards.* The Company is considering whether to adopt the alternative transition method provided in the FSP for calculating the tax effects of stock-based compensation pursuant to SFAS 123(R). The alternative transition method includes simplified methods to establish the beginning balance of the additional paid-in-capital pool (APIC pool) related to the excess tax benefits available to absorb tax deficiencies recognized subsequent to the adoption of SFAS 123(R). The Company is evaluating which transition method it will use for calculating its APIC pool. An entity may take up to one year from the later of its initial adoption of SFAS 123(R) or the effective date of this FSP to evaluate its available transition alternatives and make its one-time election. Until and unless the Company elects the transition method described in the FSP, the transition method provided in SFAS 123(R) will be used.

5. 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 nine months ended September 30:

(In thousands)	2006	2005
Series A, B and C Convertible Preferred Stock:		
Preferred shares		10,767
Preferred stock warrants		1,653
Options to purchase Common Stock	3,743	3,034
Warrants to purchase Common Stock	3,653	2,468
Total	7,396	17,922

6. INVESTMENTS

The Company invests available cash primarily in bank certificates of deposit and investment-grade commercial paper, corporate notes and government securities. Securities that the Company has the positive intent and ability to hold to maturity are reported at amortized cost and are classified as held-to-maturity at September 30, 2006. All of the Company s investments are classified as held-to-maturity.

Investments consisted of the following at September 30, 2006:

(In thousands)	Amortized Cost	Net Unrealized Losses	Aggregate Fair Value
Corporate fixed income	$ 2,938	$ (1)	$ 2,937
Government securities	47,788	(2)	47,786
Commercial paper	2,713	(1)	2,712
Total	$ 53,439	$ (4)	$ 53,435

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Investments consisted of the following at December 31, 2005:

(In thousands)	Amortized Cost	Net Unrealized Losses	Aggregate Fair Value
Corporate fixed income	$ 10,904	$ (38)	$ 10,866
Government securities	5,985	(5)	5,980
Certificates of deposit	300	(1)	299
Total	$ 17,189	$ (44)	$ 17,145

7. RECENT ACCOUNTING PRONOUNCEMENTS

In June 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109* (FIN 48). FIN 48 clarifies the accounting for uncertainties in income taxes recognized in an enterprise s financial statements. FIN 48 requires that the Company determine whether it is more likely than not that a tax position will be sustained upon examination by the appropriate taxing authority. If a tax position meets the more likely than not recognition criteria, FIN 48 requires the tax position be measured at the largest amount of benefit greater than 50 percent likely of being realized upon ultimate settlement. This accounting standard is effective for fiscal years beginning after December 15, 2006. The Company does not believe the effect, if any, of adopting FIN 48 will have a material impact on the Company s financial position and results of operations.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* (SFAS 157), which establishes a framework for measuring fair value and expands disclosures about the use of fair value measurements and liabilities in interim and annual reporting periods subsequent to initial recognition. Prior to the issuance of SFAS 157, which emphasizes that fair value is a market-based measurement and not an entity-specific measurement, there were different definitions of fair value and limited definitions for applying those definitions in GAAP. SFAS 157 is effective for the Company on a prospective basis for the reporting period beginning January 1, 2008. The Company does not believe the effect, if any, of adopting SFAS 157 will have a material impact on the Company s financial position and results of operations.

8. CONTINGENCIES

Dr. Falk Pharma GmbH The Company s collaborator, Dr. Falk Pharma GmbH, or Dr. Falk, has asserted that there is a third-party foreign patent with claims that may be relevant to ALTU-135 and, therefore, that the Company breached a representation in its agreement with Dr. Falk and may be liable for damages under the agreement. The Company does not believe that it breached its agreement and is in discussions with Dr. Falk to resolve this matter. The Company also believes that if this patent were asserted against it, it is likely that the Company would not be found to infringe any valid claim of the patent relevant to its development and commercialization of ALTU-135. The Company cannot currently predict with certainty the outcome of this matter.

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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 for gastrointestinal and metabolic disorders, with two product candidates in clinical development. We are using our proprietary protein crystallization technology to develop protein therapies, which we believe will have significant advantages over existing products and will address unmet medical needs. Our product candidates are designed to either increase the amount of a protein that is in short supply in the body or degrade and remove toxic metabolites from the blood stream. Our two lead product candidates are: ALTU-135, for which we have completed a Phase II clinical trial in cystic fibrosis patients for the treatment of malabsorption due to exocrine pancreatic insufficiency, and ALTU-238, for which we have completed a Phase II clinical trial in adults for the treatment of growth hormone deficiency. We also have a pipeline of other product candidates in preclinical research and development. We have generated significant losses as we have advanced our lead product candidates into clinical development and expect to continue to generate losses as ALTU-135 and ALTU-238 move into later stages of clinical development. As of September 30, 2006, we had an accumulated deficit of $161.4 million.

On January 31, 2006, we completed an initial public offering of 8,050,000 shares of common stock at a price of $15.00 per share. Net proceeds to us from the offering were approximately $110.2 million (net of underwriting discounts and commissions and offering expenses of approximately $10.6 million). We are using our existing cash and short-term investments to fund a portion of the development activities for ALTU-135 and ALTU-238, and the remainder to fund research and development activities for our preclinical product candidates and general corporate purposes, including capital expenditures and working capital.

Financial Operations Overview

Revenue. Our contract revenue consists primarily of amounts earned under collaborative research and development agreements relating to ALTU-135 with Cystic Fibrosis Foundation Therapeutics Inc., or CFFTI, and Dr. Falk Pharma GmbH, or Dr. Falk.

In February 2001, we entered into a strategic alliance agreement with CFFTI to collaborate on the development of ALTU-135 and specified derivatives of ALTU-135 in North America for the treatment of malabsorption due to exocrine pancreatic insufficiency in patients with cystic fibrosis and other indications. The agreement, in general terms, provides us with funding from CFFTI for a portion of the development costs of ALTU-135 upon the achievement of specified development milestones, up to a total of $25.0 million, in return for specified payment obligations and our obligation to use good faith reasonable efforts to develop and bring ALTU-135 to market in North America. As of September 30, 2006, we had received a total of $18.4 million of the $25.0 million available under the CFFTI agreement and recognized cumulative revenue of $11.3 million. Under the terms of the agreement, we may receive an additional milestone payment of $6.6 million, less an amount determined based on when we achieve the milestone.

In December 2002, we entered into a development, commercialization and marketing agreement with Dr. Falk for the development by us of ALTU-135 and the commercialization by Dr. Falk of ALTU-135, if approved, in Europe, the countries of the former Soviet Union, Israel and Egypt (the Licensed Territory). Under the agreement, we granted Dr. Falk an exclusive, sublicensable license under specified patents that cover ALTU-135 to commercialize ALTU-135 in the Licensed Territory for the treatment of symptoms caused by exocrine pancreatic insufficiency. As of September 30, 2006, we had received upfront and milestone payments from Dr. Falk under the agreement totaling 11.0 million, which equated to $12.9 million based on exchange rates in effect at the times we received the milestone payments, and recognized cumulative revenue of $9.6 million. In addition, Dr. Falk has agreed to pay a portion of the development expenses we incur in connection with conducting an international long term safety study of ALTU-135, including costs relating to the process of obtaining regulatory approval, project management costs, statistical design and studies, and preparation of reports.

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Dr. Falk holds all commercialization and marketing rights in the licensed territory, and we are entitled to receive royalties based on the net sales of ALTU-135 in the licensed territory and revenue for the ALTU-135 product supplied by us to Dr. Falk. Under the terms of the agreement, the license to Dr. Falk will continue in each country in the licensed territory until the later of the expiration of the last-to-expire of specified patents that cover ALTU-135 in that country or 12 years from the date of first commercial sale of ALTU-135 in that country.

In addition to contract revenue under our collaborations with CFFTI and Dr. Falk, we also receive research and development funding through grants from various United States government and non-government institutions. Research and development funding generally compensates us for a portion of our costs for development and testing related to collaborative research programs or grants.

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 acquiring 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 capital resources used to develop our products and costs of facilities.

We expense research and development costs as incurred.

We have completed a Phase II clinical trial of ALTU-135 and are designing and preparing for a Phase III clinical trial of the solid form of ALTU-135 and conducting related development activities. Our current estimate of the total costs we will incur to complete the development of ALTU-135 and submit a New Drug Application, or NDA, to the U.S. Food and Drug Administration, or FDA, is approximately $137.5 million, excluding non-cash compensation expense and depreciation. This estimate was revised during the third quarter of 2006, from a previous estimate of $118.0 million. The possibility exists that we may revise this estimate again in the future. As of September 30, 2006, we had incurred approximately $66.6 million of these total costs. We have also completed a Phase II clinical trial and are designing and preparing for a Phase III clinical trial of ALTU-238. From January 1, 2003, the date on which we began separately tracking development costs for ALTU-238, through September 30, 2006, we incurred approximately $23.4 million in total development costs for this product candidate. We expect our research and development costs to increase substantially in the foreseeable future.

Product candidates in clinical development have higher associated development costs than those in the preclinical stage since the former involve testing on humans while the latter involve shorter-term animal studies. Moreover, as a product candidate moves into later-stage clinical trials, such as from Phase I to Phase II or Phase II to Phase III, the costs are significantly higher due to the increased size and length of the later stage trial.

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

We expect that general and administrative expenses will increase in the future due to increased payroll, expanded infrastructure, increased consulting, legal, accounting and investor relations expenses associated with

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being a public company and costs incurred to seek collaborations with respect to any of our product candidates. We expect that our sales and marketing costs will also increase in the future due to increased payroll and additional market research, promotion and trade show expenses as we continue to advance ALTU-135 and ALTU-238.

Interest and Other Income (Expense), Net. Interest income consists of interest earned on our cash and cash equivalents and investments. Interest expense consists of interest incurred on capital leases and other debt financings, which are primarily equipment loans. Other income (expense), net also consists of foreign currency gains (losses).

Preferred Stock Dividends and Accretion. Preferred stock dividends and accretion consists of cumulative but undeclared dividends payable and accretion of the issuance costs and warrants, where applicable, on our redeemable preferred stock and Series B and C convertible preferred stock. The issuance costs on these shares and warrants were recorded as a reduction to the carrying value of the preferred stock when issued, and are accreted to preferred stock ratably through December 31, 2010 by a charge to additional paid-in capital and earnings attributable to common stockholders. As of December 31, 2005, the cumulative dividends payable on the Series B and C convertible preferred stock totaled $20.2 million. Upon the completion of our initial public offering on January 31, 2006, the Series B and Series C convertible preferred stock converted into an aggregate of 10,385,710 shares of common stock, and the cumulative but unpaid dividends on the Series B and C convertible preferred stock were paid in an aggregate of 1,391,828 shares of common stock at the price of the common stock sold in the offering. Accordingly, we no longer record preferred dividends and accretion on the Series B and Series C convertible preferred stock.

Critical Accounting Policies and Significant Judgments and Estimates

As fully described in the Management s Discussion and Analysis of Financial Condition and Results of Operations section of our Annual Report on Form 10-K for the year ended December 31, 2005, and as discussed below, we consider our critical accounting policies to be as follows. We refer the reader to our Annual Report on Form 10-K for more information on these policies.

Accrued expenses; and

Income taxes

Revenue. Our existing collaborative agreements that generate contract revenue relate solely to ALTU-135. We recognize contract revenue under these collaborative agreements using the proportional performance method based on the percentage of costs incurred relative to the total costs estimated to be incurred to complete the program, to the extent such amount is not greater than the cash received. At each reporting period, we review the status of the product candidate in light of the most recently completed development activities and related results and the estimated remaining development costs and, to the extent such estimates change, the impact of such change on revenue is recorded in operations at that time. Significant judgments and estimates are involved in determining the estimated costs to complete the development programs, and different assumptions could yield materially different cost estimates and resulting revenue.

For the purpose of recognizing revenue, we use an input based measure, specifically, direct costs, to determine proportional performance under our collaboration agreements. We do so because we believe that for our current agreements, the use of an input measure is a more accurate representation of proportional performance than an output based measure, such as milestones. We also believe that the direct cost method most closely reflects the level of effort related to our research and development collaborations. While we have considered using an output based measure, we believe that such an approach would accelerate the recognition of revenue and result in reported revenue that would be disproportionate to the progress made in the earlier stages of development of ALTU-135, where the product development risk is highest, as well as the level of effort over the life of the agreements.

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Since the inception of our collaboration agreements with CFFTI and Dr. Falk, we have adjusted our estimated costs to complete the development program for ALTU-135 on four occasions, including during the third quarters of 2005 and 2006, resulting in cumulative changes in our revenue at each time of the change in the estimate. During the third quarter of 2005, we reduced our estimated development costs for ALTU-135, which resulted in a $3.3 million increase in our cumulative revenue in the third quarter of 2005. During the third quarter of 2006, we increased our estimated development costs for ALTU-135, which resulted in a $3.7 million decrease in our cumulative revenue in the third quarter of 2006. In addition, our agreement with Dr. Falk is denominated in Euros. Accordingly, the impact of fluctuations in exchange rates under collaborative agreements that are denominated in a foreign currency is reflected in deferred revenue at the time the cash is received and in revenue at each reporting period. The possibility exists that revenue may increase or decrease in future periods as estimated costs of the underlying program increase or decrease or as exchange rates impact the value of foreign currency denominated collaborations, without additional cash inflows from the collaborative partner or non-government institution. For example, as of September 30, 2006, if our estimated total development costs for ALTU-135 were to increase by 10%, it would result in a $1.9 million reduction of cumulative revenue. If our estimated total development costs for ALTU-135 were to decrease by 10%, it would result in a $2.3 million increase in cumulative revenue.

Contract amounts which are not due until the customer accepts or verifies the research results are not recognized as revenue until payment is received or the customer s acceptance or verification of the results is evidenced, whichever occurs earlier. Contract revenue recorded under the CFFTI agreement is recognized net of amortization of the fair value of the warrants issued in connection with the execution of the agreement.

Deferred revenue is recorded when payments are received in advance of revenue recognized under collaborative agreements. Since the payments received under the collaboration agreements are non-refundable, the termination of a collaboration agreement prior to its completion could result in an immediate recognition of deferred revenue relating to payments already received from the collaboration partner but not previously recognized as revenue.

Revenue from research and development funding under grants from the United States government and its agencies is recognized as revenue as development costs are incurred and billed in accordance with the terms of the grant. Revenue from product sales is recognized when there is persuasive evidence that an arrangement exists, delivery and, if applicable, acceptance by the customer has occurred, the price is fixed or determinable, and collectibility is reasonably assured.

Research and Development Expenses. Our research and development expenses include employee compensation and related benefits, laboratory supplies, temporary employment costs, external research costs, consulting costs, and other costs directly related to our research and development activities. Research and development expenses are incurred in conjunction with the development of our proprietary product candidates.

External research costs and expenses related to materials (e.g., active pharmaceutical ingredients, or API s), technology transfer costs (e.g. the cost of transferring our technology to a contract manufacturing organization), the cost of pre-clinical and clinical studies and analytical testing are included as research and development costs and expensed as incurred.

Stock-based Compensation. In December 2004, the FASB issued SFAS 123 (revised 2004), "*Share-Based Payment*, which is known as SFAS 123(R) and replaces SFAS 123, *Accounting for Stock-Based Compensation,* as amended by SFAS 148, *Accounting for Stock-Based Compensation-Transition and Disclosure*. Among other things, SFAS 123(R) eliminates the alternative to use the intrinsic value method of accounting for stock-based compensation. SFAS 123(R) requires public entities to recognize compensation expense for awards of equity instruments to employees based on the grant-date fair value of the awards.

We adopted SFAS 123(R) effective January 1, 2006. We applied the modified prospective application transition method of adoption. Under this application, entities must recognize compensation expense based on the grant-date fair value for new awards granted or modified after the effective date and for unvested awards

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outstanding on the effective date. The adoption of SFAS 123(R) did not have a significant impact on our condensed consolidated financial statements, since we adopted the fair value method of accounting for stock-based compensation, as described by SFAS 123, effective January 1, 2003. See Note 4 of our unaudited condensed consolidated financial statements for the disclosures required by SFAS 123(R).

Results of Operations

Three Months Ended September 30, 2006 Compared to Three Months Ended September 30, 2005

Revenue

Contract revenue for the three months ended September 30, 2006 was a net negative adjustment of $2.0 million compared to contract revenue of $4.1 million for the three months ended September 30, 2005. The net negative revenue in the 2006 period is the result of an upward adjustment in our estimate of the total estimated development costs of ALTU-135 which, under the proportional performance revenue recognition method, necessitated a $3.7 million negative revenue adjustment. This negative revenue adjustment was partially offset by $1.7 million of contract revenue recorded in the three months ended September 30, 2006 based on development activities during the period. During the three months ended September 30, 2005 we recorded a favorable catch-up revenue adjustment of $3.3 million related to a reduction of our estimated development costs in addition to $0.8 million of contract revenue based on development activities during the period. A significant portion of our contract revenue is generated from revenue recognized under the proportional performance method from collaboration agreements for ALTU-135 with CFFTI and Dr. Falk.

Research and development expense

	Three Months Ended September 30,		Change	
	2006	2005	$	%
	(dollars in thousands)			
ALTU-135	$ 4,123	$ 2,502	$ 1,621	65%
ALTU-238	3,000	2,147	853	40%
Other research and development	3,775	1,463	2,312	158%
Total research and development	$ 10,898	$ 6,112	$ 4,786	78%

Research and development expense for the three months ended September 30, 2006 increased 78% to $10.9 million from $6.1 million for the three months ended September 30, 2005, due primarily to an increase in third-party development costs relating to ALTU-135, ALTU-238 and our pre-clinical product candidates, increased non-cash compensation expense and an increase in personnel. ALTU-135 costs for the three months ended September 30, 2006 related to the manufacturing of materials for planned toxicity and Phase III studies, and additional manufacturing activities, including increased formulation and process development work for ALTU-135. ALTU-238 costs during the three months ended September 30, 2006 related to the purchase of materials for ongoing process development and formulation activities relating to our planned Phase III clinical trials, facility modification costs, technology transfer costs and validation costs relating to our clinical supply agreement with Althea Technologies, Inc. for the production of ALTU-238 Phase III product and the continuation of Phase III-related toxicology studies. In addition, we incurred increased pre-clinical costs during the three months ended September 30, 2006 associated with the development of our product candidate ALTU-237. Product candidates in clinical development have greater associated development costs than those in the research or preclinical stage, and as a product candidate moves to later stage clinical trials, such as a Phase II or Phase III clinical trial, the costs are higher due to the increased size and length of the clinical trial versus an earlier stage clinical trial. As a result, we anticipate that our research and development costs will continue to increase in coming periods. In addition, we had other preclinical product candidates advancing in our pipeline. To support the increased activities, our headcount in the research and development area increased to 98 full-time employees as of September 30, 2006 from 66 as of September 30, 2005.

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General, sales and administrative expense

General, sales and administrative expense for the three months ended September 30, 2006 increased 89% to $4.2 million from $2.2 million for the three months ended September 30, 2005, due primarily to $0.5 million of increased salaries and professional fees related to our accounting, human resource and information technology functions as total headcount increased, $0.4 million of increase in outside legal fees, $0.2 million of increased insurance costs, $0.2 million of costs associated with being a public company, and $0.3 of increased non-cash compensation expense. We expect that general and administrative expenses will continue to increase in the future due to increased payroll, expanded infrastructure, increased consulting, legal, accounting and investor relations expenses associated with being a public company and costs incurred to seek collaborations with respect to any of our product candidates. We expect that our sales and marketing costs will also increase in the future due to increased payroll and additional market research, promotion and trade show expenses as we continue to advance the development of ALTU-135 and ALTU-238.

Interest income and interest expense

Interest income for the three months ended September 30, 2006 increased to $1.3 million from $0.2 million for the three months ended September 30, 2005, due to higher average cash and investment balances resulting from the completion of our initial public offering in January 2006 and higher average interest rates on our investments.

Interest expense for the three months ended September 30, 2006 decreased 25% to $0.2 million due to a decrease in our average outstanding debt for the three months ended September 30, 2006 compared to our average outstanding debt for the three months ended September 30, 2005.

Preferred stock dividends and accretion

Preferred stock dividends and accretion for the three months ended September 30, 2006 decreased to $0.1 million from $2.7 million for the three months ended September 30, 2005 due to the automatic conversion of all shares of Series B Preferred Stock and Series C Preferred Stock into common stock in connection with the initial public offering in January 2006. The preferred stock dividends and accretion for the three months ended September 30, 2006 relates entirely to dividends and accretion on our redeemable preferred stock, which remains outstanding at September 30, 2006.

Nine Months Ended September 30, 2006 Compared to Nine Months Ended September 30, 2005

Revenue

Contract revenue for the nine months ended September 30, 2006 and 2005 was $4.0 million and $6.7 million, respectively. As a result of an increase in our estimate of the total estimated development costs for ALTU-135 in the third quarter of 2006, we recorded a negative revenue adjustment of $3.7 million, which offset contract revenue of $7.7 million for the nine months ended September 30, 2006 based on development activities during the period. For the nine months ended September 30, 2005, we recognized a favorable catch-up revenue adjustment of $3.3 million which resulted from a reduction of our estimated total development costs in the third quarter of 2005, in addition to $3.4 million of contract revenue based on development activities during the period. The increase in contract revenue in 2006 compared to 2005, absent the adjustments in each period based on changes to the estimated ALTU-135 development costs, was $4.3 million and reflect the approximate 100% increase in development efforts in the 2006 period, primarily related to manufacturing activities. During the nine months ended September 30, 2005, we also recognized $0.3 million of revenue related to government grants. We did not have any revenue related to government grants during the nine months ended September 30, 2006.

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Research and development expense

	Nine Months Ended September 30,		Change	
	2006	2005	$	%
	(dollars in thousands)			
ALTU-135	$ 18,246	$ 9,134	$ 9,112	100%
ALTU-238	10,728	5,865	4,863	83%
Other research and development	9,027	4,793	4,234	88%
Total research and development	$ 38,001	$ 19,792	$ 18,209	92%

Research and development expense for the nine months ended September 30, 2006 increased 92% to $38.0 million from $19.8 million for the nine months ended September 30, 2005, due primarily to an increase in development costs relating to ALTU-135, ALTU-238 and our pre-clinical product candidates, increased non-cash compensation expense and an increase in personnel. During the nine months ended September 30, 2006, we incurred $6.4 million in costs related to initial equipment funding payments and start up costs for the manufacture of commercial supply of ALTU-135 by a contract manufacturing organization. Other ALTU-135 costs for the period related to the manufacturing of materials for planned toxicity and Phase III studies, and additional manufacturing activities, including increased formulation and process development work for ALTU-135, as well as activities relating to a technical transfer to Amano Enzyme Inc., or Amano, of processes related to the manufacture of ALTU-135. ALTU-238 costs during the nine months ended September 30, 2006 related to the completion of a Phase II study in growth hormone deficient adults, the purchase of materials for ongoing process development and formulation activities related to our planned Phase III clinical trials, facility modification costs, technology transfer costs and validation costs relating to our clinical supply agreement with Althea and the Phase III-related toxicology studies. In addition, we incurred increased pre-clinical costs in 2006 associated with our product candidates ALTU-237 and ALTU-236. During the nine months ended September 30, 2005, we completed a Phase II clinical trial for ALTU-135. We also filed an Investigational New Drug Application, or IND, and completed a Phase I clinical trial for ALTU-238 during that period. In addition, we had other preclinical product candidates advancing in our pipeline.

General, sales and administrative expense

General, sales and administrative expense for the nine months ended September 30, 2006 increased 77% to $10.6 million from $6.0 million for the nine months ended September 30, 2005, due primarily to $1.1 million of increased salaries and professional fees related to our accounting, human resource and information technology functions, $0.6 million of increased outside legal fees, $0.9 million of increased marketing fees, $0.5 million of increased insurance costs, $0.3 million of costs associated with being a public company and $0.4 million of increased non-cash compensation expense.

Interest income and interest expense

Interest income for the nine months ended September 30, 2006 increased to $3.9 million from $0.7 million for the nine months ended September 30, 2005, due to higher average cash and investment balances resulting from the completion of our initial public offering in January 2006 and higher average interest rates on our investments.

Interest expense for the nine months ended September 30, 2006 decreased 14% to $0.5 million due to a decrease in our average outstanding debt for the nine months ended September 30, 2006 compared to our average outstanding debt for the nine months ended September 30, 2005.

Preferred stock dividends and accretion

Preferred stock dividends and accretion for the nine months ended September 30, 2006 decreased to $1.2 million from $8.2 million for the nine months ended September 30, 2005 due to the automatic conversion of all shares of Series B Preferred Stock and Series C Preferred Stock into common stock in connection with the initial public offering in January 2006.

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Liquidity and Capital Resources

On January 31, 2006, we completed an initial public offering of 8,050,000 shares of common stock, including 1,050,000 shares of common stock sold upon the exercise of the underwriters over-allotment option, at a price to the public of $15.00 per share. Net proceeds to us from the offering were approximately $110.2 million (net of underwriting discounts and commissions and offering expenses of approximately $10.6 million). We currently intend to use our existing cash resources to fund a portion of the development activities for ALTU-135 and ALTU-238, and the remainder to fund research and development activities for our preclinical product candidates and general corporate purposes, including capital expenditures and working capital. To date, we have used a portion of the net proceeds of the initial public offering consistent with our intent discussed immediately above. At September 30, 2006, we had approximately $97.7 million in cash and cash equivalents and short-term investments available to finance future operations.

Prior to the initial public offering, we financed our business primarily through the issuance of equity securities, revenues from collaboration agreements and product sales, debt financings and equipment loans and leases. In May 2004, we received net proceeds of approximately $50.4 million, net of issuance costs of approximately $0.6 million, from the private placement of our Series C convertible preferred stock and warrants. In September and December 2001, we received net proceeds of approximately $46.2 million, net of issuance costs of approximately $4.6 million, from the private placement of our Series B convertible preferred stock and warrants. Prior to September 2001, we received most of our equity and debt financing proceeds from issuances of notes, common stock and preferred stock to Vertex Pharmaceuticals, or Vertex, including redeemable preferred stock and Series A convertible preferred stock. The redeemable preferred stock is redeemable, at the option of Vertex, on or after December 31, 2010, or by us at our option at any time. The redeemable preferred stock is not convertible into common stock. Accrued but unpaid dividends on the redeemable preferred stock amounted to $1.7 million at September 30, 2006 and are expected to be approximately $2.7 million on December 31, 2010, assuming we do not exercise our right to repurchase the redeemable preferred stock prior to such date. The Series A, B and C convertible preferred stock were converted into shares of common stock upon the closing of the initial public offering. Accrued but unpaid dividends relating to the Series B and C convertible preferred stock outstanding at the time of the initial public offering were paid in shares of common stock upon the closing of the offering at a price of $15.00 per share.

Our contract revenue is primarily derived from our research and development collaborations for ALTU-135 with CFFTI and Dr. Falk. As of September 30, 2006, we had received $18.4 million from CFFTI under our strategic alliance agreement. We may receive an additional milestone payment of $6.6 million, less an amount determined based on when we achieve the milestone.

As of September 30, 2006, we had received 11.0 million, which equated to $12.9 million based on the exchange rates in effect at the time we received the milestone payments, under our development, commercialization and marketing agreement with Dr. Falk. In addition, Dr. Falk has agreed to pay a portion of the development expenses we incur in connection with conducting an international long-term safety study for ALTU-135, including costs relating to the process of obtaining regulatory approval, project management costs, statistical design and studies, and preparation of reports.

As of September 30, 2006, we are entitled to receive up to $25.6 million of future milestone payments under these two collaborations if all development milestones are met. We have no other external sources of funding.

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 nine months ended September 30, 2006 and 2005, we used approximately $40.7 million and $19.9 million in cash, respectively, to fund our operating activities. As we continue to advance our product candidates through development and begin to incur increased sales and marketing costs related to commercialization of our product candidates, we expect to incur additional operating losses until such time, if any, as our efforts result in commercially viable drug products. We do not expect our existing capital resources, together with the milestone payments and research and development funding we expect to receive, to be sufficient to fund the completion of

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the development of any of our product candidates, and we expect that we will need to raise additional funds prior to being able to market any products.

Capital expenditures totaled $1.7 million and $1.9 million in the nine months ended September 30, 2006 and nine months ended September 30, 2005, respectively, and was primarily related to equipment in support of our research and development activities and to leasehold improvements for our facilities. We expect capital expenditures to range from $2.0 million $3.0 million in 2006. However, our capital expenditures may increase depending upon the equipment requirements of any additional contract manufacturers with whom we work and our needs for additional facilities.

We have generally financed a substantial portion of our capital expenditures through equipment loans and leases under which the lender retains a security interest in the equipment. Our ability to borrow under our existing capital equipment and lease credit facilities expired on June 30, 2005. The capital equipment facility is governed by a security agreement that contains the key terms of the loans. The facility provided us with the ability to borrow at different points in time based upon our purchase of equipment. Each borrowing carries a fixed rate of interest which was established at the time of borrowing and is payable in fixed monthly installments over a four year period. Under the terms of the capital equipment lease, we lease equipment purchased under the agreement. Each lease has a four-year term with fixed monthly payments. At the end of the lease term, we will have the option to purchase the equipment from the lessor. Both facilities require us to maintain insurance on the collateral. We intend to secure additional equipment loan facilities to continue to finance a substantial portion of our future capital expenditures under equipment financing arrangements. We do not engage in off-balance sheet financing arrangements.

The following table summarizes our contractual obligations at September 30, 2006 and the effects such obligations are expected to have on our liquidity and cash flows in future periods:

Payments Due by Period
(In thousands)

	Total	October 1, 2006 to December 31, 2006	2007 Through 2008	2009 Through 2010	After 2010
Contractual Obligations (1):					
Short and long-term debt (2)	$ 4,651	$ 569	$ 3,942	$ 140	$
Capital lease obligations (2)	55	30	25		
Operating lease obligations	2,004	376	1,628		
Purchase obligations	7,034	1,294	5,695	45	
Total contractual cash obligations	$ 13,744	$ 2,269	$ 11,290	$ 185	$

(1) Excludes estimated payment of $7.2 million to Vertex in connection with its optional redemption of shares of redeemable preferred stock

on or after December 31, 2010, plus dividends accruing after that date, and amounts payable to CFFTI upon FDA approval of ALTU-135 and royalties to CFFTI on product sales of ALTU-135.

(2) Includes interest expense.

Based on our operating plans, we estimate that our net cash used in operating activities will be between $55 million and $65 million in 2006. We believe that our existing cash resources, investment securities and funding we expect to receive under our collaborations will be sufficient to finance our planned operations, including increases in spending for our ALTU-135 and ALTU-238 clinical programs and for our preclinical product candidates through the third quarter of 2007. However, over the next several years, we may require significant additional funds to conduct clinical and non-clinical trials, achieve regulatory approvals and, subject to such approvals, commercially launch ALTU-135 and ALTU-238. Our future capital requirements will depend on many factors, including the scope and progress made in our research and development activities and our clinical trials. We may also need additional funds for possible future strategic acquisitions of businesses, products or technologies complementary to our business. If additional funds are required, we may raise such funds from time

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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 growth plans and our financial condition and results of operations. 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.

Forward Looking Statements and Risk Factors

This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. The forward-looking statements reflect 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. In some cases, you can identify forward-looking statements by terms such as anticipates, believes, could, estimates, expects, intends, may, plans, potential, predicts, projects, should, expressions intended to identify forward-looking statements. Forward-looking statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. 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, 2005 under the heading Risk Factors .

Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent our estimates and assumptions 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 from what we expect. 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.

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PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not currently a party to any material legal proceedings.

ITEM 1A. RISK FACTORS

Our business is subject to numerous risks. Our existing and potential stockholders should consider carefully the risks described below and the other information in this Quarterly Report on Form 10-Q, including Management s Discussion and Analysis of Financial Condition and Results of Operations and our condensed consolidated financial statements and the related notes appearing elsewhere in this Quarterly Report on Form 10-Q. We may be unable, for many reasons, including those that are beyond our control, to implement our current business strategy. Those reasons could include unfavorable clinical trial results; delays in obtaining, or a failure to obtain, regulatory approval for our product candidates; problems that may arise under our licensing and collaboration agreements; and failure to maintain and protect our proprietary intellectual property assets. If any of the following risks actually occur, they may materially harm our business, our financial condition and our results of operations. In that event, the market price of our common stock could decline.

Risks Related to Our Business and Strategy

If we fail to obtain the additional capital necessary to fund our operations, we will be unable to successfully develop and commercialize our product candidates.

We will require substantial future capital in order to continue to complete clinical development and commercialize our clinical-stage product candidates, ALTU-135 and ALTU-238, and to conduct the research and development and clinical and regulatory activities necessary to bring our other product candidates to market. Our future capital requirements will depend on many factors, including:

- the progress and results of our toxicology studies and proposed Phase III clinical efficacy trial and long-term safety study for ALTU-135 and any other trials we may initiate based on the results of these trials or additional discussions with regulatory authorities;
- the results of our contemplated Phase III clinical trials for ALTU-238 and any other trials we may initiate;
- the timing, progress and results of ongoing manufacturing development work for ALTU-135 and ALTU-238;
- the results of our preclinical studies and testing for our earlier stage product candidates, and any decisions to initiate clinical trials if supported by the preclinical results;
- the costs, timing and outcome of regulatory review of ALTU-135 and ALTU-238, and any of our preclinical product candidates that progress to clinical trials;
- the costs of establishing sales and marketing functions, if any of our product candidates are approved, and of establishing commercial manufacturing and distribution arrangements;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our issued patents, and defending intellectual property-related claims;
- our ability to establish and maintain collaborative arrangements and obtain milestone, royalty and other payments from collaborators; and
- the extent to which we acquire or invest in businesses, products or technologies.

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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, we may be required to:

terminate or delay preclinical studies, clinical trials or other development activities for one or more of our product candidates; or

delay our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates.

Based on our operating plans, we estimate that our net cash used in operating activities will be between $55 million and $65 million in 2006. We currently expect that our existing cash resources, investment securities and payments we expect to receive under agreements with our existing collaborators will be sufficient to support the development of our product candidates and our other operations through the third quarter of 2007. We do not expect that we will be required to make any payments to our existing collaborators prior to regulatory approval of ALTU-135. However, 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 planned. We do not expect our available funds to be sufficient to fund the completion of the development of any of our product candidates, and we expect that we will need to raise additional funds prior to being able to market any products. Additional funding may not be available to us on acceptable terms, or at all.

We are obligated under our agreement with CFFTI and under the terms of our redeemable preferred stock to make significant payments upon the occurrence of specified events. We may not have sufficient resources to make these payments when they become due.

If we receive FDA approval for ALTU-135 or related products, we must pay one of our collaborators, CFFTI, an amount equal to CFFTI s aggregate funding to us plus interest, up to a maximum of $40.0 million, less the fair market value of the shares of common stock underlying the warrants we issued to CFFTI. This amount, together with accrued interest, will be due in four annual installments, commencing 30 days after the approval date. We will also be required to pay an additional $1.5 million to CFFTI within 30 days after the approval date. These initial payments to CFFTI, if we receive FDA approval of ALTU-135, will be due before we receive revenue from commercial sales of the product, which could require us to raise additional funds or make it difficult for us to make the payments in a timely manner. In addition, if the holder of our redeemable preferred stock elects to redeem those shares on or after December 31, 2010, we will be required to pay an aggregate of $7.2 million plus dividends accruing after that date. We may require additional funding to make any such payments. Additional funds may not be available to us on acceptable terms, or at all.

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 September 30, 2006, our accumulated deficit was $161.4 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 our collaboration agreements, and payments for funded research and development, as well as from products we no longer sell. We expect that our annual operating losses will increase over the next several years as we expand our research, development and commercialization efforts to advance ALTU-135, ALTU-238 and our other product candidates towards commercialization.

We must generate significant revenue to achieve and maintain profitability. All of our product candidates are still in early-to-mid stages of 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 or achieve or maintain profitability. Our failure to become and remain profitable would 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.

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

Competition in the pharmaceutical and biotechnology industries is intense and expected to increase. We face competition from pharmaceutical and biotechnology companies, as well as numerous academic and research institutions and governmental agencies engaged in drug discovery activities or funding, both in the United States and abroad. Some of these competitors may have greater financial resources than us and 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. In addition, there may be others of which we are unaware.

ALTU-135. If approved, ALTU-135, the product candidate we are developing for the treatment of malabsorption due to exocrine pancreatic insufficiency, will compete with currently marketed porcine-derived pancreatic enzyme replacement therapies from companies such as Axcan Pharma, Johnson & Johnson, and Solvay Pharmaceuticals, as well as from generic drug manufacturers such as KV Pharmaceutical and IMPAX Laboratories. In addition, we understand that Biovitrium and Eurand have product candidates in clinical development that could compete with ALTU-135.

ALTU-238. If approved, ALTU-238, the product candidate we are developing as a once-weekly treatment for hGH deficiency and related disorders, will compete with approved hGH therapies from companies such as Eli Lilly, Genentech, Novo Nordisk, Pfizer, Sandoz, Serono 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.

Existing products to treat exocrine pancreatic insufficiency have been marketed in the United States since before the passage of the Federal Food, Drug, and Cosmetic Act, or FDCA, in 1938 and are currently marketed without FDA-approved NDAs. In 1995, the FDA issued a final rule requiring that these pancreatic enzyme products be marketed by prescription only, and in April 2004, the FDA issued a notice that manufacturers of these products will be subject to regulatory action if they do not obtain approved NDAs for their products by April 28, 2008. Despite the FDA s announced position, the agency may not pursue regulatory action against these companies if they fail to meet the 2008 deadline because there are currently no other products on the market for the treatment of exocrine pancreatic insufficiency. The level of competition that ALTU-135, if approved, will face from these products in the United States will depend on whether the manufacturers of these products obtain approved NDAs by the deadline set by the FDA and, if they are unable to do so, whether the FDA takes regulatory action against these manufacturers and the nature of any such action. The nature of the competition that ALTU-135, if approved, faces from existing pancreatic enzyme products could affect the market acceptance of ALTU-135 or require us to lower the price of ALTU-135, which would negatively impact our margins and our ability to achieve profitability.

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, and 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, and the terms of such securities may include liquidation or other preferences that adversely affect the rights of our existing stockholders. In addition, many of the warrants that we have issued contain anti-dilution provisions that will result in the issuance of additional shares of common stock upon exercise, and thus further dilution, if we issue or are deemed to issue equity at a per share price less than the exercise price of the warrants. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures, or declaring dividends. If we raise

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additional funds through collaboration and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us.

We may not be successful in maintaining our existing collaborations or in establishing and maintaining additional 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, particularly with regard to development, regulatory approval, sales, marketing and distribution of our products outside of North America. We may also collaborate with other companies to accelerate the development of some of our early-stage product candidates, to co-commercialize our product candidates in North America in instances where we believe that a larger sales and marketing presence will expand the market or accelerate penetration, 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. 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.

For example, we have entered into a collaboration agreement with CFFTI under which we have received significant funding for the development of ALTU-135. We are also eligible to receive an additional payment if we achieve a specified milestone under the agreement. Additionally, the collaboration provides us with access to the Cystic Fibrosis Foundation s network of medical providers, patients, researchers and others involved in the care and treatment of cystic fibrosis patients. Our agreement with CFFTI provides for an exclusive license from us to CFFTI, and an exclusive sublicense back with a right to further sublicense from CFFTI, of intellectual property rights covering the development and commercialization of ALTU-135 in North America. The agreement with CFFTI requires us to use commercially reasonable efforts to develop and commercialize ALTU-135 in North America for the treatment of malabsorption due to exocrine pancreatic insufficiency in patients with cystic fibrosis and other indications. We are also required to meet specified milestones under the agreement by agreed upon dates. If we are unable to satisfy our obligations under the agreement, we may lose further funding under the agreement and lose our exclusive sublicense to ALTU-135 in North America, which will materially harm our business.

We are in discussions with our collaborator Dr. Falk regarding its claim that we have breached a representation in our collaboration agreement. If we are unable to successfully resolve this matter, our business may be materially harmed.

We have entered into a collaboration agreement with Dr. Falk. We have received substantial funding from Dr. Falk for the development and commercialization of ALTU-135 in Europe, the countries of the former Soviet Union, Egypt and Israel, and we are eligible to receive additional payments if we achieve specified milestones under the agreement. Dr. Falk has asserted that there is a third-party European patent issued in specified countries, including Germany, France and the United Kingdom, with claims that may be relevant to ALTU-135 and, therefore, that we breached a representation in our agreement with Dr. Falk and may be liable for damages under our agreement. We do not believe that we breached our agreement, and we are in discussions with Dr. Falk to resolve this matter. We also believe that if this patent were asserted against us, it is likely that we would not be found to infringe any valid claim of the patent relevant to our development and commercialization of ALTU-135. However, if the patent were successfully asserted against us or Dr. Falk and we were unable to obtain a license on commercially acceptable terms, we and Dr. Falk would be prevented during the patent term from commercializing ALTU-135 in the covered countries. Based on our current development timeline for ALTU-135 in Europe and excluding any patent term extensions, we expect that the patent in question would expire approximately three years after we would expect to receive marketing authorization for ALTU-135 in Europe. We may not reach a resolution of this matter with Dr. Falk, or prevail if the patent were asserted against us, or, if necessary, be able to

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obtain a license under the patent on commercially acceptable terms, if at all. If we are unable to do so, our business could be materially harmed.

Risks Related to Development of Our Product Candidates

If we are unable to commercialize either of 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 ALTU-135 and ALTU-238, for the treatment of gastrointestinal and metabolic disorders. Our ability to successfully develop and commercialize ALTU-135 and ALTU-238, and therefore our ability to generate revenues, will depend on numerous factors, including:

- successfully scaling up the manufacturing processes for, and obtaining sufficient supplies of, ALTU-135 and ALTU-238 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 products with contract manufacturers whose manufacturing facilities are operated 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 or through third parties;
- establishing favorable pricing from foreign regulatory authorities; and
- obtaining commercial acceptance of ALTU-135 and ALTU-238, if approved, in the medical community and by third-party payors.

If we are not successful in commercializing ALTU-135 or 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 conducted 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 processes 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.

We have not yet completed late-stage clinical trials for our two lead product candidates, and we have not advanced, and may never advance, any of our other product candidates into clinical trials. We have completed a Phase II clinical trial for the solid form of ALTU-135 and plan to conduct a Phase III clinical trial for ALTU-135 beginning in the second quarter of 2007. In order for ALTU-135 to be approved by the FDA, we will be required to demonstrate in the Phase III clinical trial, to a statistically significant degree, that ALTU-135 improves absorption of fat in patients suffering from malabsorption as a result of exocrine pancreatic insufficiency. We will also be required to demonstrate the safety of ALTU-135 in a long-term study. However, we may not be successful in meeting the primary or secondary endpoints for this Phase III trial or the goal of the long-term safety study. The possibility exists that even if these trials are successful, we may still be required to perform additional studies for approval or in order to achieve a broad indication for the labeling of the drug. In addition, we will need to complete specified toxicology studies in animals before submitting an NDA, and the results of those studies may not demonstrate sufficient safety.

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For ALTU-238, we have completed a Phase I clinical trial in healthy adults and a Phase II clinical trial in adults with hGH deficiency. Our current plan is to conduct additional clinical trials for ALTU-238 including a Phase III clinical trial in adults with hGH deficiency and a Phase II dose-finding study in children with hGH deficiency, to be followed by a Phase III trial in children with hGH deficiency. We have not yet tested the efficacy of ALTU-238 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 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.

In connection with our completed Phase II clinical trial of ALTU-135, there was one serious adverse event considered by an investigator in our clinical trials as probably or possibly related to treatment with that product candidate. There have not been any serious adverse events related to our other product candidates. The one serious adverse event in our Phase II clinical trial of ALTU-135 involved a subject in the lowest dose group who developed distal intestinal obstructive syndrome, or DIOS, which resolved itself without further complications. DIOS is a unique condition to cystic fibrosis and occurs due to the accumulation of viscous mucous and fecal material in the colon. According to a 1987 study, DIOS is relatively common in cystic fibrosis patients, occurring in about 16% of those patients. In our Phase II clinical trial of ALTU-135 we also observed elevated levels of liver transaminases, which can be associated with harm to the liver. These elevations were transient and asymptomatic and were not reported as drug-related serious adverse events. Elevation of liver transaminases is common among cystic fibrosis patients. The elevations we observed may or may not have been caused by ALTU-135. The increases we observed were not associated with increases in bilirubin, which are typically associated with harm to the liver.

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 pre-clinical or clinical trials, make changes in labeling of any such products, reformulate any such products, or implement changes to or obtain new approvals of our or our contractors 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.

If clinical trials for our product candidates are prolonged or delayed, we may be unable to commercialize our product candidates on a timely basis, or at all, which would require us to incur additional costs and delay our receipt of any revenue from potential product sales.

We may encounter problems with our ongoing or planned clinical trials that will cause us or a regulatory authority to delay or suspend those clinical trials or delay the analysis of data derived from them. A number of

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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 obtain regulatory approval for, and to market and sell, a particular product candidate, including our clinical-stage product candidates, ALTU-135 and ALTU-238:

- conditions 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 participation in our clinical trials;
- delays in the completion of manufacturing development work for ALTU-135 and ALTU-238;
- 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 finding pediatric subjects with hGH deficiency who have not previously received hGH therapy for our pediatric trials of ALTU-238;
- high drop-out rates of subjects in our clinical trials;
- negative or inconclusive results from clinical trials, or results that are inconsistent with earlier results, that necessitate additional clinical studies;
- serious or unexpected drug-related 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.

Our clinical trials may not begin as planned, may need to be redesigned, and may not be completed on schedule, if at all. On July 24, 2006, we announced that we expect to perform additional manufacturing development work before initiating the planned Phase III clinical trial of ALTU-135, in order to ensure a consistent production process for that product candidate. In addition, on that same date, we announced that the delivery of certain equipment for the production of ALTU-238 had been delayed, which will result in a delay in the initiation of planned Phase III trials of ALTU-238. Delays in our clinical trials may result in increased development costs for our product candidates, which would cause our stock price to decline and could limit our ability to obtain additional financing. In addition, if one or more of our clinical trials are delayed, our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates, including our clinical-stage product candidates, ALTU-135 and ALTU-238, could be significantly reduced.

Conducting clinical studies in Eastern Europe involves risks not typically associated with U.S. studies which may result in timing, cost and/or quality problems in our Phase III studies for ALTU-238.

We expect that a large number of the patients in our upcoming clinical trials for ALTU-238 will be enrolled in Eastern European countries. We plan to conduct these trials in compliance with good clinical practices. However, ensuring compliance with good clinical practices at Eastern European clinical sites will involve risks, including risks associated with language barriers and the fact that some European clinical investigators have only limited experience in conducting clinical studies in accordance with standards set forth by the FDA and the European Medicines Agency, or EMEA. We will seek to mitigate this risk by monitoring and auditing the ongoing performance of our study, using both our employees and outside contract research organizations, to ensure compliance with good clinical practices and all other regulatory requirements. Failure to attain and document good clinical practices compliance would adversely impact the value of any data generated from these trials. In addition, should it require more time or money than we currently anticipate to perform any required site training, monitoring or auditing activities, these trials could be delayed, exceed their budgets, or both, which could have a material adverse impact on our business.

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

If we 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-135, ALTU-238 and any other product candidates we may discover or acquire and seek to commercialize 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, rigorous preclinical testing and clinical trials and an extensive regulatory review process must be successfully completed 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. Our product candidates may fail to receive regulatory approval for many reasons, including:

- our failure to demonstrate to the satisfaction of the FDA or comparable foreign regulatory 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;
- our inability to demonstrate that a product candidate s benefits outweigh its risks;
- our 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 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 manufacturers with which we contract for clinical and commercial supplies; and
- a change in the approval policies or regulations of 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 our 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 we may market the product. It is possible that none of our existing product candidates or any product candidates we may seek to develop in the future 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 our collaborators from marketing our products internationally.

We intend to have our product candidates marketed outside the United States, including in Germany, Japan, the United Kingdom, France and the countries of the former Soviet Union. In order to market products in the European Union and many other non-United States jurisdictions, we or our collaborators must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. We have no experience in obtaining foreign regulatory approvals. 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 may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks

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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 or our collaborators 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 milestones or royalties in our collaboration agreements.

We also face challenges arising from the different regulatory requirements imposed by United States and foreign regulators with respect to clinical trials. The EMEA often imposes different requirements than the FDA with respect to the design of a pivotal Phase III clinical trial. For example, we believe that based on our interactions with the EMEA, we will be required to compare ALTU-135 with a currently marketed pancreatic enzyme replacement therapy. Our agreement with Dr. Falk contemplates that we will conduct a combined Phase III clinical trial, with both United States and European clinical sites, to be performed in a manner consistent with the requirements of both the FDA and the EMEA. However, the FDA does not require a comparison of ALTU-135 with a currently marketed pancreatic enzyme replacement therapy and in light of what we believe to be the different requirements of the FDA and EMEA, we are developing with Dr. Falk an alternate strategy for the Phase III clinical development of ALTU-135 in the European Union.

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. Even if regulatory approval of a product is granted, the approval may be subject to limitations on the uses 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 expands after approval because it is typically used by a greater number 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;

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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 or our collaborators are slow to adapt, or are unable to adapt, to changes in existing regulatory requirements or adoption of new regulatory requirements or policies, we or our collaborators 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.

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. We and our manufacturers 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 million, should be sufficient for typical risks regarding our handling of these materials, it may not be sufficient to cover 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 a manufacturing capacity, 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 ALTU-135, ALTU-238 or any of the compounds that we are testing in our preclinical programs, and we lack the 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 active pharmaceutical ingredients, or APIs, for our product candidates and to produce and package our drug products. 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, 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.

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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 single manufacturer for the clinical supply of each of our product candidates, and we have no arrangements in place for the commercial supply of any of our product candidates, which could delay or prevent the clinical development and commercialization of our product candidates.

We currently depend on a single source supplier for each of our product candidates. Any disruption in production, inability of a supplier to produce adequate quantities 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 do not currently have any agreements in place to manufacture our product candidates on a commercial scale. In order to commercialize our product candidates, our existing suppliers will need to scale up their manufacturing of our product candidates and transfer the technology to a commercial supplier. We may be required to fund capital improvements to support scale-up of manufacturing and related activities. Our existing manufacturers may not be able to successfully increase their manufacturing capacity for any of our product candidates for which we obtain marketing approval in a timely or economic manner, or at all. We may need to engage other manufacturers to provide commercial supplies of our product candidates. It may be difficult for us to enter into commercial supply arrangements on a timely basis or on acceptable terms, which could delay or prevent our ability to commercialize our product candidates. If our existing manufacturers are unable or unwilling to increase their manufacturing capacity or we are unable to establish alternative arrangements, the development and commercialization of our product candidates may be delayed or there may be a shortage in supply.

With respect to ALTU-135, we currently rely on two contract manufacturers to supply us with ALTU-135. Amano Enzyme Inc., located in Nagoya, Japan, is the sole supplier of the enzymes that comprise the APIs for ALTU-135 and Patheon Inc., located in Ontario Canada is the sole manufacturer of the ALTU-135 drug product which contains the three APIs. Both Amano and Patheon have only supplied us with materials for our clinical trials and our toxicology studies, and we do not have an arrangement with either organization for the commercial supplies of ALTU-135. In addition, Amano s manufacturing facility that produces the APIs for ALTU-135 has not been inspected or approved by the FDA, EMEA or the Japanese Ministry of Health, Labour and Welfare. Pursuant to our agreement with Amano, they have notified us that they will not be the primary manufacturer of the APIs for the initial commercial supply of ALTU-135.

We are in the process of selecting a commercial manufacturer of the APIs for ALTU-135. Switching manufacturers will require cooperation with Amano, technology transfers, training, and validation of the alternative manufacturer s processes. 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 to supply the APIs for ALTU-135 at an acceptable cost, our commercialization of ALTU-135 could be delayed, prevented or impaired, including an increase in our costs of obtaining the APIs for ALTU-135. Any dispute over the terms of, or decisions regarding, our collaboration with Amano or other adverse developments in our relationship would materially harm our business and might accelerate our need for additional capital.

With respect to ALTU-238, we have purchased the hGH, the API in ALTU-238, for our clinical trials to date from Sandoz. We will need additional supplies of hGH to complete our development program and are also negotiating with several manufacturers for the long-term, commercial supply of hGH. On August 15, 2006, we entered into an agreement with Althea Technologies, Inc., or Althea, a contract manufacturing organization, to use the hGH supplied by Sandoz to manufacture ALTU-238 for use in the planned Phase II clinical trial in children and the planned Phase III clinical trials in adults and children with hGH deficiency. In order for Althea to successfully produce materials for these trials, we will need to transfer and validate the process for manufacturing ALTU-238 and they will need to complete renovations to their facility including the installation and qualification

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of specialized manufacturing equipment. Delays in these activities could delay our planned clinical trials for ALTU-238 and result in additional unforeseen expenses.

In addition, our agreement with Althea covers only the manufacture of ALTU-238 for our planned clinical trials of ALTU-238. We will need to negotiate an additional agreement under which Althea would manufacture and supply our needs for the commercial supply of ALTU-238 or find an alternative commercial manufacturer. Switching manufacturers would require cooperation with Althea, technology transfers, training, and validation of the alternative manufacturer s processes. 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, our 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.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or regulatory approval of our product candidates or commercialization of any approved products.

The failure of any of our contract manufacturers 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 have limited control over third-party manufacturers compliance with these regulations and standards. Our present or future manufacturers might not be able to comply with cGMP and other FDA regulatory requirements or similar regulatory requirements outside of the United States.

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

Our current sales or collaboration agreements or any that we may enter into with respect to our product development candidates may reduce the control we have over the development and commercialization of our product candidates. Our current or future partners 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. Any partner may be unwilling or

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unable to fulfill its obligations to us, including its development and commercialization responsibilities. Our partners 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, the possibility exists that, our collaborators may develop and commercialize, either alone or with others, 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 would be materially and adversely affected for that reason.

Risks Related to Commercialization of Our Product Candidates

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate product revenue.

We have no commercial products, and we do not currently have an organization for the sales and distribution of pharmaceutical products. In order to successfully commercialize any products that may be approved in the future by the FDA or comparable foreign regulatory authorities, we must build our sales and marketing capabilities or make arrangements with third parties to perform these services. Though we currently plan to retain North American commercialization rights to our products in circumstances where we believe that we can successfully commercialize such products on our own, we may not be able to successfully develop our own sales and marketing force for product candidates for which we have retained marketing rights. If we develop our own sales and marketing capability, we may be competing with other companies that currently have experienced and well-funded sales and marketing operations.

In addition, we may co-commercialize our product candidates in North America with pharmaceutical and biotechnology companies to achieve a variety of business objectives including expanding the market or accelerating penetration. If we do enter into arrangements with third parties to perform sales and marketing services, our product revenues will be lower than if we directly sold and marketed our products and any revenues received under such arrangements will depend on the skills and efforts of others. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and may not become profitable.

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

Even if we receive regulatory approval for ALTU-135, ALTU-238 or any other product candidates we may develop or acquire in the future, these product candidates may not gain market acceptance among physicians, healthcare payors, patients and 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;
- ineffective marketing and distribution support;
- timing of market introduction of competitive products.
- lack of availability of reimbursement from managed care plans and other third-party payors;
- lower demonstrated clinical safety and efficacy compared to other products;
- other potential advantages of alternative treatment methods;
- lack of cost-effectiveness; and

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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.

We might need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of any future products to such payors satisfaction. Such studies might require us to commit a significant amount of management time and financial and other resources. Our future products might not ultimately be considered cost-effective. Adequate third-party reimbursement might not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in product development.

Governments continue to propose and pass legislation designed to reduce the cost of healthcare. In the United States, we expect that there will continue to be federal and state proposals to implement similar governmental controls. For example, in December 2003, Congress enacted a limited prescription drug benefit for Medicare recipients in the Medicare Prescription Drug and Modernization Act of 2003. While this program may increase demand for our products, if we participate in this program, our prices will be negotiated with drug procurement organizations for Medicare beneficiaries and are likely to be lower than we might otherwise obtain. In some foreign markets, the government controls the pricing of prescription pharmaceuticals. In these countries, pricing negotiated with governmental authorities can take six to 12 months or longer after the receipt of regulatory marketing approval for a product. Cost control initiatives could decrease the price that we would receive for any products in the future, which would limit our revenue and profitability. Accordingly, legislation and regulations affecting the pricing of pharmaceuticals might change before our product candidates are approved for marketing. Adoption of such legislation could further limit reimbursement for pharmaceuticals.

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 us of our product candidates. We have product liability insurance covering our clinical trials in the amount of $5 million, which we currently believe is adequate to cover any 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;

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regulatory investigations that could require costly recalls or product modifications;
litigation costs; and
the diversion of management s attention from managing our business.

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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, 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 on our ability to obtain, maintain and enforce our intellectual property rights 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 these 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 can involve substantial costs and distraction. If the outcome of such litigation 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 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 we or they were the first to make the inventions claimed in patents or pending patent applications, or that we or they 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. Such patents may not, however, prevent our competitors from developing products using the same APIs but different technology that is 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 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, which 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 certain issued United States and/or foreign patents that may be relevant to our development and commercialization of ALTU-135 and ALTU-238. 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 ALTU-135 or ALTU-238, our development and commercialization of these products could be materially adversely affected. With respect to one of these patents, Dr. Falk, which holds a license from us to commercialize ALTU-135 in Europe, has asserted that we would be liable for damages to Dr. Falk if the patent were successfully asserted against us. We do not believe that Dr. Falk s assertion has merit, and we are in discussions with Dr. Falk concerning this matter. The outcome of these discussions is uncertain.

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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. We and our collaborators may enforce our patent rights under the terms of our major collaboration and license agreements, but neither 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 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

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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 license development or commercialization 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.

Several of our collaboration 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. For example, under the terms of our strategic alliance agreement with CFFTI, we granted CFFTI an exclusive license under our intellectual property rights covering ALTU-135 and specified derivatives for use in all applications and indications in North America, and CFFTI granted us back an exclusive sublicense of the same scope, including the right to grant sublicenses. CFFTI has the right to retain its exclusive license and terminate our sublicense if we fail to meet specified development milestones, there occurs an unresolved deadlock under the agreement and we discontinue our development activities, there occurs a material default in our obligations under the agreement not cured on a timely basis, including a failure to make required license fee payments to CFFTI on a timely basis if ALTU-135 is approved by the FDA, or a bankruptcy or similar proceeding is filed by or against us. The retention by CFFTI of its exclusive license to ALTU-135 and termination of our sublicense would have a material adverse effect on our business.

In addition, we rely on Amano s intellectual property relating to the manufacturing process used to produce the APIs for ALTU-135, as well as upon technology jointly developed by us and Amano related to the production of those enzymes. Amano is required to grant a license to us of its proprietary technology and its rights under technology jointly developed during our collaboration, which we may sublicense to contract manufacturers we mutually select. Our agreement with Amano requires us to pay Amano a royalty based on the cost of the materials supplied to us by other contract manufacturers. If we were to breach our agreement with Amano, we would be required to pay Amano a royalty based on net sales of ALTU-135 to retain our rights to Amano s independently and jointly-developed process technology.

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Risks Related to Our Employees and Growth

Our future success depends on our ability to retain our chief executive officer, our chief scientific officer and other key executives and to attract, retain and motivate qualified personnel.

We are a small company with 136 employees as of September 30, 2006. Our success depends on our ability to attract, retain and motivate highly qualified management and scientific personnel. In particular, we are highly dependent on Sheldon Berkle, our President and Chief Executive Officer, Dr. Alexey L. Margolin, our Chief Scientific Officer, and the other principal members of our executive and scientific teams. All of the arrangements with these principal members of our executive and scientific teams may be terminated by us or the employee at any time without notice. Although we do not have any reason to believe that we may lose the services of any of these persons in the foreseeable future, 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 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 scientific personnel from universities and research institutions. We do not maintain key person insurance on any of our employees other than Dr. Margolin. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research, clinical development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

We intend to grow our company, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations over the next several years. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, and continue to recruit and train additional qualified personnel. Due to our limited resources, we may not be able to effectively manage the expansion of our operations or to recruit and train additional qualified personnel. 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

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. However, the stock market 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. Some of the factors that may cause the market price of our common stock to fluctuate include:

- results of clinical trials or studies for our product candidates;
- our entry into or the loss of a significant collaboration;
- results of clinical trials conducted by others on drugs that would compete with our product candidates;
- delays or other problems with manufacturing our product candidates or approved products;

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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 developments or enforcement 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;

public concern over our product candidates or any approved products;

litigation;

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

general market conditions;

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; and

period-to-period fluctuations in our financial results.

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 outcome. Such a lawsuit could also divert the time and attention of our management.

Insiders have substantial control over us which could delay or prevent a change in corporate control or result in the entrenchment of management and the board of directors.

Our directors and executive officers, together with their affiliates and related persons as of September 30, 2006, beneficially owned, in the aggregate, approximately 38% of our outstanding common stock. As a result, these stockholders, if acting together, may have the ability to determine the outcome of matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these persons, acting together, may have the ability to control the management and affairs of our company. Accordingly, this concentration of ownership may harm the market price of our common stock by:

delaying, deferring or preventing a change in control;

entrenching our management and the board of directors;

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impeding a merger, consolidation, takeover or other business combination involving Altus; or

discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of Altus.

Entities affiliated with Warburg Pincus Private Equity VIII, L.P., or Warburg Pincus, one of our principal stockholders, are entitled to designate up to two individuals as candidates to our board of directors, for so long as Warburg Pincus owns at least 2,691,935 shares of our common stock, or one individual for so long as Warburg Pincus owns at least 1,794,623 shares of our common stock. We have agreed to nominate and use our reasonable efforts to cause the election of such candidates. Currently, Stewart Hen and Jonathan S. Leff are the members of our board of directors designated by Warburg Pincus.

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 22,674,735 shares of common stock outstanding as of September 30, 2006. Holders of an aggregate of 12,747,339 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 be 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

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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

(a) Recent Sales of Unregistered Securities

During the three months ended September 30, 2006, common stock warrants were exercised on a net issuance exercise basis, resulting in 187,427 shares of common stock that were not registered under the Securities Act of 1933, as amended, or the Securities Act. These shares were issued pursuant to the exemption from registration provided by Section 4(2) of the Securities Act.

(b) Use of Proceeds from Registered Securities

We registered shares of our common stock in connection with our initial public offering under the Securities Act. Our Registration Statement on Form S-1 (No. 333-129037) in connection with our initial public offering was declared effective by the SEC on January 25, 2006. The offering commenced as of January 26, 2006 and did not terminate before all securities were sold. The offering has terminated. The offering was co-managed by Merrill Lynch & Co., Morgan Stanley and S.G. Cowen. A total of 8,050,000 shares of common stock were registered and sold in the initial public offering, including 1,050,000 shares of common stock sold upon exercise of the underwriters over-allotment option. No payments for expenses related to the initial public offering were made directly or indirectly to (i) any of our directors, officers, or their associates, (ii) any person owning 10% or more of any class or our equity securities, or (iii) any of our affiliates. The net proceeds of approximately $110.2 million from the initial public offering are invested in investment grade securities. The dollar weighted average effective maturity of the portfolio is less than nine months, and no security has an effective maturity in excess of 18 months. As of September 30, 2006, we have used a portion of the net proceeds of the initial public offering to fund our operations including preparatory activities for the Phase III trial for the solid form of ALTU-135, preparatory activities for the Phase III trial of ALTU-238, including manufacturing related activities, activities related to the development of our preclinical product candidates and general corporate purposes. There has been no material change in the planned use of proceeds from our initial public offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b).

(c) Repurchase of Equity Securities

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

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

None.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

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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.

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 November 14, 2006.

ALTUS PHARMACEUTICALS INC.

By /s/ Sheldon Berkle

Sheldon Berkle
President and Chief Executive Officer

By /s/ Jonathan I. Lieber

Jonathan I. Lieber
Vice President, Chief Financial Officer
and Treasurer

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Exhibit Index

Exhibit Number	Description of Exhibit
10.1+	Drug Product Production and Clinical Supply Agreement by and between Altus Pharmaceuticals Inc. and Althea Technologies, Inc., dated as of August 15, 2006
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

+ Confidential treatment has been requested for portions of this exhibit.