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

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**FORM 10-Q**

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**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**

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

**Commission File Number 000-**

**ACHILLION PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**52-2113479**  
(I.R.S. Employer  
Identification No.)

**300 George Street, New Haven, CT**  
(Address of principal executive offices)

**06511**  
(Zip Code)

**(203) 624-7000**  
(Registrant's telephone number, including area code)

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  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or 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  Accelerated filer  Non-accelerated filer

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

As of November 15, 2006, the registrant had 15,523,637 shares of Common Stock, \$0.001 par value per share, outstanding.

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**PART I. FINANCIAL INFORMATION**

**ITEM 1. FINANCIAL STATEMENTS**

**Achillion Pharmaceuticals, Inc.**  
**Balance Sheets**  
**(in thousands, except per share amounts)**  
**(Unaudited)**

	September 30, 2006	December 31, 2005
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 14,459	\$ 9,583
Accounts receivable	615	761
Prepaid expenses and other current assets	1,887	707
Total current assets	16,961	11,051
Fixed assets, net	2,107	2,295
Other non-current assets	322	404
Total assets	<u>\$ 19,390</u>	<u>\$ 13,750</u>
<b>Liabilities and Stockholders' (Deficit) Equity</b>		
Current liabilities:		
Current portion of long-term debt	\$ 3,528	\$ 2,083
Accounts payable	957	896
Accrued expenses	2,892	2,216
Deferred revenue	2,172	5,202
Total current liabilities	9,549	10,397
Long-term debt, net of current portion	6,188	4,373
Accrued expenses, net of current portion	265	267
Other long-term liabilities	483	381
Total liabilities	16,485	15,418
Redeemable Convertible Preferred Stock:		
Series A Preferred Stock, \$.01 par value; 250 shares authorized, issued and outstanding at December 31, 2005 and September 30, 2006 (liquidation preference of \$250 at December 31, 2005 and September 30, 2006)	250	250
Series B Preferred Stock, \$.01 par value; 15,817 shares authorized, issued and outstanding at December 31, 2005 and September 30, 2006 (liquidation preference of \$27,968 at December 31, 2005 and \$28,692 at September 30, 2006)	28,617	27,893
Series C Preferred Stock, \$.01 par value; 22,436 shares authorized, 22,418 shares issued and outstanding at December 31, 2005 and September 30, 2006 (liquidation preference of \$47,258 at December 31, 2005 and \$48,478 at September 30, 2006)	48,348	47,128
Series C-1 Preferred Stock, \$.01 par value; 2,300 shares authorized, issued and outstanding at December 31, 2005 and September 30, 2006 (liquidation preference of \$5,217 at December 31, 2005 and \$5,362 at September 30, 2006)	2,387	2,241
Series C-2 Preferred Stock, \$.01 par value; 20,334 and 24,000 shares authorized at December 31, 2005 and September 30, 2006, 11,155 and 23,425 shares issued and outstanding at December 31, 2005 and September 30, 2006, respectively (liquidation preference of \$33,631 at December 31, 2005 and \$73,816 at September 30, 2006)	36,670	16,842
	<u>116,272</u>	<u>94,354</u>
Stockholders' (Deficit):		
Common stock, \$.001 par value; 85,000 and 90,000 shares authorized at December 31, 2005 and September 30, 2006; 513 and 515 shares issued and outstanding at December 31, 2005 and September 30, 2006, respectively	4	4
Additional paid-in capital	—	—
Stock warrants	341	341
Stock subscription receivable	(83)	(181)
Retained deficit	(113,633)	(96,186)
Unrealized gain on marketable securities	4	—
Total stockholders' (deficit)	<u>(113,367)</u>	<u>(96,022)</u>
Total liabilities and stockholders' (deficit) equity	<u>\$ 19,390</u>	<u>\$ 13,750</u>

*The accompanying notes are an integral part of these condensed financial statements.*

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**Achillion Pharmaceuticals, Inc.**  
**Statements of Operations**  
**(in thousands, except per share amounts)**  
**(Unaudited)**

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2006	2005	2006	2005
Revenue	\$ 1,196	\$ 2,293	\$ 5,514	\$ 7,157
Operating expenses				
Research and development	5,300	4,472	16,338	13,887
General and administrative	1,023	707	3,340	2,326
Total operating expenses	<u>6,323</u>	<u>5,179</u>	<u>19,678</u>	<u>16,213</u>
Loss from operations	(5,127)	(2,886)	(14,164)	(9,056)
Other income (expense)				
Interest income	162	43	430	186
Interest expense	(232)	(297)	(679)	(958)
Change in fair value of put right liability	72	0	72	0
Net loss before benefit from state taxes	<u>(5,125)</u>	<u>(3,140)</u>	<u>(14,341)</u>	<u>(9,828)</u>
Tax benefit	9	15	59	75
Net loss	<u>(5,116)</u>	<u>(3,125)</u>	<u>(14,282)</u>	<u>(9,753)</u>
Accretion of preferred stock dividends	<u>(1,407)</u>	<u>(693)</u>	<u>(3,693)</u>	<u>(2,078)</u>
Loss attributable to common stockholders	<u><u>\$(6,523)</u></u>	<u><u>\$(3,818)</u></u>	<u><u>\$(17,975)</u></u>	<u><u>\$(11,831)</u></u>
Basic and diluted net loss per share attributable to common stockholders (Note 3)	<u><u>\$(12.69)</u></u>	<u><u>\$( 7.58)</u></u>	<u><u>\$( 35.11)</u></u>	<u><u>\$( 23.71)</u></u>
Weighted average shares used in computing basic and diluted net loss per share attributable to common stockholders	<u>514</u>	<u>504</u>	<u>512</u>	<u>499</u>

*The accompanying notes are an integral part of these condensed financial statements.*

**Achillion Pharmaceuticals, Inc.**  
**Statements of Stockholders' (Deficit)**  
**(in thousands)**  
**(Unaudited)**

	<u>Common Stock</u>		<u>Additional Paid-In Capital</u>	<u>Stock Warrants</u>	<u>Stock Subscription Receivable</u>	<u>Retained Earnings (Deficit)</u>	<u>Unrealized Gain (Loss)</u>	<u>Total Stockholders' (Deficit)</u>
	<u>Shares</u>	<u>Amount</u>						
Balances at December 31, 2005	513	4	—	341	(181)	(96,186)	—	(96,022)
Stock compensation			525					525
Exercise of stock options	2		3					3
Settlement of stock subscription receivable					98			98
Unrealized gain on marketable securities							4	4
Net (loss)						(14,282)		(14,282)
Convertible preferred stock dividends			(528)			(3,165)		(3,693)
Balances at September 30, 2006	<u>515</u>	<u>\$ 4</u>	<u>\$ —</u>	<u>\$ 341</u>	<u>\$ (83)</u>	<u>\$(113,633)</u>	<u>\$ 4</u>	<u>\$(113,367)</u>

*The accompanying notes are an integral part of these condensed financial statements.*

**Achillion Pharmaceuticals, Inc.**  
**Statements of Cash Flows**  
**(in thousands)**  
**(Unaudited)**

	Nine Months Ended September 30,	
	2006	2005
<b>Cash flows from operating activities</b>		
Net loss	\$(14,282)	\$ (9,753)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	545	764
Noncash stock-based compensation	525	53
Noncash interest expense	—	785
Change in fair value of put right liability	(72)	—
Loss on disposal of equipment	27	—
Amortization of premium on securities	4	22
Changes in assets and liabilities:		
Accounts receivable	146	(784)
Prepaid expenses and other current assets	223	330
Account payable	61	(746)
Accrued expenses and other liabilities	848	431
Deferred revenue	(3,030)	(1,780)
Net cash (used in) operating activities	<u>(15,005)</u>	<u>(10,678)</u>
<b>Cash flows from investing activities</b>		
Purchase of property and equipment	(355)	(98)
Release of restriction on cash	52	52
Maturities of marketable securities	—	4,879
Net cash provided by (used in) investing activities	<u>(303)</u>	<u>4,833</u>
<b>Cash flows from financing activities</b>		
Proceeds from issuance of Series C-2 Preferred Stock, net of issuance costs of \$182	18,224	—
Proceeds from exercise of stock options	3	27
Proceeds from repayment of subscription receivable	98	101
Borrowings under notes payable	5,355	150
Repayments of notes payable	(2,094)	(810)
Deferred initial public offering costs	(1,402)	—
Net cash provided by (used in) financing activities	<u>20,184</u>	<u>(532)</u>
Net (decrease) increase in cash and cash equivalents	4,876	(6,377)
Cash and cash equivalents, beginning of period	9,583	9,481
Cash and cash equivalents, end of period	<u>\$ 14,459</u>	<u>\$ 3,104</u>
<b>Supplemental disclosure of cash flow information</b>		
Cash paid for interest	\$ 587	\$ 137
<b>Supplemental disclosure of noncash financing activities</b>		
Issuance of warrants in connection with debt financing	\$ 174	—

*The accompanying notes are an integral part of these condensed financial statements.*

**Achillion Pharmaceuticals, Inc.**  
**Notes to Financial Statements**  
**(in thousands, except per share amounts)**

**1. Basis of Presentation**

The accompanying unaudited condensed financial statements of Achillion Pharmaceuticals, Inc. (the “Company”) should be read in conjunction with the audited financial statements and notes as of and for the year ended December 31, 2005 included in the Company’s Registration Statement on Form S-1/A filed with the Securities and Exchange Commission (“SEC”) on October 25, 2006. The accompanying financial statements have been prepared in accordance with U.S. generally accepted accounting principles (“U.S. GAAP”) for interim financial information, in accordance with the instructions to Form 10-Q and the guidance in Article 10 of Regulation S-X. Accordingly, since they are interim financial statements, the accompanying financial statements do not include all of the information and disclosures required by U.S. GAAP for complete financial statements. The accompanying financial statements reflect all adjustments, consisting of normal recurring adjustments, that are, in the opinion of management, necessary for a fair statement of the results of operations for the interim periods presented. Interim results are not necessarily indicative of results for a full year.

The preparation of financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect amounts reported in the financial statements and notes thereto. A discussion of the Company’s critical accounting policies and management estimates is described in the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included elsewhere in this quarterly report on Form 10-Q.

**2. Recent Financings and Initial Public Offering**

In March 2006 and May 2006, the Company raised \$18,406 through the issuance of 12,271 shares of Series C-2 Convertible Preferred Stock (“Series C-2”). Per share price, rights and preferences were the same as those offered in a November 2005 close of the Series C-2 financing. Simultaneous with the May 2006 issuance of Series C-2, the Company raised an additional \$5,000 through the issuance of promissory notes under its 2005 credit facility (see Note 6). As a result of the issuance of these promissory notes, the Company issued to the lenders warrants to purchase an additional 167 shares of Series C-2 at an exercise price of \$1.50 per share. The relative fair value of such warrants at the date of issuance was estimated to be \$174, utilizing the Black-Scholes method, using assumptions similar to those outlined in Note 3 below. Such value was recorded as a debt discount which is being amortized as interest expense over the life of the related obligation, and is classified as a liability in the accompanying September 30, 2006 balance sheet.

In October 2006, the Company amended its certificate of incorporation to effect a 1-for-8 reverse stock split of outstanding common stock. Such reverse stock split had been previously approved by the Company’s Board of Directors in September 2006. The accompanying financial statements have been restated to retroactively reflect this reverse stock split. As a result of the reverse stock split, the conversion ratios of the Company’s preferred stock changed as follows:

	<u>Prior</u>	<u>After</u>
Series A	1 : 1	1 : 0.1250
Series B	1 : 1	1 : 0.1250
Series C	1 : 1.196	1 : 0.1495
Series C-1	1 : 1.196	1 : 0.1495
Series C-2	1 : 1	1 : 0.1250

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In October 2006, the Company completed an initial public offering of 5,175 shares of its common stock, including the underwriters' overallotment option that closed in November, at a public offering price of \$11.50 per share. Net proceeds to the Company were approximately \$55.3 million, after deducting underwriting discounts and commissions but before deducting estimated offering expenses.

In connection with the initial public offering, the Company's outstanding shares of Series A, Series B, Series C, Series C-1 and Series C-2 Convertible Preferred Stock (the "Preferred Stock") were converted into 9,834 shares of common stock, including shares issued in satisfaction of \$15.4 million of accrued but unpaid dividends on the Preferred Stock as of October 31, 2006, the closing date of the initial public offering. Also in connection with the initial public offering, outstanding warrants to purchase Series C convertible preferred stock were automatically converted into warrants to purchase 2,683 shares of the Company's common stock at an exercise price of \$12.11 per share, and outstanding warrants to purchase Series C-2 were automatically converted into warrants to purchase 41,664 shares of the Company's common stock at an exercise price of \$12.00 per share.

### 3. Earnings (Loss) Per Share ("EPS")

Basic EPS is calculated in accordance with SFAS No. 128, *Earnings per Share*, by dividing net income or loss attributable to common stockholders by the weighted average common stock outstanding. Diluted EPS is calculated in accordance with SFAS No. 128 by adjusting weighted average common shares outstanding for the dilutive effect of common stock options, warrants, convertible preferred stock and accrued but unpaid convertible preferred stock dividends. In periods where a net loss is recorded, no effect is given to potentially dilutive securities, since the effect would be antidilutive. Total securities that could potentially dilute basic EPS in the future that were not included in the computation of diluted EPS because to do so would have been antidilutive for the nine months ended September 30, 2006 and 2005 were as follows:

	Nine Months Ended September 30,	
	2006	2005
Options	807	613
Warrants	335	294
Convertible Preferred Stock, as converted	8,631	5,531
Accrued but unpaid Convertible Preferred Stock dividends	1,165	803
Total potentially dilutive securities outstanding	<u>10,938</u>	<u>7,241</u>

Excluded from the weighted average shares are 1 and 7 restricted shares subject to repurchase as of September 30, 2006 and 2005, respectively.

The pro forma basic and diluted net loss per share calculations assume the conversion of the Series A, B, C, C-1 and C-2 Preferred Stock and related accrued but unpaid dividends into shares of common stock, as well as the issuance of 5,175 shares of common stock in the Company's initial public offering, at the beginning of the respective periods.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Loss attributable to common stockholders	<u>\$ (6,523)</u>	<u>\$ (3,818)</u>	<u>\$ (17,975)</u>	<u>\$ (11,831)</u>
Basic and diluted net loss per share attributable to common stockholders	<u>\$ (12.69)</u>	<u>\$ (7.58)</u>	<u>\$ (35.11)</u>	<u>\$ (23.71)</u>
Weighted average shares used in computing basic and diluted net loss per share attributable to common stockholders	<u>514</u>	<u>504</u>	<u>512</u>	<u>499</u>
Pro forma net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.34)</u>	<u>\$ (0.98)</u>		
Pro forma weighted average shares used in computing basic and diluted net loss per share attributable to common stockholders	<u>15,192</u>		<u>14,602</u>	



#### 4. Revenue Recognition

The Company recognizes revenue from contract research and development and research progress payments in accordance with Staff Accounting Bulletin (“SAB”), No. 104, *Revenue Recognition* (“SAB 104”) and Financial Accounting Standards Board (“FASB”), Emerging Issue Task Force Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables* (“EITF 00-21”). Revenue-generating research and development collaborations are often multiple element arrangements, providing for a license as well as research and development services. Such arrangements are analyzed to determine whether the deliverables, including research and development services, can be separated or whether they must be accounted for as a single unit of accounting in accordance with EITF 00-21. The Company recognizes upfront license payments as revenue upon delivery of the license only if the license has standalone value and the fair value of the undelivered performance obligations can be determined. If the fair value of the undelivered performance obligations can be determined, such obligations would then be accounted for separately as performed. If the license is considered to either (i) not have standalone value or (ii) have standalone value but the fair value of any of the undelivered performance obligations cannot be determined, the arrangement would then be accounted for as a single unit of accounting and the upfront license payments are recognized as revenue over the estimated period of when the Company’s performance obligations are performed.

When the Company determines that an arrangement should be accounted for as a single unit of accounting, it must determine the period over which the performance obligations will be performed and revenue related to upfront license payments will be recognized. Revenue will be recognized using either a proportionate performance or straight-line method. The Company recognizes revenue using the proportionate performance method provided that it can reasonably estimate the level of effort required to complete its performance obligations under an arrangement and such performance obligations are provided on a best-efforts basis. Direct labor hours or full-time equivalents are typically used as the measure of performance. Under the proportionate performance method, periodic revenue related to upfront license payments is recognized as the percentage of actual effort expended in that period to total effort budgeted for all of the Company’s performance obligations under the arrangement. Significant management judgment is required in determining the level of effort required under an arrangement and the period over which the Company expects to complete the related performance obligations. Estimates may change in the future, resulting in a change in the amount of revenue recognized in future periods.

Collaborations may also involve substantive milestone payments. Substantive milestone payments are considered to be performance bonuses that are recognized upon achievement of the milestone only if all of the following conditions are met: (1) the milestone payments are non-refundable, (2) achievement of the milestone involves a degree of risk and was not reasonably assured at the inception of the arrangement, (3) substantive effort is involved in achieving the milestone, (4) the amount of the milestone payment is reasonable in relation to the effort expended or the risk associated with achievement of the milestone and (5) a reasonable amount of time passes between the upfront license payment and the first milestone payment as well as between each subsequent milestone payment (the “Substantive Milestone Method”).

Reimbursement of costs is recognized as revenue provided the provisions of EITF Issue No. 99-19 are met, the amounts are determinable and collection of the related receivable is reasonably assured.

##### ***Collaboration with Gilead Sciences, Inc.***

In November 2004, the Company entered into a collaboration arrangement (the “Gilead Arrangement”) with Gilead Sciences Inc. (“Gilead”) to jointly develop and commercialize compounds for use in treating hepatitis C infection which inhibit viral replication through a specified novel mechanism of action. Under the Gilead Arrangement, the Company and Gilead will work together to develop one or more compounds for use in treating hepatitis C infection until proof-of-concept in one compound, as defined, is achieved (the “Research Period”). Subsequent to the achievement of proof-of-concept, the Company has no further obligation to continue providing services to Gilead but, at Gilead’s request, the Company may agree to extend the Research Period for up to an additional two years.

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Under the Gilead Arrangement, agreed upon research or development expenses, including internal full-time equivalent (“FTE”) costs and external costs, incurred by both companies during the period up to proof-of-concept will be borne equally by both parties. The Company is incurring the majority of those expenses and, therefore, is the net receiver of funds under this cost-sharing portion of the arrangement. Payments of \$375 and \$1,282 made by the Company to Gilead for the three and nine months ended September 30, 2006 in connection with this collaboration, respectively, have been recognized as a reduction in revenue.

During the three and nine months ended September 30, 2006, the Company recognized revenue of \$1,123 and \$5,283, respectively, under this collaboration agreement, of which \$529 and \$3,030, respectively, related to the recognition of the non-refundable fee and first milestone under the proportionate performance model. The remaining \$594 and \$2,253, respectively, recognized during the three and nine months ended September 30, 2006, relate to FTE and other external costs billed under the collaboration. Included in the accompanying September 30, 2006 balance sheet is \$2,172 of deferred revenue resulting from the up-front fee and a milestone payment received during the Research Period.

### **5. Share-based Payments**

Under the Company’s 1998 Stock Option Plan (“1998 Plan”), incentive and nonqualified stock options may be granted to directors, officers, employees and consultants of the Company for up to a maximum of 1,094 shares of common stock. Options granted under the 1998 Plan are exercisable for a period determined by the Company, but in no event longer than ten years from the date of the grant. Options generally vest ratably over four years. The 1998 Plan expired upon the Company’s initial public offering in October 2006. Also in connection with the Company’s initial public offering in October 2006, stockholders adopted the 2006 Stock Incentive Plan (the “2006 Plan”), which provides for incentive and nonqualified stock option grants and other stock awards to directors, officers, employees and consultants of the Company for up to a maximum of 750 shares. Exercise terms and vesting periods remain the same as those under the 1998 Plan.

In addition, in connection with the Company’s initial public offering, stockholders adopted the 2006 Employee Stock Purchase Plan, providing for the issuance of up to 250 shares to participating employees.

#### ***Stock Options under SFAS No. 123R***

In December 2004, the FASB issued SFAS No. 123R, *Shared-Based Payment* (“SFAS No. 123R”) which replaced SFAS No. 123, *Accounting for Stock-Based Compensation* (“SFAS No. 123”) and superseded APB Opinion No. 25. SFAS No. 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values, and was effective beginning in the first quarter of 2006. Effective January 1, 2006, the Company began accounting for grants of stock options and restricted stock to employees utilizing the fair value recognition provisions of SFAS No. 123R.

Adoption of SFAS No. 123R was implemented utilizing modified prospective application (“MPA”). Under MPA, the Company applied SFAS No. 123R for new awards granted after December 31, 2005 and for any awards that were granted prior to December 31, 2005 but were still vesting after December 31, 2005. As of September 30, 2006, no liability awards have been granted.

The Company also had a choice of two attribution methods for allocating compensation cost under SFAS No. 123R: the “straight-line” method, which allocates expense on a straight-line basis over the requisite service period of the last separately vesting portion of an award, or the “graded vesting attribution method,” which allocates expense on a straight-line basis over the requisite service period for each separately vesting portion of the award as if the award was, in-substance, multiple awards. The Company chose the former method (i.e. straight-line).

The Company also chose to continue utilizing the Black-Scholes-Merton (referred to herein as “Black- Scholes”) model as its chosen option-pricing model. Management concluded that this was the most appropriate

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method with which to value the Company's share-based payment arrangements, but notes that if any share-based payment instruments should be granted for which the Black-Scholes method does not meet the measurement objective as stated within SFAS No. 123R, management would utilize a more appropriate method for valuing that instrument. However, management does not believe that any instruments granted to date and accounted for under SFAS No. 123R would require a method other than Black-Scholes in order to meet the measurement objective discussed above.

Management also revisited its conclusions regarding the assumptions that underlie the valuation of share-based payment awards. In regards to the calculation of expected term, the Company chose to utilize the "simplified" method for "plain vanilla" options as discussed within SAB No. 107. The Company believes that all factors listed within SAB No. 107 as pre-requisites for utilizing the simplified method are true for the Company and its share-based payment arrangements. The Company currently intends to utilize the simplified method through December 31, 2007, at which point it is anticipated that more detailed information about exercise behavior will be more widely available. When valuing share-based payment awards reported via pro forma results for SFAS No. 123 and SFAS No. 148 prior to the adoption of SFAS No. 123R, an estimate of a five-year expected term for all employees as one weighted-average group was utilized, as this represented an estimate at the lower end of the reasonable range of possible expected terms, given the vesting schedule and maximum contractual maturity, in accordance with the guidance for estimates provided in SFAS No. 123.

For the calculation of expected volatility, because the Company was a private company as of September 30, 2006, and is only newly public at the time of this filing, and therefore lacks company specific historical and implied volatility information, the Company based its estimate of expected volatility on the historical volatility of similar entities whose share prices are publicly available. The Company intends to continue to consistently apply this process using the same similar entities until a sufficient amount of historical information regarding the volatility of the Company's own share price becomes available, or unless circumstances change such that the identified entities are no longer similar to the Company. In this latter case, more suitable, similar entities whose share prices are publicly available, would be utilized in the calculation. This conclusion and approach is consistent with the approach utilized by management when valuing share-based payment awards reported via pro forma results for SFAS No. 123 and SFAS No. 148.

Under SFAS No. 123R, the Company has separated its employees into two groupings, which can be summarized as 1) management, including the board of directors; and 2) non-management. However, given the Company's current use of the simplified method, as discussed above, the establishment of these groupings will not affect the expected term utilized by the Company until the Company ceases to employ the simplified method of estimating expected term. All employees were viewed as one grouping by the Company when valuing share-based payment awards reported via pro forma results for SFAS No. 123 and SFAS No. 148 prior to the adoption of SFAS No. 123R.

The risk-free rate utilized when valuing share-based payment arrangements is based on the U.S. Treasury yield curve in effect at the time of grant for the expected term of the particular instrument being valued. This is consistent with the approach utilized by management when valuing share-based payment awards reported via pro forma results for SFAS No. 123 and SFAS No. 148.

The Company occasionally grants stock option awards to consultants. Such grants are accounted for pursuant to EITF Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, and, accordingly, recognizes non-cash compensation expense equal to the fair value of such awards and amortizes such expense over the performance period. The unvested equity instruments are revalued on each subsequent reporting date until performance is complete with an adjustment recognized for any changes in their fair value. The Company amortizes expenses related to non-employee stock options in accordance with FIN 28. Total expense for the nine months ended September 30, 2006 was \$44. The total expense for the nine months ended September 30, 2005 was \$54.

The weighted-average grant-date fair value of options granted during the first quarter of 2006 was \$8.74 and no options were granted during the second or third quarters of 2006.

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The fair value of each employee option grant in the first quarter of 2006 was estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions, which were determined as described above. No options were granted during the second or third quarters of 2006.

	Q1 2006
Risk free interest rate	4.83%
Expected dividend yield	0%
Expected lives	6.11 years
Expected volatility	70%

The Company recorded \$481 of expense for option grants made to employees in the nine months ended September 30, 2006. The Company recorded no tax benefit related to these options during the first three quarters of 2006 since the Company currently maintains a full valuation allowance.

As of September 30, 2006, the aggregate intrinsic value of all in-the-money options outstanding is \$7,440. As of September 30, 2006, the total weighted average remaining contractual life of the vested options outstanding is 6.5 years, and the aggregate intrinsic value related to these vested options is approximately \$3,612.

As of September 30, 2006, the total compensation cost related to nonvested options not yet recognized in the financial statements is approximately \$1,790, and the weighted average period over which it is expected to be recognized is 1.6 years.

The Company has a policy of issuing new shares to satisfy share option exercises and expects to continue this practice for the foreseeable future.

### Stock Options under APB 25

Through December 31, 2005, the Company accounted for grants of stock options and restricted stock utilizing the intrinsic value method in accordance with Accounting Principle Board ("APB") Opinion No. 25, *Accounting for Stock Issued to Employees* ("APB 25"), and, accordingly, recognized no compensation expense for options when the option grants had an exercise price equal to the fair market value at the date of grant. Under APB 25, compensation expense was computed to the extent that the fair market value of the underlying stock on the date of grant exceeded the exercise price of the employee stock option or stock award. Compensation so computed was then recognized on a straight-line basis over the vesting period. Also through December 31, 2005, the Company had adopted the disclosure-only provisions of SFAS No. 123, as amended by SFAS No. 148, *Accounting for Stock Based Compensation—Transition and Disclosure* ("SFAS No. 148").

Had compensation cost for the Company's stock option plans been determined based on the fair value at the grant dates of awards under these plans consistent with the method prescribed by SFAS 123, the Company's net loss and pro forma net loss would have been as follows for the nine months ending September 30, 2005:

	Three Months Ended September 30, 2005	Nine Months Ended September 30, 2005
Net loss attributable to common shareholders as reported	\$ (3,818)	\$ (11,831)
Add: Stock-based employee compensation expense included in net loss	15	55
Less: Total stock based employee compensation expense determined under fair-value based methods for all awards	(79)	(289)
Pro Forma net loss attributable to common shareholders	\$ (3,882)	\$ (12,065)
Net loss per share attributable to common shareholders ( basic and diluted):		
As Reported	\$ (7.58)	\$ (23.71)
Pro Forma	\$ (7.70)	\$ (24.18)

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The fair value of each employee option grant is estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions for the three and nine months ended September 30, 2005:

	2005
Risk free interest rate	4.30%
Expected dividend yield	0%
Expected lives	5 years
Expected volatility	70%

During 2006, in connection with its initial public offering, the Company's board of directors determined to undertake a reassessment of the fair value of common stock in connection with options granted to employees on December 20, 2005. In connection with this undertaking, the Company's board of directors considered the following:

- the valuation indicated by the May 2006 closing of the Company's series C-2 convertible preferred stock financing, which included participation by investors who had not participated in earlier financing rounds; and
- events that occurred toward the end of 2005, including (i) initiation of phase II clinical trials in elvucitabine, and (ii) initiation of phase I clinical trials in ACH-806.

Following this assessment, the Company's board of directors, with input from management, determined that the fair value of the Company's common stock was \$11.00 per share in December 2005. Accordingly, the fair value of options granted on December 20, 2005, calculated in accordance with SFAS 123R using this \$11.00 per share fair value, was determined to be \$2,184. Such value is being recognized over the four-year vesting period of the options commencing January 1, 2006.

### *Current Period Option Activity*

A summary of the status of the Company's stock options is presented in the table and narrative below:

	2006	
	Number of Shares Underlying Grant	Weighted Average Exercise Price
Outstanding at January 1, 2006	864	\$ 2.28
Granted	1	4.00
Exercised	(2)	1.60
Forfeited/Cancelled	(56)	2.42
Outstanding at September 30	807	2.28
Options exercisable at September 30	807	2.28
Weighted-average fair value of options granted during the period		\$ 8.74

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The following table presents weighted average price and life information about significant option groups outstanding at September 30, 2006.

Exercise Prices	Options Outstanding			Options Vested	
	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number Vested	Weighted Average Exercise Price
\$1.20	41	2.4	\$ 1.20	41	\$ 1.20
\$1.60	532	7.3	1.60	322	1.60
\$4.00	234	9.2	4.00	—	—
	<u>807</u>	<u>7.6</u>	<u>\$ 2.28</u>	<u>363</u>	<u>\$ 1.55</u>

Through the nine months ended September 30, 2006, the Company granted the following options to employees and recognized expense accordingly:

Date of Grant	Number of Shares Underlying Grant	Exercise Price	Market Value as Determined by Management and Board	Intrinsic Value of Grant	Compensation Expense to be Recognized over 4 Year Vesting Period
January 1 through September 30, 2006	<u>1</u>	\$ 4.00	\$ 11.00	\$ 7.00	\$ 8

The total intrinsic value of options exercised for the nine months ended September 30, 2006, was \$20.

## 6. Long-Term Debt

Long-term debt consists of the following:

	As of September 30, 2006	As of December 31, 2005
CII Term Loan, payable in monthly installments of \$13 through September 2010 with a final balloon payment of \$686, with interest at 7.5% per annum	\$ 1,035	\$ 1,091
2002 CII Term Loan, payable in monthly installments of \$6 through October 2007, with interest at 7.5% per annum	69	114
2002 Credit Facility, payable in monthly installments as the individual notes mature through January 2007, with interest ranging from 8.01% to 10.17% per annum	68	321
2003 Credit Facility, payable in monthly installments as the individual notes mature through May 2008, with interest ranging from 6.72% to 8.72% per annum	478	266
2005 Credit Facility, payable in monthly installments as notes mature through April 2009, with interest ranging from 10.92% to 11.54% per annum	<u>8,066</u>	<u>4,664</u>
Total long-term debt	9,716	6,456
Less: current portion	<u>(3,528)</u>	<u>(2,083)</u>
Total long-term debt, net of current portion	<u>\$ 6,188</u>	<u>\$ 4,373</u>

In May 2006, the Company expanded the 2005 Credit Facility and issued warrants to purchase an additional 167 shares of Series C-2 at an exercise price of \$1.50 per share. Substantially all terms and conditions remain the same as those under the 2005 Credit Facility. See also — Note 2 — “Recent Financings and Initial Public Offering”.

## **7. Comprehensive Income (Loss)**

The Company reports and presents comprehensive income (loss) in accordance with SFAS No. 130, *Reporting Comprehensive Income*, which establishes standards for reporting and display of comprehensive income (loss) and its components in a full set of general purpose financial statements. The objective of the statement is to report a measure of all changes in equity of an enterprise that result from transactions and other economic events of the period other than transactions with owners (comprehensive income (loss)). The Company's other comprehensive income (loss) arises from net unrealized gains (losses) on marketable securities. Other comprehensive income (loss) was de minimis for all periods presented.

## **8. Recently Issued Accounting Pronouncements**

In July 2006, the FASB issues Interpretation No.48, *Accounting for Uncertainty in Income Taxes - an interpretation of FASB Statement No.109 ("FIN 48")*. FIN 48 prescribes a comprehensive model for how a company should recognize, measure, present, and disclose in its financial statements uncertain tax positions that the company has taken or expects to take on a tax return (including a decision whether to file or not file a return in a particular jurisdiction). Under FIN 48, the financial statements will reflect expected future tax consequences of such positions presuming the taxing authorities' full knowledge of the position and all relevant facts, but without considering time values. FIN 48 substantially changes the applicable accounting model and is likely to cause greater volatility in income statements as more items are recognized discretely within income tax expense. FIN 48 also revises disclosure requirements and introduces a prescriptive, annual tabular rollforward of the unrecognized tax benefits. FIN 48 is effective for the Company beginning January 1, 2007. The Company is evaluating the impact of adopting FIN 48 on its financial position and results of operations.

In September 2006, the FASB issued SFAS No.157, *Fair Value Measurements*. SFAS No. 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. The standard is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. The Company does not believe that its adoption in the first quarter of 2008 will have a material impact on the Company's financial statements.

In September 2006, the SEC issued Staff Accounting Bulletin No.108, *Considering the Effects of Prior year Misstatements when Quantifying Misstatements in Current Year Financial Statements ("SAB 108")*. SAB 108 provides interpretive guidance on how the effects of the carryover or reversal of prior year misstatements should be considered in quantifying a current year misstatement. The SEC staff believes that registrants should quantify errors using both a balance sheet and an income statement approach and evaluate whether either approach results in quantifying a misstatement that, when all relevant quantitative and qualitative factors are considered, is material. The Company does not believe that its adoption for the full year ending December 31, 2006 will have a material impact on the Company's financial statements.

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

*The following discussion should be read with our unaudited financial statements and notes included in Item 1 of this Quarterly Report on Form 10-Q for the three and nine months ended September 30, 2006 and 2005, as well as the audited financial statements and notes and Management's Discussion and Analysis of Financial Condition and Results of Operations for the fiscal year ended December 31, 2005, included in our final prospectus dated October 25, 2006 filed with the Securities and Exchange Commission, or SEC. This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Without limiting the foregoing, the words "may," "will," "should," "could," "expect," "plan," "intend," "anticipate," "believe," "estimate," "predict," "potential," "continue," "target" and variations of these terms or the negatives of those terms and similar expressions are intended to identify forward-looking statements. All forward-looking statements included in this Quarterly Report on Form 10-Q are based on current expectations, estimates, forecasts and projections and the beliefs and assumptions of our management including, without limitation, our expectations regarding our results of operations, general and administrative expenses, research and development expenses, and the sufficiency of our cash for future operations. We assume no obligation to revise or update any such forward-looking statements. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain important factors, including those set forth below under this Item 2 — "Management's Discussion and Analysis of Financial Condition and Results of Operations," Part II, Item 1A — "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q. You should carefully review those factors and also carefully review the risks outlined in other documents that we file from time to time with the Securities and Exchange Commission, including our final prospectus dated October 25, 2006.*

### Overview

We are a biopharmaceutical company focused on the discovery, development and commercialization of innovative treatments for infectious diseases. Within the anti-infective market, we are currently concentrating on the development of antivirals and antibacterials. We are targeting our antiviral development efforts on treatments for HIV infection and chronic hepatitis C, and we are directing our antibacterial development efforts toward treatments for serious hospital-based bacterial infections. Our two lead drug candidates are elvucitabine, which we are currently evaluating in phase II clinical trials in HIV-infected patients, and ACH-806 (also known as GS 9132), which we are currently evaluating in collaboration with Gilead Sciences, Inc. in a proof-of-concept clinical trial for the treatment of chronic hepatitis C. We are also evaluating our third drug candidate, ACH-702, in late-stage preclinical studies for the treatment of serious hospital-based bacterial infections.

We have devoted and are continuing to devote substantially all of our efforts toward product research and development. We have incurred losses of \$100.1 million from inception to September 30, 2006 and had an accumulated deficit of \$113.6 million through September 30, 2006. Our net losses were \$13.6 million for the year ended December 31, 2005 and \$14.3 million for the nine months ended September 30, 2006.

On October 31, 2006, we completed an initial public offering of 5,175,000 shares of common stock at a price of \$11.50 per share, which includes the exercise of the underwriters' over-allotment option. Net proceeds to us from the offering were approximately \$53.4 million (net of underwriting discounts and commissions and offering expenses).

### Financial Operations Overview

#### Revenue

To date, we have not generated any revenue from the sale of any drugs. The majority of our revenue recognized to date has been derived from our collaboration with Gilead Sciences to develop compounds for use



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in treating chronic hepatitis C. Through September 30, 2006, we have recognized approximately \$14.4 million in revenue from our collaboration with Gilead Sciences.

Upon initiating our collaboration with Gilead Sciences, we received a payment of \$10.0 million, which included an equity investment by Gilead Sciences determined to be worth approximately \$2.0 million. The remaining \$8.0 million is being accounted for as a nonrefundable up-front fee recognized under the proportionate performance model. Revenue under the proportionate performance model is recognized as our effort under the collaboration is incurred. When our performance obligation is complete, we will recognize milestone payments, if any, when the corresponding milestone is achieved. We will recognize royalty payments, if any, upon product sales.

Research and development expenses under our collaboration with Gilead Sciences, including internal full-time equivalent costs and external research costs, incurred by both companies prior to proof-of-concept, are borne equally by both parties. As we are providing the majority of those services and are incurring the majority of those expenses, we are the net recipient of funds under this cost-sharing portion of the arrangement and therefore recognize the reimbursed costs as revenue rather than research expense. Payments made by us to Gilead Sciences in connection with this collaboration are being recognized as a reduction of revenue.

We have also recognized revenue under a Small Business Innovation Research, or SBIR, grant by the National Institutes of Health, or NIH, related to our HIV capsid research program. Through September 30, 2006, we have recognized approximately \$479,000 in revenue under this grant.

### ***Research and Development***

Our research and development expenses reflect costs incurred for our proprietary research and development projects as well as costs for research and development projects conducted as part of collaborative arrangements we establish. These costs consist primarily of salaries and benefits for our research and development personnel, costs of services by clinical research organizations, other outsourced research, materials used during research and development activities, facility-related costs such as rent and utilities associated with our laboratory and clinical development space, operating supplies and other costs associated with our research and development activities. We expect research and development costs to increase significantly over the next several years as our drug development programs progress.

All costs associated with internal research and development, and research and development services for which we have externally contracted, are expensed as incurred. Our research and development expenses are outlined in the table below.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Direct external costs:				
Elvucitabine	\$1,115	\$ 597	\$ 3,724	\$ 1,812
ACH-806	420	877	2,254	3,400
ACH-702	995	218	1,914	708
	<u>2,530</u>	<u>1,692</u>	<u>7,892</u>	<u>5,920</u>
Direct internal personnel costs	<u>1,488</u>	<u>1,352</u>	<u>4,652</u>	<u>3,952</u>
Sub-total direct costs	<u>4,018</u>	<u>3,044</u>	<u>12,544</u>	<u>9,872</u>
Indirect costs and overhead	<u>1,282</u>	<u>1,428</u>	<u>3,794</u>	<u>4,015</u>
Total research and development	<u>\$5,300</u>	<u>\$4,472</u>	<u>\$16,338</u>	<u>\$13,887</u>

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Currently, we are conducting two phase II clinical trials for elvucitabine, a proof-of-concept clinical trial for ACH-806 and preclinical studies for ACH-702. From the inception of each respective program through September 30, 2006, we incurred approximately \$30.3 million in total costs for elvucitabine, approximately \$19.9 million in total costs for ACH-806 and approximately \$11.6 million in total costs for ACH-702. These figures include our internal research and development personnel costs and related facilities overhead. We expect our research and development costs to increase substantially in the foreseeable future. We currently estimate that the clinical trial costs for two phase III clinical trials of elvucitabine in different HIV populations, which we expect to begin in 2007, will be approximately \$48.0 million, exclusive of the internal personnel costs associated with conducting these trials. We anticipate that our costs associated with ACH-806 will cease after the first quarter of 2007 after completion of our proof-of-concept trial under our collaboration with Gilead Sciences. We estimate that the costs associated with completing preclinical studies and phase I clinical trials for ACH-702, which we expect to complete in 2007, will be approximately \$3.0 million, exclusive of the internal personnel costs associated with conducting these studies and trials.

### ***General and Administrative***

Our general and administrative expenses consist primarily of salaries and benefits for management and administrative personnel, professional fees for legal, accounting and other services, travel costs and facility-related costs such as rent, utilities and other general office expenses. We expect our general and administrative expenses to increase as we continue to hire additional employees, increase our recruiting efforts, expand our infrastructure and incur additional costs related to the growth of our business and operations as a public company.

### **Critical Accounting Policies and Estimates**

The discussion and analysis of our financial condition and results of operations set forth below are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, we evaluate our estimates and assumptions, including those described below. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Management makes estimates and exercises judgment in revenue recognition, research and development costs, stock-based compensation and accrued expenses. Actual results may differ from these estimates under different assumptions or conditions.

We believe the following critical accounting policies affect management's more significant judgments and estimates used in the preparation of our financial statements:

### ***Revenue Recognition***

We recognize revenue from contract research and development and research progress payments in accordance with Staff Accounting Bulletin, or SAB, No. 104, *Revenue Recognition*, or SAB 104, and Financial Accounting Standards Board, or FASB, Emerging Issue Task Force, or EITF, Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*, or EITF 00-21. Revenue-generating research and development collaborations are often multiple element arrangements, providing for a license as well as research and development services. Such arrangements are analyzed to determine whether the deliverables, including research and development services, can be separated or whether they must be accounted for as a single unit of accounting in accordance with EITF 00-21. We recognize upfront license payments as revenue upon delivery of the license only if the license has standalone value and the fair value of the undelivered performance obligations can be determined. If the fair value of the undelivered performance obligations can be determined, such

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obligations would then be accounted for separately as performed. If the license is considered to either (i) not have standalone value or (ii) have standalone value but the fair value of any of the undelivered performance obligations cannot be determined, the arrangement would then be accounted for as a single unit of accounting and the upfront license payments are recognized as revenue over the estimated period of when our performance obligations are performed.

When we determine that an arrangement should be accounted for as a single unit of accounting, we must determine the period over which the performance obligations will be performed and revenue related to upfront license payments will be recognized. Revenue will be recognized using either a proportionate performance or straight-line method. We recognize revenue using the proportionate performance method provided that we can reasonably estimate the level of effort required to complete our performance obligations under an arrangement and such performance obligations are provided on a best-efforts basis. Direct labor hours or full-time equivalents are typically used as the measure of performance. Under the proportionate performance method, periodic revenue related to upfront license payments is recognized as the percentage of actual effort expended in that period to total effort budgeted for all of our performance obligations under the arrangement. Significant management judgment is required in determining the level of effort required under an arrangement and the period over which we expect to complete our related performance obligations. Estimates may change in the future, resulting in a change in the amount of revenue recognized in future periods.

Collaborations may also involve substantive milestone payments. Substantive milestone payments are considered to be performance bonuses that are recognized upon achievement of the milestone only if all of the following conditions are met: (1) the milestone payments are non-refundable, (2) achievement of the milestone involves a degree of risk and was not reasonably assured at the inception of the arrangement, (3) substantive effort is involved in achieving the milestone, (4) the amount of the milestone payment is reasonable in relation to the effort expended or the risk associated with achievement of the milestone and (5) a reasonable amount of time passes between the upfront license payment and the first milestone payment as well as between each subsequent milestone payment.

Reimbursement of costs is recognized as revenue provided the provisions of EITF Issue No. 99-19 are met, the amounts are determinable and collection of the related receivable is reasonably assured.

### ***Stock-Based Compensation***

Effective January 1, 2006, we began accounting for grants of stock options and restricted stock to employees utilizing the fair value recognition provisions of SFAS No. 123R, *Share Based Payment*, or SFAS No. 123R.

We occasionally grant stock option awards to consultants. Such grants are accounted for pursuant to EITF Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, and, accordingly, we recognize compensation expense equal to the fair value of such awards and amortize such expense over the performance period. We estimate the fair value of each award using the Black-Scholes-Merton, or Black-Scholes, model. The unvested equity instruments are revalued on each subsequent reporting date until performance is complete, with an adjustment recognized for any changes in their fair value. We amortize expense related to non-employee stock options in accordance with FASB Interpretation 28.

We primarily grant qualified stock options for a fixed number of shares to employees with an exercise price equal to the market value of the shares at the date of grant. Under the fair value recognition provisions of SFAS No. 123R, stock-based compensation cost is measured at the grant date based on the value of the award and is recognized as expense over the requisite service period of the award. Determining the fair value of stock-based awards at the grant date requires judgment, including estimating the expected term of stock options, the expected volatility of our stock and expected dividends. In addition, judgment is also required in estimating the amount of stock-based awards that are expected to be forfeited. If actual results differ significantly from these estimates,

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stock-based compensation expense and our results of operations could be materially impacted. The fair value of each award is estimated using the Black-Scholes model. Please see note 4 to the financial statements included in the condensed financial statements for additional information regarding the adoption of SFAS No. 123R.

We adopted SFAS No. 123R utilizing modified prospective application, or MPA. Under MPA, we applied SFAS No. 123R for new awards granted after December 31, 2005 and for any awards that were granted prior to December 31, 2005 but were still vesting after December 31, 2005. As of September 30, 2006, no liability awards have been granted.

We also had a choice of two attribution methods for allocating compensation cost under SFAS No. 123R: the “straight-line” method, which allocates expense on a straight-line basis over the requisite service period of the last separately vesting portion of an award, or the “graded vesting attribution method,” which allocates expense on a straight-line basis over the requisite service period for each separately vesting portion of the award as if the award was, in substance, multiple awards. We chose the straight-line method.

We also chose to continue utilizing the Black-Scholes model as our option-pricing model. We concluded that this was the most appropriate method for valuing our share-based payment arrangements. However, if we grant any share-based payment instruments for which the Black-Scholes method does not meet the measurement objective as stated within SFAS No. 123R, we would utilize a more appropriate method for valuing that instrument. At this time, we do not believe that any instruments granted to date and accounted for under SFAS No. 123R would require a method other than Black-Scholes in order to meet the measurement objective discussed above.

We also revisited our conclusions regarding the assumptions that underlie the valuation of share-based payment awards. With respect to the calculation of expected term, we chose to utilize the “simplified” method for “plain vanilla” options as discussed within SAB No. 107, *Share-based Payment*, or SAB 107. We believe that all factors listed within SAB 107 as prerequisites for utilizing the simplified method are true for our share-based payment arrangements. We currently intend to utilize the simplified method through December 31, 2007, at which point we anticipate that more detailed information about exercise behavior will be more widely available. When valuing share-based payment awards reported via pro forma results for SFAS No. 123 and SFAS No. 148 prior to the adoption of SFAS No. 123R, an estimate of a five-year expected term for all employees as one weighted-average group was utilized, as this represented an estimate at the lower end of the reasonable range of possible expected terms, given the vesting schedule and maximum contractual maturity, in accordance with the guidance for estimates provided in SFAS No. 123.

For the calculation of expected volatility, because we were a private company as of September 30, 2006 and therefore lacked company-specific historical and implied volatility information, we based our estimate of expected volatility on the historical volatility of similar entities whose share prices are publicly available. We intend to continue to consistently apply this process using the same group of similar entities until sufficient historical information regarding the volatility of our share price becomes available, or unless circumstances change such that the identified entities are no longer similar to us. In this latter case, more suitable, similar entities whose share prices are publicly available would be utilized in the calculation. This conclusion and approach is consistent with the approach utilized by management when valuing share-based payment awards reported via pro forma results for SFAS No. 123 and SFAS No. 148, *Accounting for Stock-based Compensation-Transition and Disclosure*, or SFAS No. 148.

Under SFAS No. 123R, we have separated our employees into two groupings: management, including the board of directors, and non-management. However, given our current use of the simplified method, as discussed above, the establishment of these groupings will not affect the expected term we utilize until we cease to employ the simplified method of estimating expected term. We viewed all employees as one grouping when valuing share-based payment awards reported via pro forma results for SFAS No. 123 and SFAS No. 148 prior to the adoption of SFAS No. 123R.

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The risk-free rate utilized when valuing share-based payment arrangements is based on the U.S. Treasury yield curve in effect at the time of grant for the expected term of the particular instrument being valued. This is consistent with the approach we utilized when valuing share-based payment awards reported via pro forma results for SFAS No. 123 and SFAS No. 148.

As of September 30, 2006, due to the adoption of SFAS No. 123R, the total compensation cost related to nonvested options not yet recognized in the financial statements is approximately \$1.8 million and the weighted average period over which it is expected to be recognized is 1.6 years.

Based on the initial public offering price of \$11.50 per share, the intrinsic value of the options outstanding at September 30, 2006 was \$7.6 million, of which \$3.5 million related to vested options and \$4.1 million related to unvested options.

Determining the market value of our stock requires making complex and subjective judgments. From inception through 2004, our management and board of directors concluded on the market value of our common stock after performing an internal valuation analysis. In addition, in July 2005, we obtained an unrelated third-party valuation analysis as of November 2004. Prior to obtaining the independent third-party valuation, the internal valuation conducted by management and our board of directors included consideration of market conditions, the liquidation preferences, dividends and voting rights of our various classes of stock, our financial and operating performance, progress against development goals as well as the value of other companies that are similar to ours. We used this internal valuation approach to determine the market value for all equity issuances prior to November 2004.

During 2005, we engaged Fletcher Spaght Inc., a third-party valuation firm, to assist our board of directors in assessing the market value of our common stock as of November 2004. This third-party valuation analysis was based on an analysis of comparable companies, as well as on an income approach, which uses discounted future cash flow that includes our estimates of revenue, driven by assumed market growth rates, and estimated costs as well as appropriate discount rates. This valuation analysis also utilized the methods outlined in the AICPA Practice Aid, *Valuation of Privately Held Company Equity Securities Issued as Compensation*. We allocated the enterprise value resulting from this analysis to preferred and common shares using the option-pricing method. The option-pricing method involves making estimates of the anticipated timing of a potential liquidity event, such as a sale of our company or an initial public offering, and estimates of the volatility of our enterprise value. The anticipated timing is based on the plans of our board of directors and management. Estimating the volatility of the share price of a privately held company is complex because there is no readily available market for the shares. We estimated the volatility of our enterprise value based on available information on volatility of stocks of comparable publicly traded companies in our industry. Had we used different estimates, the allocations between preferred and common shares would have been different. We used this valuation to determine the value of the series C-1 convertible preferred stock issued to Gilead Sciences in connection with our collaboration, as well as to determine the fair value of the common stock underlying options granted from July 2005 through November 2005. In addition, we retroactively applied this valuation to option grants from November 2004 until July 2005.

In December 2005, our board of directors made a determination of the fair value of our common stock for accounting purposes in connection with the issuance of stock options. We did not, at that time, obtain a contemporaneous independent third-party valuation due to the cost of obtaining such valuations and the close proximity of a recent financing round. In making the determination of fair value, our board of directors drew on the knowledge of its directors who have experience in early-stage life sciences companies and considered the following information:

- pricing of actual and potential private sales of our convertible preferred stock;
- prior valuations of stock grants and convertible preferred stock sales and the effect of events, including the progression of our drug candidates, that occurred between the time of the grants;
- comparative rights and preferences of the security being granted compared to the rights and preferences of our other outstanding equity;

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- comparative values of public companies discounted for the risk and limited liquidity provided for in the shares we are issuing;
- the independent analysis of Fletcher Spaght described above and events occurring during the period from the Fletcher Spaght valuation through the date of grant;
- any perspective provided by any investment banks, including the likelihood of an initial public offering and the potential value of the company in an initial public offering; and
- general economic trends.

During 2005, we granted stock options to acquire 15,159 shares of common stock at an exercise price of \$1.60 per share and 252,618 shares at an exercise price of \$4.00 per share, of which 250,118 options were granted on December 20, 2005 as part of our recurring year-end compensation adjustments.

During 2006, in connection with our initial public offering, our board of directors determined to undertake a reassessment of the fair value of common stock as of the December 20, 2005 grant date. In connection with this undertaking, our board of directors considered the following:

- the valuation indicated by the May 2006 closing of our series C-2 convertible preferred stock financing, which included participation by investors who had not participated in prior financing rounds; and
- events that occurred toward the end of 2005, including (i) initiation of phase II clinical trials in elvucitabine, and (ii) initiation of phase I clinical trials in ACH-806.

Following this assessment, our board of directors, with input from management, reassessed the fair value of our common stock and determined that the exercise price of the employee stock options granted on December 20, 2005 was less than the reassessed fair value of \$11.00 per share of our common stock at the date of grant for accounting purposes. In connection with our adoption of SFAS No. 123R effective January 1, 2006, we reassessed the fair value of our unvested options using a Black-Scholes model. As a result, the restated aggregate fair value of this grant to be recognized over the four-year vesting period is \$2.2 million, or \$8.73 per share. We had previously assigned an aggregate fair value of \$611 to this grant.

There is inherent uncertainty in making valuation estimates. For example, increases in the volatility of our stock, increased expected term, and higher stock prices would all, individually and in aggregate, increase the expense taken related to share based payments, whereas decreases would decrease expense.

### *Accrued Expenses*

As part of the process of preparing financial statements, we are required to estimate accrued expenses. This process involves identifying services which have been performed on our behalf and estimating the level of service performed and the associated cost incurred for such service as of each balance sheet date in our financial statements.

In accruing service fees, we estimate the time period over which services will be provided and the level of effort in each period. If the actual timing of the provision of services or the level of effort varies from the estimate, we will adjust the accrual accordingly. The majority of our service providers invoice us monthly in arrears for services performed. In the event that we do not identify costs that have begun to be incurred or we underestimate or overestimate the level of services performed or the costs of such services, our actual expenses could differ from such estimates. The date on which some services commence, the level of services performed on or before a given date and the cost of such services are often subjective determinations. We make judgments based upon facts and circumstances known to us in accordance with GAAP.

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[Table of Contents](#)**Results of Operations**

Results of operations may vary from period to period depending on numerous factors, including the timing of payments received under existing or future strategic alliances, joint ventures or financings, if any, the progress of our research and development projects, technological advances and determinations as to the commercial potential of proposed products.

**Comparison of Three Months Ended September 30, 2006 and 2005**

*Revenue.* Revenue was \$1.2 million and \$2.3 million for the three months ended September 30, 2006 and 2005, respectively. The decrease in 2006 as compared to 2005 is the result of a reduction in the rate of amortization of upfront and milestone payments under our collaboration with Gilead Sciences. Amortization decreased as the result of lengthening the period of our expected effort under the collaboration. In addition, cost-sharing revenue declined as a result of the fewer number of Achillion personnel hours charged to the ACH-806 program, as well as the greater number of Gilead personnel hours charged to the program. Under our collaboration with Gilead Sciences, we recognize cost-sharing revenue as one-half of our costs under the ACH-806 program, less one-half of Gilead Sciences' costs. Revenue consisted of the following:

	Three Months Ended September 30,	
	2006	2005
	(in thousands)	
Amortization of up-front and milestone payments	\$ 529	\$ 1,075
Cost-sharing revenue	594	1,109
Grant revenue	73	109
Total revenue	<u>\$ 1,196</u>	<u>\$ 2,293</u>

In the first quarter of 2007, we expect to complete the proof-of-concept clinical trial for ACH-806, after which our amortization revenue under the collaboration with Gilead Sciences will have been substantially recognized.

*Research and development expenses.* Research and development expenses were \$5.3 million and \$4.5 million for the three months ended September 30, 2006 and 2005, respectively. The approximate \$828,000 increase from 2005 to 2006 was the result of: (i) increased personnel costs for our research and development staff, including an increase in headcount as well as increased wages, (ii) the costs associated with two on-going clinical trials using elvucitabine during 2006, as compared to one on-going trial during the same period in 2005, and (iii) the costs associated with phase I and Ib/II clinical development of ACH-806 in 2006 but not in 2005. Research and development expenses for the nine months ended September 30, 2006 and 2005 are comprised as follows:

	Three Months Ended September 30,		Change
	2006	2005	
	(in thousands)		
Personnel costs	\$ 1,488	\$ 1,352	\$ 136
Outsourced research and supplies	2,617	1,900	717
Professional and consulting fees	414	470	(56)
Facilities costs	713	688	25
Travel and other costs	68	62	6
Total	<u>\$ 5,300</u>	<u>\$ 4,472</u>	<u>\$ 828</u>

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*General and administrative expenses.* General and administrative expenses were \$1.0 million and \$707,000 for the three months ended September 30, 2006 and 2005, respectively. The \$316,000 increase from 2005 to 2006 was due to increased professional fees, particularly accounting fees associated with our new quarterly reporting obligations, and recruitment fees associated with our search for a new head of business development. We expect that general and administrative expenses will increase in the future due to increased payroll, expanded infrastructure, increased consulting, recruiting, legal, accounting and investor relations expenses associated with being a public company. General and administrative expenses for the three months ended September 30, 2006 and 2005 are comprised as follows:

	Three Months Ended September 30,		Change
	2006	2005	
		(in thousands)	
Personnel costs	\$ 505	\$ 439	\$ 66
Professional and consulting fees	282	110	172
Facilities costs	174	150	24
Travel and other costs	62	8	54
Total	<u>\$ 1,023</u>	<u>\$ 707</u>	<u>\$ 316</u>

*Interest income (expense).* Interest income was \$162,000 and \$43,000 for the three months ended September 30, 2006 and 2005, respectively. The \$119,000 increase from 2005 to 2006 was primarily due to increased average cash balances over the three-month period. Cash balances increased in March and May 2006 with receipt of \$18.4 million in proceeds from the sale of shares of our series C-2 convertible preferred stock and \$5.0 million in proceeds from a debt facility. Interest expense was \$232,000 and \$297,000 for the three months ended September 30, 2006 and 2005, respectively. The \$65,000 decrease from 2005 to 2006 was primarily attributable to conversion of notes payable in November 2005 on which we had incurred \$245,000 of interest expense, offset in part by interest expense on a debt facility entered into on December 30, 2005. Under FSP-150-5, *Issuer's Accounting under FASB No. 150 for Freestanding Warrants and Other Similar Instruments on Shares that are Redeemable*, or FSP-150-5, we increased other income in the amount of \$72,000 to adjust preferred warrant values.

*Tax Benefit.* The State of Connecticut provides companies with the opportunity to forego certain research and development tax credit carryforwards in exchange for cash. The program provides for such exchange of the research and development credits at a rate of 65% of the annual incremental and non-incremental research and development credits, as defined. The amount of tax benefit we recognized in connection with this exchange program was \$9,000 and \$15,000 for the three months ended September 30, 2006 and 2005, respectively. The \$6,000 decrease from 2005 to 2006 was due to the specific types of research and development expenses incurred and the decreasing amount of such costs incurred within the State of Connecticut.

*Accretion of preferred stock dividends.* Accretion of preferred stock dividends was \$1.4 million and \$693,000 for the three months ended September 30, 2006 and 2005, respectively. The \$714,000 increase from 2005 to 2006 was due to an increased number of shares outstanding during the period, particularly 23,425,462 shares of series C-2 convertible preferred stock issued in November 2005, March 2006 and May 2006, none of which were outstanding during the three months ended September 30, 2005. There will be no accretion of preferred stock dividends following the conversion of our convertible preferred stock which occurred on October 31, 2006.

### Comparison of Nine Months Ended September 30, 2006 and 2005

*Revenue.* Revenue was \$5.5 million and \$7.2 million for the nine months ended September 30, 2006 and 2005, respectively. The decrease in 2006 as compared to 2005 was due to a reduction in the rate of amortization of upfront and milestone payments under our collaboration with Gilead Sciences, due to lengthening the term of



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our expected effort under the collaboration. In addition, the decrease results from increased costs related to ACH-806 formulation and manufacturing incurred by Gilead Sciences, and to a lesser extent, to the fewer number of Achillion personnel hours charged to the ACH-806 program. Under our collaboration with Gilead Sciences, we recognize cost-sharing revenue as one-half of our costs under the ACH-806 program, less one-half of Gilead Sciences' costs. In addition, the rate of amortization of upfront and milestone payments decreased as the result of the lengthening of the period of our expected effort under the collaboration. Revenue consisted of the following:

	Nine Months Ended September 30,	
	2006	2005
	(in thousands)	
Amortization of up-front and milestone payments	\$ 3,030	\$ 3,780
Cost-sharing revenue	2,253	3,215
Grant revenue	231	162
Total revenue	<u>\$ 5,514</u>	<u>\$ 7,157</u>

In the first quarter of 2007, we expect to complete the proof-of-concept clinical trial for ACH-806, after which our amortization revenue under the collaboration with Gilead Sciences will have been substantially recognized.

*Research and development expenses.* Research and development expenses were \$16.3 million and \$13.9 million for the nine months ended September 30, 2006 and 2005, respectively. The approximate \$2.4 million increase from 2005 to 2006 was the result of: (i) increased personnel costs for our research and development staff, including an increase in headcount as well as increased wages, (ii) the costs associated with on-going clinical trials using elvucitabine, as compared to one on-going trial during most of 2005, and (iii) the costs associated with phase I and phase Ib/II clinical development of ACH-806. In addition, during the first half of 2006, we incurred increased costs associated with the manufacturing and formulation of both elvucitabine and ACH-806. Research and development expenses for the nine months ended September 30, 2006 and 2005 are comprised as follows:

	Nine Months Ended September 30,		Change
	2006	2005	
	(in thousands)		
Personnel costs	\$ 4,675	\$ 3,952	\$ 723
Outsourced research and supplies	8,199	6,482	1,717
Professional and consulting fees	1,198	1,137	61
Facilities costs	2,066	2,111	(45)
Travel and other costs	200	205	(5)
Total	<u>\$16,338</u>	<u>\$13,887</u>	<u>\$2,451</u>

Drug candidates in clinical development have greater associated development costs than those in the research or preclinical stage, and as a drug 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 with respect to elvucitabine and ACH-702, but will be offset somewhat by reduced costs from our ACH-806 program if and when we achieve proof-of-concept for that drug candidate.

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*General and administrative expenses.* General and administrative expenses were \$3.3 million and \$2.3 million for the nine months ended September 30, 2006 and 2005, respectively. The approximate \$1.0 million increase from 2005 to 2006 was due to increased professional fees, particularly (i) accounting fees associated with our new quarterly reporting obligations, (ii) recruiting fees associated with our search for a business development head and (iii) increased legal and other costs associated with preparation for our initial public offering. We expect that general and administrative expenses will increase in the future due to increased payroll, expanded infrastructure and increased consulting, legal, accounting and investor relations expenses associated with being a public company. General and administrative expenses for the nine months ended September 30, 2006 and 2005 are comprised as follows:

	Nine Months Ended September 30,		Change
	2006	2005 (in thousands)	
Personnel costs	\$ 1,404	\$ 1,326	\$ 78
Professional and consulting fees	1,186	323	863
Facilities costs	524	471	53
Travel and other costs	226	206	20
Total	<u>\$ 3,340</u>	<u>\$ 2,326</u>	<u>\$ 1,014</u>

*Interest income (expense).* Interest income was \$430,000 and \$186,000 for the nine months ended September 30, 2006 and 2005, respectively. The \$244,000 increase from 2005 to 2006 was primarily due to increased average cash balances over the nine-month period. Cash balances increased on March 22, 2006 and May 12, 2006 with receipt of \$18.4 million in proceeds from the sale of shares of our series C-2 convertible preferred stock and \$5.0 million in proceeds from a debt facility. Interest expense was \$679,000 and \$958,000 for the nine months ended September 30, 2006 and 2005, respectively. The \$279,000 decrease from 2005 to 2006 was primarily attributable to conversion of notes payable in November 2005 on which we incurred \$791 of interest expense, offset in part by interest expense on a debt facility entered into on December 30, 2005. Under FSP-150-5, we increased other income in the amount of \$72,000 to adjust preferred warrant values.

*Tax Benefit.* The State of Connecticut provides companies with the opportunity to forego certain research and development tax credit carryforwards in exchange for cash. The program provides for such exchange of the research and development credits at a rate of 65% of the annual incremental and non-incremental research and development credits, as defined. The amount of tax benefit we recognized in connection with this exchange program was \$59,000 and \$75,000 for the nine months ended September 30, 2006 and 2005, respectively. The \$16,000 decrease from 2005 to 2006 was due to the specific types of research and development expenses incurred and the decreasing amount of such costs incurred within the State of Connecticut.

*Accretion of preferred stock dividends.* Accretion of preferred stock dividends was \$3.7 million and \$2.1 million for the nine months ended September 30, 2005 and 2006, respectively. The \$1.6 million increase from 2006 to 2005 was due to an increased number of shares outstanding during the period, particularly 23,425,462 shares of series C-2 convertible preferred stock issued in November 2005, March 2006 and May 2006, some of which were outstanding for the first three quarters of 2006 but not for the corresponding quarters of 2005.

## Liquidity and Capital Resources

In October 2006, we completed an initial public offering of 5,175,000 shares of common stock at a price of \$11.50 per share, which includes the exercise of the underwriters' over-allotment option. Net proceeds to us from the offering were approximately \$53.4 million (net of underwriting discounts and commissions and offering expenses).

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Prior to our initial public offering, we had financed our operations primarily through the issuance of our convertible preferred stock and borrowings under debt facilities, as well as through receipts from our collaboration with Gilead Sciences. Through September 30, 2006, we had received approximately \$101.8 million in aggregate net proceeds from stock issuances, \$15.2 million from Gilead Sciences under our collaboration agreement with them and approximately \$15.8 million under debt facilities. Please see note 6 to the financial statements included in Item 1 of this Quarterly Report on Form 10-Q for additional information regarding our debt facilities.

In March and May 2006, we received \$18.4 million in net proceeds from the sale of 12,270,815 additional shares of our series C-2 convertible preferred stock at \$1.50 per share, and \$5.0 million in proceeds from the issuance of promissory notes under existing debt facilities.

We had approximately \$14.4 million in cash, cash equivalents and marketable securities as of September 30, 2006.

Cash used in operating activities was \$10.7 million for the nine months ended September 30, 2005 and was primarily attributable to our \$9.8 million net loss, and the \$1.8 million amortization of deferred revenue, offset somewhat by \$1.6 million in non-cash charges such as depreciation, amortization and non-cash interest expense. Cash used in operating activities was \$15.0 million for the nine months ended September 30, 2006 and was primarily attributable to our net operating loss and the \$3.0 million amortization of deferred revenue, offset by non-cash charges for depreciation, amortization, and stock based compensation.

Cash provided by investing activities was \$4.8 million for the nine months ended September 30, 2005 and was primarily attributable to the maturity of marketable securities. Cash used in investing activities was \$303,000 during the nine months ended September 30, 2006, substantially related to the purchase of laboratory equipment.

Cash used in financing activities was \$532 for the nine months ended September 30, 2005 and was primarily attributable to debt repayments. Cash provided by financing activities was \$20.1 million for the nine months ended September 30, 2006 and was primarily attributable to \$18.2 million in proceeds from the issuance of an additional 12,270,815 shares of our series C-2 convertible preferred stock on March 22, 2006 and May 12, 2006 and \$5.0 million in proceeds from the issuance of debt on May 12, 2006.

We expect to incur substantial and increasing losses for at least the next several years as we seek to:

- complete our phase II clinical trials for elvucitabine and, if supported by favorable data from the phase II trials, initiate phase III clinical trials;
- complete our proof-of-concept clinical trial for ACH-806 (also known as GS 9132);
- advance ACH-702 through preclinical testing, submit an IND to the FDA and begin a phase I clinical trial; and
- continue to advance our other research and development programs in HIV and HCV and identify additional drug candidates.

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 the development of any of our drug candidates. As a result, we expect that we will need to raise additional funds prior to being able to market any drug candidates, to, among other things, obtain regulatory approvals, fund operating losses, and, if deemed appropriate, establish manufacturing and sales and marketing capabilities. We will seek to raise such additional financing through public or private equity or debt financings, collaborative or other arrangements with third parties or through other sources of financing.

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We believe that the net proceeds from our initial public offering, together with interest thereon and our existing cash and cash equivalents, as supplemented by research funding pursuant to our collaboration with Gilead Sciences, will be sufficient to meet our projected operating requirements for at least the next twelve months.

However, our funding requirements may change and will depend upon numerous factors, including but not limited to:

- the progress of our research and development programs;
- the timing and results of preclinical testing and clinical studies;
- the receipt and timing of regulatory approvals, if any;
- determinations as to the commercial potential of our proposed products;
- the status of competitive products;
- our ability to establish and maintain collaborative arrangements with others for the purpose of funding certain research and development programs;
- the acquisition of technologies or drug candidates; and
- our participation in the manufacture, sale and marketing of any approved drugs.

Although we anticipate that we will augment our cash balance through financing transactions, no arrangements have been entered into for any future financing, and there can be no assurance that we will be able to obtain adequate levels of additional funding on favorable terms, if at all. If adequate funds are not available, we may be required to:

- delay, reduce the scope of or eliminate our research and development programs;
- reduce our planned commercialization efforts;
- obtain funds through arrangements with collaborators or others on terms unfavorable to us or that may require us to relinquish rights to certain drug candidates that we might otherwise seek to develop or commercialize independently; and/or
- pursue merger or acquisition strategies.

### **Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements or relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities.

### **Contractual Obligations and Commitments**

The following table sets forth a summary of our commitments as of September 30, 2006:

	Payment Due by Period				
	Total	Less Than 1 Year	1-3 Years (in thousands)	3-5 Years	More than 5 Years
Long-term debt	\$11,581	\$ 4,425	\$ 6,328	\$ 828	\$ —
Operating lease obligations	3,821	953	1,960	908	—
Clinical research obligations	4,431	4,431	—	—	—
Other research obligations and licenses	4,723	4,270	234	219	—
Total	<u>\$24,556</u>	<u>\$ 14,079</u>	<u>\$ 8,522</u>	<u>\$ 1,955</u>	<u>\$ —</u>

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The above amounts exclude potential payments that are based on the progress of our drug candidates in development, to be made under our license agreements, as these payments are not yet determinable.

### **Recently Issued Accounting Pronouncements**

In July 2006, the FASB issues Interpretation No. 48, *Accounting for Uncertainty in Income Taxes — an interpretation of FASB Statement No. 109*, or FIN 48. FIN 48 prescribes a comprehensive model for how a company should recognize, measure, present, and disclose in its financial statements uncertain tax positions that the company has taken or expects to take on a tax return (including a decision whether to file or not file a return in a particular jurisdiction). Under FIN 48, the financial statements will reflect expected future tax consequences of such positions presuming the taxing authorities' full knowledge of the position and all relevant facts, but without considering time values. FIN 48 substantially changes the applicable accounting model and is likely to cause greater volatility in income statements as more items are recognized discretely within income tax expense. FIN 48 also revises disclosure requirements and introduces a prescriptive, annual tabular rollforward of the unrecognized tax benefits. FIN 48 is effective for us beginning January 1, 2007. We are evaluating the impact of adopting FIN 48 on its financial position and results of operations.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*. SFAS No. 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. The standard is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. We do not believe that the adoption of SFAS No. 157 in the first quarter of 2008 will have a material impact on our financial statements.

In September 2006, the SEC issued Staff Accounting Bulletin No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements*, or SAB 108. SAB 108 provides interpretive guidance on how the effects of the carryover or reversal of prior year misstatements should be considered in quantifying a current year misstatement. The SEC staff believes that registrants should quantify errors using both a balance sheet and an income statement approach and evaluate whether either approach results in quantifying a misstatement that, when all relevant quantitative and qualitative factors are considered, is material. We do not believe that the adoption of SAB 108 for the full year ending December 31, 2006 will have a material impact on our financial statements.

**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

*Interest Rate Risk.* Our exposure to market risk is confined to our cash, cash equivalents and marketable securities. We invest in high-quality financial instruments, primarily money market funds, federal agency notes, asset backed securities, corporate debt securities and U.S. treasury notes, with the effective duration of the portfolio less than six months and no security with an effective duration in excess of 12 months, which we believe are subject to limited credit risk. We currently do not hedge interest rate exposure. Due to the short-term nature of our investments, we do not believe that we have any material exposure to interest rate risk arising from our investments.

*Capital Market Risk.* We currently have no product revenues and depend on funds raised through other sources. One source of funding is through further equity offerings. Our ability to raise funds in this manner depends upon capital market forces affecting our stock price.

**ITEM 4. CONTROLS AND PROCEDURES**

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2006. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2006, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

No change in our internal control over financial reporting (as defined in Rules 13a-15(d) and 15d-15(d) under the Exchange Act) occurred during the fiscal quarter ended September 30, 2006 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## PART II. OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS

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

### ITEM 1A. RISK FACTORS

You should carefully consider the following risk factors, in addition to other information included in this Quarterly Report on Form 10-Q and the other reports that we file with the SEC, in evaluating Achillion Pharmaceuticals and our business. If any of the following risks occur, our business, financial condition and operating results could be materially adversely affected.

#### Risks Related to Our Business

**We have a limited operating history and have incurred a cumulative loss since inception. If we do not generate significant revenues, we will not be profitable.**

We have incurred significant losses since our inception in August 1998. At September 30, 2006, our accumulated deficit was approximately \$113.6 million. We have not generated any revenue from the sale of drug candidates to date. We expect that our annual operating losses will increase substantially over the next several years as we expand our research, development and commercialization efforts, including:

- completing the phase II clinical trials for elvucitabine and, if supported by favorable data from the phase II clinical trials, moving into pivotal phase III clinical trials;
- completing the proof-of-concept clinical trial for ACH-806 (also known as GS 9132);
- advancing ACH-702 through preclinical testing, submitting an IND application to the FDA and beginning a phase I clinical trial; and
- continuing to advance our other research and discovery programs in HIV and HCV, and identifying other infectious disease drug candidates.

To become profitable, we must successfully develop and obtain regulatory approval for our drug candidates and effectively manufacture, market and sell any drug candidates we develop. Accordingly, we may never generate significant revenues and, even if we do generate significant revenues, we may never achieve profitability.

**We will need substantial additional capital to fund our operations, including drug candidate development, manufacturing and commercialization. If we do not have or cannot raise additional capital when needed, we will be unable to develop and commercialize our drug candidates successfully, and our ability to operate as a going concern may be adversely affected.**

We believe that our existing cash and cash equivalents, as supplemented by research funding pursuant to our collaboration with Gilead Sciences, will be sufficient to support our current operating plan through at least the next twelve months. However, our operating plan may change as a result of many factors, including:

- the costs involved in the preclinical and clinical development and manufacturing of elvucitabine, ACH-806 and ACH-702;
- the costs involved in obtaining regulatory approvals for our drug candidates;
- the scope, prioritization and number of programs we pursue;
- the costs involved in preparing, filing, prosecuting, maintaining, enforcing and defending patent and other intellectual property claims;

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- the costs associated with manufacturing our drug candidates;
- our ability to enter into corporate collaborations and the terms and success of these collaborations;
- our acquisition and development of new technologies and drug candidates; and
- competing technological and market developments currently unknown to us.

If our operating plan changes, we may need additional funds sooner than planned. Such additional financing may not be available when we need it or may not be available on terms that are favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. If adequate funds are not available to us on a timely basis, or at all, we may be required to:

- terminate or delay preclinical studies, clinical trials or other development activities for one or more of our drug candidates; or
- delay our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our drug candidates, if approved for sale.

We may seek additional financing through a combination of private and public equity offerings, debt financings and collaboration, strategic alliance and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include adverse liquidation or other preferences that adversely affect your rights as a stockholder. 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 additional funds through collaboration, strategic alliance and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or drug candidates, or grant licenses on terms that are not favorable to us.

### **We depend heavily on the success of our most advanced drug candidate, elvucitabine, for the treatment of HIV infection, which is still under development.**

We have invested a significant portion of our efforts and financial resources in the development of our most advanced drug candidate, elvucitabine, for the treatment of HIV infection. Our ability to generate revenues will depend heavily on the successful development and commercialization of this drug candidate. The commercial success of elvucitabine will depend on several factors, including the following:

- our ability to provide acceptable evidence of its safety and efficacy in current and future clinical trials;
- receipt of marketing approvals from the FDA and similar foreign regulatory authorities;
- establishing commercial manufacturing arrangements with third-party manufacturers;
- launching commercial sales of the drug, whether alone or in collaboration with others; and
- acceptance of the drug in the medical community and with third-party payors.

We are currently studying elvucitabine in two phase II clinical trials. One or both of these clinical trials may not be successful, and the results of our phase II clinical trials, even if positive, may not be necessarily indicative of the results we will obtain in our planned phase III or other subsequent clinical trials that may be required for regulatory approval of this drug candidate. If we are not successful in commercializing elvucitabine, or are significantly delayed in doing so, our business will be materially harmed.

**Our market is subject to intense competition. If we are unable to compete effectively, our drug candidates may be rendered noncompetitive or obsolete.**



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We are engaged in segments of the pharmaceutical industry that are highly competitive and rapidly changing. Many large pharmaceutical and biotechnology companies, academic institutions, governmental agencies and other public and private research organizations are pursuing the development of novel drugs that target infectious diseases. We face, and expect to continue to face, intense and increasing competition as new products enter the market and advanced technologies become available. In addition to currently approved drugs, there are a significant number of drugs that are currently under development and may become available in the future for the treatment of HIV infection, chronic hepatitis C and serious hospital-based bacterial infections. We would expect elvucitabine, ACH-806 and ACH-702 to compete with the following approved drugs and drug candidates currently under development:

- *Elvucitabine*. If approved, we would expect elvucitabine to compete with currently approved drugs for the treatment of HIV infection, including Efavirenz (3TC), Zidovudine (AZT) and Emtriva (abacavir), marketed by GlaxoSmithKline, Emtriva (FTC) and Viread (tenofovir), marketed by Gilead Sciences, and Zidovudine (d4T) and Videx (ddI), marketed by Bristol-Myers Squibb. Elvucitabine may also compete with NRTI drug candidates currently in clinical development by other companies such as Avexa, Medivir, Pharmasset and Koronis, as well as other classes of drugs currently in clinical development by companies such as Abbott, Boehringer Ingelheim, Johnson & Johnson, Merck, Panacos, Pfizer, Roche, Schering-Plough, Trimeris and Vertex.
- *ACH-806*. If approved, we would expect ACH-806 to compete with currently approved drugs for the treatment of chronic hepatitis C, including Pegasys and Roferon-A, marketed by Roche, and Intron-A and Peg-Intron, marketed by Schering-Plough. ACH-806 may also compete with drug candidates currently in clinical development by other companies such as Abbott, Anadys, Arrow Pharmaceuticals, Boehringer Ingelheim, Bristol-Myers Squibb, Gilead Sciences, GlaxoSmithKline, Human Genome Sciences, Idenix Pharmaceuticals, Intermune, Johnson & Johnson, Medivir, Merck, Novartis, Panacos, Pfizer, Pharmasset, Roche, Schering-Plough, Trimeris, Valeant and Vertex.
- *ACH-702*. If approved, we would expect ACH-702 to compete with currently approved drugs for the treatment of bacterial infections, including Cubicin (daptomycin), marketed by Cubist Pharmaceuticals, Zyvox (linezolid), marketed by Pfizer, and Synercid (dalbavancin + quinupristin), marketed by King Pharmaceuticals. ACH-702 may also compete with drug candidates currently in clinical development by other companies such as Intermune, Theravance, Basilea and Johnson & Johnson.

Many of our competitors have:

- significantly greater financial, technical and human resources than we have and may be better equipped to discover, develop, manufacture and commercialize drug candidates;
- more extensive experience in preclinical testing and clinical trials, obtaining regulatory approvals and manufacturing and marketing pharmaceutical products;
- drug candidates that have been approved or are in late-stage clinical development; and/or
- collaborative arrangements in our target markets with leading companies and research institutions.

Competitive products may render our products obsolete or noncompetitive before we can recover the expenses of developing and commercializing our drug candidates. Furthermore, the development of new treatment methods and/or the widespread adoption or increased utilization of any vaccine for the diseases we are targeting could render our drug candidates noncompetitive, obsolete or uneconomical. If we successfully develop and obtain approval for our drug candidates, we will face competition based on the safety and effectiveness of our drug candidates, the timing of their entry into the market in relation to competitive products in development, the availability and cost of supply, marketing and sales capabilities, reimbursement coverage, price, patent position and other factors. If we successfully develop drug candidates but those drug candidates do not achieve and maintain market acceptance, our business will not be successful.

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### **If we are not able to attract and retain key management and scientific personnel and advisors, we may not successfully develop our drug candidates or achieve our other business objectives.**

We depend upon our senior management and scientific staff for our business success. Key members of our senior team include Michael Kishbauch, our president and chief executive officer, Dr. Milind Deshpande, our senior vice president and chief scientific officer, and Dr. John Pottage, our senior vice president and chief medical officer. Our employment agreements with all of our senior management employees are terminable without notice by the employee. The loss of the service of any of the key members of our senior management may significantly delay or prevent the achievement of drug development and other business objectives. Our ability to attract and retain qualified personnel, consultants and advisors is critical to our success. We face intense competition for qualified individuals from numerous pharmaceutical and biotechnology companies, universities, governmental entities and other research institutions. We may be unable to attract and retain these individuals, and our failure to do so would adversely affect our business.

### **Our business has a substantial risk of product liability claims. If we are unable to obtain appropriate levels of insurance, a product liability claim could adversely affect our business.**

Our business exposes us to significant potential product liability risks that are inherent in the development, manufacturing and sales and marketing of human therapeutic products. Although we do not currently commercialize any products, claims could be made against us based on the use of our drug candidates in clinical trials. We currently have clinical trial insurance in an amount equal to up to \$9.0 million in the aggregate and will seek to obtain product liability insurance prior to the sales and marketing of any of our drug candidates. However, our insurance may not provide adequate coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to maintain current amounts of insurance coverage or obtain additional or sufficient insurance at a reasonable cost to protect against losses that could have a material adverse effect on us. If a claim is brought against us, we might be required to pay legal and other expenses to defend the claim, as well as uncovered damages awards resulting from a claim brought successfully against us. Furthermore, whether or not we are ultimately successful in defending any such claims, we might be required to direct significant financial and managerial resources to such defense, and adverse publicity is likely to result.

### **Risks Related to the Development of Our Drug Candidates**

#### **All of our drug candidates are still in the early stages of development and remain subject to clinical testing and regulatory approval. If we are unable to successfully develop and test our drug candidates, we will not be successful.**

To date, we have not marketed, distributed or sold any drug candidates. The success of our business depends primarily upon our ability to develop and commercialize our drug candidates successfully. Our most advanced drug candidates are elvucitabine, which is currently in phase II clinical trials, and ACH-806 (also known as GS 9132), which is in a proof-of-concept clinical trial. Our other drug candidates are in various stages of preclinical development. Our drug candidates must satisfy rigorous standards of safety and efficacy before they can be approved for sale. To satisfy these standards, we must engage in expensive and lengthy testing and obtain regulatory approval of our drug candidates. Despite our efforts, our drug candidates may not:

- offer therapeutic or other improvement over existing, comparable drugs;
- be proven safe and effective in clinical trials;
- meet applicable regulatory standards;
- be capable of being produced in commercial quantities at acceptable costs; or
- be successfully commercialized.

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Positive results in preclinical studies of a drug candidate may not be predictive of similar results in humans during clinical trials, and promising results from early clinical trials of a drug candidate may not be replicated in later clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in early-stage development. Accordingly, the results from the completed preclinical studies and clinical trials and ongoing clinical trials for elvucitabine, ACH-806, ACH-702 and our other drug candidates may not be predictive of the results we may obtain in later stage trials. We do not expect any of our drug candidates to be commercially available for at least several years.

### **If we are unable to obtain U.S. and/or foreign regulatory approval, we will be unable to commercialize our drug candidates.**

Our drug candidates are subject to extensive governmental regulations relating to development, clinical trials, manufacturing and commercialization. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process are required in the United States and in many foreign jurisdictions prior to the commercial sale of our drug candidates. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. It is possible that none of the drug candidates we are developing will obtain marketing approval. In connection with the clinical trials for elvucitabine, ACH-806, ACH-702 and any other drug candidate we may seek to develop in the future, we face risks that:

- the drug candidate may not prove to be efficacious;
- the drug may not prove to be safe;
- the results may not confirm the positive results from earlier preclinical studies or clinical trials; and
- the results may not meet the level of statistical significance required by the FDA or other regulatory agencies.

We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA. The time required to complete clinical trials and for FDA and other countries' regulatory review processes is uncertain and typically takes many years. Our analysis of data obtained from preclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unanticipated delays or increased costs due to government regulation from future legislation or administrative action or changes in FDA policy during the period of product development, clinical trials and FDA regulatory review.

Any delay in obtaining or failure to obtain required approvals could materially adversely affect our ability to generate revenues from the particular drug candidate. Furthermore, any regulatory approval to market a product may be subject to limitations on the indicated uses for which we may market the product. These limitations may limit the size of the market for the product. We are also subject to numerous foreign regulatory requirements governing the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process includes all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of foreign regulations. Approval by the FDA does not ensure approval by regulatory authorities outside the United States. Foreign jurisdictions may have different approval procedures than those required by the FDA and may impose additional testing requirements for our drug candidates.

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

We cannot predict whether we will encounter problems with any of our completed, ongoing or planned clinical trials that will cause us or regulatory authorities to delay or suspend clinical trials, or delay the analysis

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of data from our completed or ongoing clinical trials. Any of the following could delay the clinical development of our drug candidates:

- ongoing discussions with the FDA or comparable foreign authorities regarding the scope or design of our clinical trials;
- delays in receiving, or the inability to obtain, required approvals from institutional review boards or other reviewing entities at clinical sites selected for participation in our clinical trials;
- delays in enrolling volunteers and patients into clinical trials;
- a lower than anticipated retention rate of volunteers and patients in clinical trials;
- the need to repeat clinical trials as a result of inconclusive or negative results or unforeseen complications in testing;
- inadequate supply or deficient quality of drug candidate materials or other materials necessary to conduct our clinical trials;
- unfavorable FDA inspection and review of a clinical trial site or records of any clinical or preclinical investigation;
- serious and unexpected drug-related side effects experienced by participants in our clinical trials; or
- the placement by the FDA of a clinical hold on a trial.

Our ability to enroll patients in our clinical trials in sufficient numbers and on a timely basis will be subject to a number of factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites, the availability of effective treatments for the relevant disease and the eligibility criteria for the clinical trial. Delays in patient enrollment may result in increased costs and longer development times. For example, we are experiencing and may continue to experience delays in patient enrollment in connection with our phase II trial of elvucitabine in HIV infected patients who have failed a HAART regimen which included Epivir (3TC) due to the strict entry criteria for this trial. We are taking steps we believe will prevent future delays in the enrollment of this trial, including expanding the number of sites at which the trial will be conducted and changing the protocol of the trial to include additional treatment with elvucitabine after the initial 14 days of treatment. We cannot assure you that these actions will prevent further delays in patient enrollment in connection with this trial. In addition, subjects may drop out of our clinical trials, and thereby impair the validity or statistical significance of the trials.

We, the FDA or other applicable regulatory authorities may suspend clinical trials of a drug candidate at any time if we or they believe the subjects or patients participating in such clinical trials are being exposed to unacceptable health risks or for other reasons.

We cannot predict whether any of our drug candidates will encounter problems during clinical trials which will cause us or regulatory authorities to delay or suspend these trials, or which will delay the analysis of data from these trials. In addition, it is impossible to predict whether legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes, if any, may be. If we experience any such problems, we may not have the financial resources to continue development of the drug candidate that is affected or the development of any of our other drug candidates.

**Even if we obtain regulatory approvals, our drug candidates will be subject to ongoing regulatory review. If we fail to comply with continuing U.S. and applicable foreign regulations, we could lose those approvals, and our business would be seriously harmed.**

Even if we receive regulatory approval of any drugs we are developing or may develop, we will be subject to continuing regulatory review, including the review of clinical results which are reported after our drug candidates become commercially available approved drugs. As greater numbers of patients use a drug following

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its approval, side effects and other problems may be observed after approval that were not seen or anticipated during pre-approval clinical trials. In addition, the manufacturer, and the manufacturing facilities we use to make any approved drugs, will also be subject to periodic review and inspection by the FDA. The subsequent discovery of previously unknown problems with the drug, manufacturer or facility may result in restrictions on the drug, manufacturer or facility, including withdrawal of the drug from the market. If we fail to comply with applicable continuing regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approval, product recalls and seizures, operating restrictions and criminal prosecutions.

### **If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected.**

Our research and development efforts involve the controlled use of hazardous materials, chemicals and various radioactive compounds. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of biohazardous materials. Additional federal, state and local laws and regulations affecting our operations may be adopted in the future. Although we maintain workers' compensation insurance to cover us for costs we may incur due to injuries to our employees resulting from the use of these materials, this insurance may not provide adequate coverage against potential liabilities. Due to the small amount of hazardous materials that we generate, we have determined that the cost to secure insurance coverage for environmental liability and toxic tort claims far exceeds the benefits. Accordingly, we do not maintain any insurance to cover pollution conditions or other extraordinary or unanticipated events relating to our use and disposal of hazardous materials. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations.

### **Risks Related to Commercialization of Our Drug Candidates**

#### **If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our drug candidates, we may not generate product revenue.**

We have no commercial products, and we do not currently have an organization for the sales and marketing of pharmaceutical products. In order to successfully commercialize any drugs 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. For certain drug candidates in selected indications where we believe that an approved product could be commercialized by a specialty sales force in North America that calls on a limited but focused group of physicians, we intend to commercialize these products ourselves. However, in therapeutic indications that require a large sales force selling to a large and diverse prescribing population and for markets outside of North America, we plan to enter into arrangements with other companies for commercialization. For example, we have entered into an agreement with Gilead Sciences for the development and commercialization of ACH-806. 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 drugs, we may be unable to generate significant revenue, if any.**

Even if elvucitabine, ACH-806 and ACH-702, or any other drug candidates we may develop or acquire in the future, obtain regulatory approval, they may not gain market acceptance among physicians, health care payors, patients and the medical community. Physicians may elect not to recommend these drugs for a variety of reasons including:

- timing of market introduction of competitive drugs;

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- lower demonstrated clinical safety and efficacy compared to other drugs;
- lack of cost-effectiveness;
- lack of availability of reimbursement from managed care plans and other third-party payors;
- convenience and ease of administration;
- prevalence and severity of adverse side effects;
- other potential advantages of alternative treatment methods; and
- ineffective marketing and distribution support.

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

**If third-party payors do not adequately reimburse patients for any of our drug candidates that are approved for marketing, they might not be purchased or used, and our revenues and profits will not develop or increase.**

Our revenues and profits will depend significantly upon the availability of adequate reimbursement for the use of any approved drug candidates from governmental and other third-party payors, both in the United States and in foreign markets. Reimbursement by a third party may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost effective; and
- neither experimental nor investigational.

Obtaining reimbursement approval for a product from each third-party and government payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of any approved drugs to each payor. We may not be able to provide data sufficient to gain acceptance with respect to reimbursement. There also exists substantial uncertainty concerning third-party reimbursement for the use of any drug candidate incorporating new technology, and even if determined eligible, coverage may be more limited than the purposes for which the drug is approved by the FDA. Moreover, eligibility for coverage does not imply that any drug will be reimbursed in all cases or at a rate that allows us to make a profit or even cover our costs. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on payments allowed for lower-cost products that are already reimbursed, may be incorporated into existing payments for other products or services, and may reflect budgetary constraints and/or imperfections in Medicare or Medicaid data used to calculate these rates. Net prices for products may be reduced by mandatory discounts or rebates required by government health care programs or by any future relaxation of laws that restrict imports of certain medical products from countries where they may be sold at lower prices than in the United States.

There have been, and we expect that there will continue to be, federal and state proposals to constrain expenditures for medical products and services, which may affect payments for any of our approved products. The Centers for Medicare and Medicaid Services frequently change product descriptors, coverage policies, product and service codes, payment methodologies and reimbursement values. Third-party payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates and may have

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sufficient market power to demand significant price reductions. As a result of actions by these third-party payors, the health care industry is experiencing a trend toward containing or reducing costs through various means, including lowering reimbursement rates, limiting therapeutic class coverage and negotiating reduced payment schedules with service providers for drug products.

Our inability to promptly obtain coverage and profitable reimbursement rates from government-funded and private payors for any approved products could have a material adverse effect on our operating results and our overall financial condition.

**Recent federal legislation will increase the pressure to reduce prices of pharmaceutical products paid for by Medicare, which could adversely affect our revenues, if any.**

The Medicare Prescription Drug Improvement and Modernization Act of 2003, or MMA, changes the way Medicare will cover and pay for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and eventually will introduce a new reimbursement methodology based on average sales prices for drugs. In addition, this legislation provides authority for limiting the number of drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

### **Risks Related to Our Dependence on Third Parties**

**We may not be able to execute our business strategy if we are unable to enter into alliances with other companies that can provide capabilities and funds for the development and commercialization of our drug candidates. If we are unsuccessful in forming or maintaining these alliances on favorable terms, our business may not succeed.**

We have entered into a collaboration arrangement with Gilead Sciences for the development and commercialization of ACH-806 and, under certain circumstances, other HCV compounds with a similar mechanism of action, and we may enter into additional collaborative arrangements in the future. For example, we may enter into alliances with major biotechnology or pharmaceutical companies to jointly develop specific drug candidates and to jointly commercialize them if they are approved. In such alliances, we would expect our biotechnology or pharmaceutical collaborators to provide substantial funding, as well as significant capabilities in clinical development, regulatory affairs, marketing and sales. We may not be successful in entering into any such alliances on favorable terms, if at all. Even if we do succeed in securing such alliances, we may not be able to maintain them if, for example, development or approval of a drug candidate is delayed or sales of an approved drug are disappointing. Furthermore, any delay in entering into collaboration agreements could delay the development and commercialization of our drug candidates and reduce their competitiveness even if they reach the market. Any such delay related to our collaborations could adversely affect our business.

**If a collaborative partner terminates or fails to perform its obligations under agreements with us, the development and commercialization of our drug candidates could be delayed or terminated.**

If Gilead Sciences or another, future collaborative partner does not devote sufficient time and resources to collaboration arrangements with us, we may not realize the potential commercial benefits of the arrangement, and our results of operations may be adversely affected. In addition, if any existing or future collaboration partner were to breach or terminate its arrangements with us, the development and commercialization of the affected drug candidate could be delayed, curtailed or terminated because we may not have sufficient financial

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resources or capabilities to continue development and commercialization of the drug candidate on our own. Under our collaboration agreement with Gilead Sciences, Gilead Sciences may terminate the collaboration for any reason at any time upon 120 days notice after the earlier of (i) proof-of-concept of ACH-806 or (ii) November 24, 2006. If Gilead Sciences were to exercise this right, the development and commercialization of ACH-806 would be adversely affected.

Much of the potential revenue from our existing and future collaborations will consist of contingent payments, such as payments for achieving development milestones and royalties payable on sales of drugs developed. The milestone and royalty revenues that we may receive under these collaborations will depend upon our collaborator's ability to successfully develop, introduce, market and sell new products. In addition, our collaborators may decide to enter into arrangements with third parties to commercialize products developed under our existing or future collaborations using our technologies, which could reduce the milestone and royalty revenue that we may receive, if any. In many cases we will not be involved in these processes and accordingly will depend entirely on our collaborators. Our collaboration partners may fail to develop or effectively commercialize products using our products or technologies because they:

- decide not to devote the necessary resources due to internal constraints, such as limited personnel with the requisite scientific expertise, limited cash resources or specialized equipment limitations, or the belief that other drug development programs may have a higher likelihood of obtaining regulatory approval or may potentially generate a greater return on investment;
- do not have sufficient resources necessary to carry the drug candidate through clinical development, regulatory approval and commercialization; or
- cannot obtain the necessary regulatory approvals.

In addition, a collaborator may decide to pursue a competitive drug candidate developed outside of the collaboration. In particular, Gilead Sciences, our collaborator for our chronic hepatitis C program, currently is developing other products for the treatment of chronic hepatitis C, and the results of its development efforts could affect its commitment to our drug candidate. If our collaboration partners fail to develop or effectively commercialize drug candidates or drugs for any of these reasons, we may not be able to replace the collaboration partner with another partner to develop and commercialize a drug candidate or drugs under the terms of the collaboration. We may also be unable to obtain, on terms acceptable to us, a license from such collaboration partner to any of its intellectual property that may be necessary or useful for us to continue to develop and commercialize a drug candidate.

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

We do not have the ability to independently conduct clinical trials for our drug candidates, and we rely on third parties such as contract research organizations, medical institutions and clinical investigators to enroll qualified patients and conduct our clinical trials. Our reliance on these third parties for clinical development activities reduces our control over these activities. Accordingly, these third-party contractors may not complete activities on schedule, or may not conduct our clinical trials in accordance with regulatory requirements or our trial design. To date, we believe our contract research organizations and other similar entities with which we are working have performed well. However, if these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be required to replace them. Although we believe that there are a number of other third-party contractors we could engage to continue these activities, it may result in a delay of the affected trial. Accordingly, our efforts to obtain regulatory approvals for and commercialize our drug candidates may be delayed.

**We currently depend on third-party manufacturers to produce our preclinical and clinical drug supplies and intend to rely upon third-party manufacturers to produce commercial supplies of any approved drug candidates. If in the future we manufacture any of our drug candidates, we will be required to incur significant costs and devote significant efforts to establish and maintain these capabilities.**



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We have relied upon third parties to produce material for preclinical and clinical testing purposes and intend to continue to do so in the future. We also expect to rely upon third parties to produce materials required for the commercial production of our drug candidates if we succeed in obtaining necessary regulatory approvals. If we are unable to arrange for third-party manufacturing, or to do so on commercially reasonable terms, we may not be able to complete development of our drug candidates or market them. Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured drug candidates ourselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control and the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or damaging to us. In addition, the FDA and other regulatory authorities require that our drug candidates be manufactured according to current good manufacturing practice regulations. Any failure by us or our third-party manufacturers to comply with current good manufacturing practices and/or our failure to scale up our manufacturing processes could lead to a delay in, or failure to obtain, regulatory approval of any of our drug candidates. In addition, such failure could be the basis for action by the FDA to withdraw approvals for drug candidates previously granted to us and for other regulatory action.

We currently rely on a single manufacturer for the preclinical and clinical supplies of each of our drug candidates and do not currently have relationships for redundant supply or a second source for any of our drug candidates. To date, our third-party manufacturers have met our manufacturing requirements, but we cannot assure you that they will continue to do so. Any performance failure on the part of our existing or future manufacturers could delay clinical development or regulatory approval of our drug candidates or commercialization of any approved products. If for some reason our current contract manufacturers cannot perform as agreed, we may be required to replace them. Although we believe there are a number of potential replacements as our manufacturing processes are not manufacturer specific, we may incur added costs and delays in identifying and qualifying any such replacements. Furthermore, although we generally do not begin a clinical trial unless we believe we have a sufficient supply of a drug candidate to complete the trial, any significant delay in the supply of a drug candidate for an ongoing trial due to the need to replace a third-party manufacturer could delay completion of the trial.

We may in the future elect to manufacture certain of our drug candidates in our own manufacturing facilities. If we do so, we will require substantial additional funds and need to recruit qualified personnel in order to build or lease and operate any manufacturing facilities.

### **Risks Related to Patents and Licenses**

**If we are unable to adequately protect our drug candidates, or if we infringe the rights of others, our ability to successfully commercialize our drug candidates will be harmed.**

As of September 30, 2006, our patent portfolio included a total of 156 patents and patent applications worldwide. We own or hold exclusive licenses to a total of seven U.S. issued patents and 21 U.S. pending patent applications, as well as 122 pending PCT applications and foreign counterparts to many of these patents and patent applications. Our success depends in part on our ability to obtain patent protection both in the United States and in other countries for our drug candidates. Our ability to protect our drug candidates from unauthorized or infringing use by third parties depends in substantial part on our ability to obtain and maintain valid and enforceable patents. Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions and the scope of claims made under these patents, our ability to maintain, obtain and enforce patents is uncertain and involves complex legal and factual questions. Accordingly, rights under any issued patents may not provide us with sufficient protection for our drug candidates or provide sufficient protection to afford us a commercial advantage against competitive products or processes. In addition, we cannot guarantee that any patents will issue from any pending or future patent applications owned by or licensed to us. Even if patents have issued or will issue, we cannot guarantee that the claims of these patents are or will be valid or enforceable or will provide us with any significant protection

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against competitive products or otherwise be commercially valuable to us. Patent applications in the United States are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the U.S. Patent and Trademark Office, which we refer to as the U.S. Patent Office, for the entire time prior to issuance as a U.S. patent. Similarly, publication of discoveries in the scientific or patent literature often lag behind actual discoveries. Consequently, we cannot be certain that we or our licensors or co-owners were the first to invent, or the first to file patent applications on, our drug candidates or their use as anti-infective drugs. In the event that a third party has also filed a U.S. patent application relating to our drug candidates or a similar invention, we may have to participate in interference proceedings declared by the U.S. Patent Office to determine priority of invention in the United States. The costs of these proceedings could be substantial and it is possible that our efforts would be unsuccessful, resulting in a loss of our U.S. patent position. Furthermore, we may not have identified all U.S. and foreign patents or published applications that affect our business either by blocking our ability to commercialize our drugs or by covering similar technologies that affect our drug market.

The laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as in the United States and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. If we encounter such difficulties in protecting or are otherwise precluded from effectively protecting our intellectual property rights in foreign jurisdictions, our business prospects could be substantially harmed.

**We license patent rights from third-party owners. If such owners do not properly maintain or enforce the patents underlying such licenses, our competitive position and business prospects will be harmed.**

We are party to a number of licenses that give us rights to third-party intellectual property that is necessary or useful for our business. In particular, we have obtained a sublicense from Vion Pharmaceuticals and a license from Emory University with respect to elvucitabine. We may enter into additional licenses to third-party intellectual property in the future. Our success will depend in part on the ability of our licensors to obtain, maintain and enforce patent protection for their intellectual property, in particular, those patents to which we have secured exclusive rights. Our licensors may not successfully prosecute the patent applications to which we are licensed. Even if patents issue in respect of these patent applications, our licensors may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents, or may pursue such litigation less aggressively than we would. In addition, our licensors may terminate their agreements with us in the event we breach the applicable license agreement and fail to cure the breach within a specified period of time. Without protection for the intellectual property we license, other companies might be able to offer substantially identical products for sale, which could adversely affect our competitive business position and harm our business prospects.

**Litigation regarding patents, patent applications and other proprietary rights may be expensive and time consuming. If we are involved in such litigation, it could cause delays in bringing drug candidates to market and harm our ability to operate.**

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. Although we are not currently aware of any litigation or other proceedings or third-party claims of intellectual property infringement related to our drug candidates, the pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may obtain patents in the future and allege that the use of our technologies infringes these patent claims or that we are employing their proprietary technology without authorization. Likewise, third parties may challenge or infringe upon our existing or future patents. Under our license agreements with Vion Pharmaceuticals and The University of Maryland, we have the right, but not an obligation, to bring actions against an infringing third party. If we do not bring an action within a specified number of days, the licensor may bring an action against the infringing party. Pursuant to our license agreement with Emory University and our research collaboration and license agreement with Gilead Sciences, Emory and Gilead Sciences have the primary right, but not an obligation, to bring actions

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against an infringing third party. However, if Gilead Sciences or Emory elects not to bring an action, we may bring an action against the infringing party.

Proceedings involving our patents or patent applications or those of others could result in adverse decisions regarding:

- the patentability of our inventions relating to our drug candidates; and/or
- the enforceability, validity or scope of protection offered by our patents relating to our drug candidates.

Even if we are successful in these proceedings, we may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid, we may:

- incur substantial monetary damages;
- encounter significant delays in bringing our drug candidates to market; and/or
- be precluded from participating in the manufacture, use or sale of our drug candidates or methods of treatment requiring licenses.

### **Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other proprietary information and may not adequately protect our intellectual property.**

We rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. In order to protect our proprietary technology and processes, we also rely in part on confidentiality and intellectual property assignment agreements with our corporate partners, employees, consultants, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of confidential information nor result in the effective assignment to us of intellectual property, and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information or other breaches of the agreements. In addition, others may independently discover our trade secrets and proprietary information, and in such case we could not assert any trade secret rights against such party. Enforcing a claim that a party illegally obtained and is using our trade secrets is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets. Costly and time-consuming litigation could be necessary to seek to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

### **Risks Relating to Our Common Stock**

#### **Our stock price is likely to be volatile, and the market price of our common stock may decline in value in the future.**

The market price of our common stock could be subject to significant fluctuations. Market prices for securities of early-stage pharmaceutical, biotechnology and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include:

- the results of our current phase II and any future clinical trials for elvucitabine;
- the results of our current proof-of-concept and any future clinical trials for ACH-806;

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- the results of ongoing preclinical studies and planned clinical trials of our preclinical drug candidates, including ACH-702;
- the entry into, or termination of, key agreements, in particular our collaboration agreement with Gilead Sciences or our sublicense agreement with Vion Pharmaceuticals;
- the results of regulatory reviews relating to the approval of our drug candidates;
- the initiation of, material developments in, or conclusion of litigation to enforce or defend any of our intellectual property rights;
- failure of any of our drug candidates, if approved, to achieve commercial success;
- general and industry-specific economic conditions that may affect our research and development expenditures;
- the results of clinical trials conducted by others on drugs that would compete with our drug candidates;
- the failure or discontinuation of any of our research programs;
- issues in manufacturing our drug candidates or any approved products;
- the 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;
- future sales of our common stock;
- changes in the structure of health care payment systems; and
- period-to-period fluctuations in our financial results.

The stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may adversely affect the trading price of our common stock.

In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation.

**Our executive officers, directors and principal stockholders own a large percentage of our voting common stock and could limit our stockholders' influence on corporate decisions or could delay or prevent a change in corporate control.**

Our directors, executive officers and current holders of more than 5% of our outstanding common stock, together with their affiliates and related persons, beneficially own, in the aggregate, approximately [60]% of our outstanding common stock. As a result, these stockholders, if acting together, have the ability to determine the outcome of all 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 and other extraordinary transactions. The interests of this group of stockholders may not always coincide with our corporate interests or the interest of other stockholders, and they may act in a manner with which you may not agree or that may not be in the best interests of other stockholders. This concentration of ownership may have the effect of:

- delaying, deferring or preventing a change in control of our company;
- entrenching our management and/or board;
- impeding a merger, consolidation, takeover or other business combination involving our company; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our company.

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**Our management is required to devote substantial time and incur additional expense to comply with public company regulations. Our failure to comply with such regulations could subject us to public investigations, fines, enforcement actions and other sanctions by regulatory agencies and authorities and, as a result, our stock price could decline in value.**

As a private company with limited resources, we maintained a small finance and accounting staff. As a public company, the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the SEC, as well as the rules of the NASDAQ Global Market, now require us to implement additional corporate governance practices and adhere to a variety of reporting requirements and complex accounting rules. Compliance with these public company obligations will increase our legal and financial compliance costs and place significant additional demands on our finance and accounting staff and on our financial, accounting and information systems.

In particular, as a public company, our management will be required to conduct an annual evaluation of our internal controls over financial reporting and include a report of management on our internal controls in our annual reports on Form 10-K. In addition, we will be required to have our independent public accounting firm attest to and report on management's assessment of the effectiveness of our internal controls over financial reporting. Under current rules, we will be subject to these requirements beginning with our annual report on Form 10-K for our fiscal year ending December 31, 2007. If we are unable to conclude that we have effective internal controls over financial reporting or, if our independent auditors are unable to provide us with an attestation and an unqualified report as to the effectiveness of our internal controls over financial reporting, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the value of our common stock.

**A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future. If there are substantial sales of our common stock, the price of our common stock could decline.**

The price of our common stock could decline if there are substantial sales of our common stock and if there is a large number of shares of our common stock available for sale. As of November 15, 2006 we had outstanding 15,523,637 shares of common stock. This includes the 5,175,000 shares that were sold in our initial public offering, which may be resold in the public market immediately. Of the remaining 10,348,637 shares, 10,336,641 shares are currently restricted as a result of securities laws or lock-up agreements but will be able to be sold in the near future. The holders of 9,833,964 shares of common stock have rights, subject to certain conditions, to require us to file registration statements to permit the resale of their shares in the public market or to include their shares in registration statements that we may file for ourselves or other stockholders. We also intend to register all shares of common stock that we may issue under our stock plans.

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 do not anticipate paying cash dividends, and accordingly stockholders must rely on stock appreciation for any return on their investment in us.**

We anticipate that we will retain our earnings, if any, for future growth and therefore do not anticipate paying cash dividends in the future. As a result, only appreciation of the price of our common stock will provide a return to stockholders.

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

We registered shares of our common stock in connection with our initial public offering under the Securities Act. The registration statement on Form S-1 (File No. 333-132921) filed in connection with our initial public

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offering was declared effective by the SEC on October 25, 2006. The offering commenced on October 25, 2006 and did not terminate before any securities were sold. As of the date of this filing, the offering has terminated and we sold 4,500,000 shares of our registered common stock in the initial public offering and an additional 675,000 shares of our registered common stock in connection with the underwriters' exercise of their over-allotment option. The underwriters of the offering were Cowen and Company, LLC, CIBC World Markets and JMP Securities.

All 5,175,000 shares of our common stock registered in the offering were sold at the initial public offering price of \$11.50 per share. The aggregate purchase price of the offering was \$59,512,500. The net offering proceeds received by us, after deducting underwriting discounts and commissions and expenses incurred in connection with the offering was approximately \$53.4 million. These expenses consisted of direct payments of:

- i. (a) \$4.2 million in underwriters discounts, fees and commissions;
- ii. (b) \$1.7 million in legal, accounting and printing fees; and
- iii. (c) \$0.2 million in miscellaneous expenses.

No payments for such expenses were directly or indirectly to (i) any of our directors, officers or their associates, (ii) any person(s) owning 10% or more of any class of our equity securities or (iii) any of our affiliates; provided, however, one of our directors, Christopher White, is Chief of Staff and Chief Administrative Officer of Cowen and Company, LLC.

The net proceeds of approximately \$53.4 million from the initial public offering are invested in short-term investment grade securities and money market accounts. We currently plan to use the net proceeds from the offering to fund our operations including: (i) the on-going phase II clinical development of elvucitabine for the treatment HIV infection, (ii) the on-going phase Ib/II clinical development of ACH-806 for the treatment of HCV infection, (iii) the on-going preclinical development of ACH-702 for the treatment of serious hospital-based infections, (iv) our further research surrounding back-up candidates in both our HCV and antibacterial programs, and (v) for general corporate and working capital 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).

### **ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

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

Pursuant to a written consent of stockholders in lieu of a meeting, the holders of an aggregate of 63,391,596 shares of our common stock and preferred stock approved the following matters: (i) the approval of a Certificate of Amendment of our Amended and Restated Certificate of Incorporation that was filed prior to the closing of our initial public offering, (ii) the approval of an Amended and Restated Certificate of Incorporation that was filed in connection with our initial public offering, (iii) the approval and adoption of our Amended and Restated Bylaws that became effective upon the closing of our initial public offering, (iv) the approval and adoption of our 2006 Stock incentive Plan that became effective upon the closing of our initial public offering and the reservation of 750,000 shares of common stock (post-split) initially available for issuance thereunder, and (v) the approval and adoption of our 2006 Employee Stock Purchase Plan that became effective upon the closing of our initial public offering and the reservation of 250,000 shares of common stock (post-split) available for issuance thereunder. All such actions were effected.

### **ITEM 5. OTHER INFORMATION**

None.

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**ITEM 6. EXHIBITS**

- 31.1 Certification of President and Chief Executive Officer of Achillion Pharmaceuticals, Inc. pursuant to Rule 13a-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
- 31.2 Certification of Chief Financial Officer of Achillion Pharmaceuticals, Inc. pursuant to Rule 13a-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
- 32.1 Certification of President and Chief Executive Officer of Achillion Pharmaceuticals, Inc. pursuant to Rule 13a-14(b) promulgated under the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code.
- 32.2 Certification of Chief Financial Officer of Achillion Pharmaceuticals, Inc. pursuant to Rule 13a-14(b) promulgated under the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code.

**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.

ACHILLION PHARMACEUTICALS, INC.

Date: November 17, 2006

By: /S/ MICHAEL D. KISHBAUCH  
President and Chief Executive Officer (Principal Executive Officer)

Date: November 17, 2006

By: /S/ MARY KAY FENTON  
Chief Financial Officer (Principal Financial and Accounting Officer)



## CERTIFICATION

I, Michael D. Kishbauch, certify that:

- 1) I have reviewed this Quarterly Report on Form 10-Q of Achillion Pharmaceuticals, Inc.;
- 2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 17, 2006

/s/ MICHAEL D. KISHBAUCH

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Michael D. Kishbauch  
President and Chief Executive Officer

## CERTIFICATION

I, Mary Kay Fenton, certify that:

- 1) I have reviewed this Quarterly Report on Form 10-Q of Achillion Pharmaceuticals, Inc.;
- 2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 17, 2006

/s/ MARY KAY FENTON  
Mary Kay Fenton  
Chief Financial Officer

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT  
TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Achillion Pharmaceuticals, Inc. (the "Company") for the quarter ended September 30, 2006 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Michael D. Kishbauch, President and Chief Executive Officer of the Company, hereby certifies, pursuant to Section 1350 of Chapter 63 of Title 18, United States Code, that:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 17, 2006

/s/ MICHAEL D. KISHBAUCH

Michael D. Kishbauch

President and Chief Executive Officer

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT  
TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Achillion Pharmaceuticals, Inc. (the "Company") for the quarter ended September 30, 2006 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Mary Kay Fenton, Chief Financial Officer of the Company, hereby certifies, pursuant to Section 1350 of Chapter 63 of Title 18, United States Code, that:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 17, 2006

/s/ MARY KAY FENTON

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Mary Kay Fenton  
Chief Financial Officer

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.