ALEXZA PHARMACEUTICALS INC.

FORM 10-Q
(Quarterly Report)

Filed 11/06/12 for the Period Ending 09/30/12

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Industry	Biotechnology & Medical Research
Sector	Healthcare
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D. C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2012

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 000-51820

ALEXZA PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**77-0567768**
(State or other Jurisdiction of Incorporation or Organization)	**(IRS Employer Identification No.)**
2091 Stierlin Court Mountain View, California	**94043**
(Address of principal executive offices)	**(Zip Code)**

(Registrant's telephone number, including area code): (650) 944-7000

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☒

Non-accelerated filer ☐ (do not check if a smaller reporting company) Smaller reporting company ☐

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

Total number of shares of common stock outstanding as of October 26, 2012: 15,688,502.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

ALEXZA PHARMACEUTICALS, INC.
(a development stage company)
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)
(unaudited)

	September 30, 2012	December 31, 2011 (1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 25,515	$ 14,902
Marketable securities	—	2,001
Restricted cash	6,469	—
Receivables	—	10,000
Prepaid expenses and other current assets	766	649
Total current assets	32,750	27,552
Property and equipment, net	17,156	20,425
Other assets	409	628
Total assets	$ 50,315	$ 48,605
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,832	$ 3,603
Accrued clinical trial expenses	96	134
Other accrued expenses	2,319	2,872
Current portion of contingent consideration liability	7,000	12,300
Financing obligations	7,994	12,280
Current portion of deferred revenue	2,915	3,759
Total current liabilities	22,156	34,948
Deferred rent	8,574	12,274
Noncurrent portion of contingent consideration liability	3,500	4,200
Noncurrent portion of deferred revenues	5,829	6,875
Stockholders' equity:		
Preferred stock	—	—
Common stock	2	1
Additional paid-in-capital	334,594	296,942
Deficit accumulated during development stage	(324,340)	(306,635)
Total stockholders' equity (deficit)	10,256	(9,692)
Total liabilities and stockholders' equity	$ 50,315	$ 48,605

(1) The condensed consolidated balance sheet at December 31, 2011 has been derived from audited consolidated financial statements at that date.

See accompanying notes to the financial statements.

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ALEXZA PHARMACEUTICALS, INC.
(a development stage company)
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(in thousands, except per share amounts)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,		Period from December 19, 2000 (inception) to September 30, 2012
	2012	2011	2012	2011	
Revenue	$ 729	$ 1,259	$ 3,341	$ 3,776	$ 68,822
Operating expenses:					
Research and development	4,784	8,051	14,826	20,977	321,077
General and administrative	2,338	3,109	6,487	8,664	110,363
Restructuring charges	—	—	—	—	2,037
Acquired in-process research and development	—	—	—	—	3,916
Total operating expenses	7,122	11,160	21,313	29,641	437,393
Loss from operations	(6,393)	(9,901)	(17,972)	(25,865)	(368,571)
Loss/ (gain) on change in fair value of contingent consideration liability	(200)	(3,000)	1,000	(3,300)	(6,145)
Interest and other income/ (expense), net	5	13	413	30	14,302
Interest expense	(333)	(529)	(1,146)	(1,703)	(9,015)
Net loss	(6,921)	(13,417)	(17,705)	(30,838)	(369,429)
Consideration paid in excess of noncontrolling interest	—	—	—	—	(61,566)
Net loss attributable to noncontrolling interest in Symphony Allegro, Inc.	—	—	—	—	45,089
Net loss attributable to Alexza common stockholders	$ (6,921)	$(13,417)	$(17,705)	$(30,838)	$ (385,906)
Basic and diluted net loss per share attributable to Alexza common stockholders	$ (0.52)	$ (1.86)	$ (1.55)	$ (4.64)	
Shares used to compute basic and diluted net loss per share attributable to Alexza common stockholders	13,235	7,213	11,394	6,644	
Change in unrealized gain (loss) on marketable securities	—	(15)	—	—	—
Comprehensive loss attributed to Alexza common stockholders	$ (6,921)	$(13,432)	$(17,705)	$(30,838)	$ (385,906)

See accompanying notes to the financial statements.

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ALEXZA PHARMACEUTICALS, INC.
(a development stage company)
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	Nine Months Ended September 30,		Period from December 19, 2000 (inception) to September 30, 2012
	2012	2011	
Cash flows from operating activities:			
Net loss	$(17,705)	$(30,838)	$ (369,429)
Adjustments to reconcile net loss attributable to Alexza common stockholders to net cash provided by (used in) operating activities:			
Share-based compensation	2,476	1,494	26,741
Change in fair value of contingent liability	(1,000)	3,300	6,145
Extinguishment of officer note receivable	—	—	2,300
Issuance of common stock for intellectual property	—	—	92
Charge for acquired in-process research and development	—	—	3,916
Amortization of assembled workforce	—	—	222
Amortization of debt discount and deferred interest	350	353	1,642
Amortization of premium (discount) on available-for-sale securities	1	180	(216)
Write off of other asset	—	—	2,800
Depreciation and amortization	3,467	3,371	34,065
Gain on disposal of property and equipment	(409)	—	(204)
Changes in operating assets and liabilities:			
Other receivables	10,000	—	—
Prepaid expenses and other current assets	(117)	79	(760)
Other assets	—	(133)	(2,843)
Accounts payable	(1,771)	345	1,703
Accrued clinical and other accrued liabilities	(688)	828	(1,512)
Deferred revenues	(1,890)	(1,814)	8,744
Other liabilities	(3,700)	(1,746)	11,964
Net cash used in operating activities	(10,986)	(24,581)	(274,630)
Cash flows from investing activities:			
Purchases of available-for-sale securities	—	(26,456)	(430,071)
Maturities of available-for-sale securities	2,000	36,237	430,288
Purchases of available-for-sale securities held by Symphony Allegro, Inc.	—	—	(49,975)
Maturities of available-for-sale securities held by Symphony Allegro, Inc.	—	—	45,093
(Increase)/decrease in noncurrent restricted cash	200	—	(200)
Purchases of property and equipment	(214)	(409)	(51,234)
Proceeds from disposal of property and equipment	425	—	482
Cash paid for merger	—	—	(250)
Net cash provided by (used in) investing activities	2,411	9,372	(55,867)

See accompanying notes to the financial statements.

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ALEXZA PHARMACEUTICALS, INC.
(a development stage company)
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	Nine Months Ended September 30,		Period from December 19, 2000 (inception) to September 30, 2012
	2012	2011	
Cash flows from financing activities:			
Proceeds from issuance of common stock and warrants and exercise of stock options and stock purchase rights	35,177	16,144	213,529
Repurchase of common stock	—	—	(8)
Proceeds from issuance of convertible preferred stock	—	—	104,681
Proceeds from repayment of stockholder note receivable	—	—	29
Proceeds from purchase of noncontrolling interest in Symphony Allegro, Inc	—	—	4,882
Proceeds from purchase of noncontrolling interest by preferred shareholders in Symphony Allegro, Inc, net of fees	—	—	47,171
Payments of contingent payments to Symphony Allegro Holdings, LLC.	(5,000)	—	(12,500)
Change in current restricted cash	(6,469)		(6,469)
Proceeds from financing obligations, net of issuance costs	—	—	33,738
Payments of financing obligations	(4,520)	(4,103)	(29,041)
Net cash provided by (used in) financing activities	19,188	12,041	356,012
Net increase (decrease) in cash and cash equivalents	10,613	(3,168)	25,515
Cash and cash equivalents at beginning of period	14,902	13,671	—
Cash and cash equivalents at end of period	$25,515	$10,503	$ 25,515

See accompanying notes to the financial statements.

ALEXZA PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. The Company and Basis of Presentation

Business

Alexza Pharmaceuticals, Inc. ("Alexza" or the "Company") was incorporated in the state of Delaware on December 19, 2000 as FaxMed, Inc. In June 2001, the Company changed its name to Alexza Corporation and in December 2001 became Alexza Molecular Delivery Corporation. In July 2005, the Company changed its name to Alexza Pharmaceuticals, Inc.

The Company is a pharmaceutical development company focused on the research, development, and commercialization of novel proprietary products for the acute treatment of central nervous system conditions. The Company's primary activities since incorporation have been establishing its offices, recruiting personnel, conducting research and development, conducting preclinical studies and clinical trials, developing and scaling the manufacturing process and quality systems for the Staccato ® technology, performing business and financial planning, and raising capital. Accordingly, the Company is considered to be in the development stage and operates in one business segment. The Company's facilities and employees are currently located in the United States.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not contain all of the information and footnotes required for complete financial statements. In the opinion of management, the accompanying unaudited condensed consolidated financial statements reflect all adjustments, which include only normal recurring adjustments, necessary to present fairly the Company's interim consolidated financial information. The results for the three and nine months ended September 30, 2012 are not necessarily indicative of the results to be expected for the year ending December 31, 2012 or for any other interim period or any other future year.

The accompanying unaudited condensed consolidated financial statements and notes to condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements for the year ended December 31, 2011 included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on March 12, 2012.

Basis of Consolidation

The unaudited condensed consolidated financial statements include the accounts of Alexza and its wholly-owned subsidiaries. All significant intercompany balances and transactions have been eliminated.

Reverse Stock Split

On June 12, 2012, we effected a 1-for-10 reverse stock split of our outstanding common stock resulting in a reduction of our total common stock issued and outstanding from 119.6 million shares to 12.0 million shares. The reverse stock split affected all stockholders of our common stock uniformly, but did not materially affect any stockholder's percentage of ownership interest. The par value of our common stock remains unchanged at $0.0001 per share and the number of authorized shares of common stock remains the same after the reverse stock split.

As the par value per share of our common stock remained unchanged at $0.0001 per share, a total of $11,000 was reclassified from common stock to additional paid-in capital. In connection with this reverse stock split, the number of shares of common stock reserved for issuance under our equity incentive, stock option and employee stock purchase plans (see Note 4) as well as the shares of common stock underlying outstanding stock options and warrants were also proportionately reduced while the exercise prices of these stock options and warrants were proportionately increased. All references to shares of common stock and per share data for all periods presented in the accompanying financial statements and notes thereto have been adjusted to reflect the reverse stock split on a retroactive basis.

Significant Risks and Uncertainties

The Company has incurred significant losses from operations since its inception and expects losses to continue for the foreseeable future. As of September 30, 2012, the Company had cash, cash equivalents, marketable securities and restricted cash (see Note 7) of $32.0 million and working capital of $10.6 million. The Company's operating and capital plans call for cash expenditures to exceed these amounts for the next twelve months. The Company plans to raise additional capital to fund its operations, to develop its product candidates, to develop its commercialization plans. to expand its market knowledge and to continue the development of its commercial manufacturing capabilities. Management plans to finance the Company's operations through the sale of equity securities, debt arrangements or partnership or licensing collaborations. Such funding may not be available or may be on terms that are not favorable to the Company. The Company's inability to raise capital as and when needed could have a negative impact on its financial condition

and its ability to continue as a going concern. Based on the Company's cash, cash equivalents, marketable securities and restricted cash balance at September 30, 2012 and its expected cash usage, management estimates that the Company has sufficient capital resources to meet its anticipated cash needs into the second quarter of 2013.

The accompanying financial statements have been prepared assuming the Company will continue to operate as a going concern, which contemplates the realization of assets and the settlement of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts of liabilities that may result from uncertainty related to the Company's ability to continue as a going concern.

Recently Adopted Accounting Standards

In June 2011, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2011-05, " *Presentation of Comprehensive Income, "* as amended by ASU 2011-12, ASU 2011-05 requires the presentation of total comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. The Company adopted ASU 2011-05 in the first quarter of 2012.

On May 12, 2011, the FASB issued ASU 2011-04, " *Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs. "* ASU 2011-04 is the result of joint efforts by the FASB and the International Accounting Standards Board to develop a single, converged fair value framework. There are few differences between ASU 2011-04 and its international counterpart, IFRS 13. ASU 2011-04 is largely consistent with existing fair value measurement principles in U.S. GAAP; however it expands existing disclosure requirements for fair value measurements and makes other amendments. The adoption of ASU 2011-04 did not have a material effect on the Company's financial position, results of operations or cash flows.

2. Equity Transactions

Underwritten Public Offering

On February 23, 2012, the Company issued an aggregate of 4,400,000 shares of the Company's common stock and warrants to purchase up to an additional 4,400,000 shares of the Company's common stock in an underwritten public offering. Net proceeds from the offering were $20.2 million, after deducting offering expenses. The warrants are exercisable beginning February 24, 2013, at an exercise price of $5.00 per share, and will expire on February 23, 2017. The shares of common stock and warrants were sold pursuant to a shelf registration statement declared effective by the SEC on May 20, 2010. The Company agreed to customary obligations, including indemnification.

Private Placement

On March 5, 2012, the Company entered into an amendment to the Collaboration, License and Supply Agreement (the "Ferrer Agreement") with Grupo Ferrer Internacional, S.A. ("Grupo Ferrer", See Note 9). Grupo Ferrer and the Company agreed to eliminate a future potential milestone payment in exchange for Grupo Ferrer's purchase of $3.0 million of the Company's common stock. On March 15, 2012 Grupo Ferrer purchased 241,936 shares of the Company's common stock for $12.40 per share. The Company classified $1,452,000 of the proceeds as deferred revenue and will recognize the amount into revenue over the estimated performance period of the Ferrer Agreement (see Note 9). During 2012, up to an additional $8 million of the Company's common stock may be purchased by Grupo Ferrer, upon a request by the Company and subject to acceptance by Grupo Ferrer, in exchange for the elimination of additional milestones at a price per share that will be a premium to the market price on the date of purchase.

Committed Equity Line of Credit

On July 20, 2012, the Company entered into a committed equity line of credit with Azimuth Opportunity, L.P. ("Azimuth") pursuant to which the Company was granted the ability to sell up to $20 million of its common stock over an approximately 24-month period pursuant to the terms of a Common Stock Purchase Agreement (the "Purchase Agreement"). In addition to the foregoing amounts, in consideration for Azimuth's execution and delivery of the Purchase Agreement, the Company issued to Azimuth 80,429 shares of its common stock on July 23, 2012. The Company has currently utilized $13.6 million of the facility. The Company is not obligated to utilize any further portion of the facility, but may do so from time to time at its discretion. This facility replaces a similar facility that was established in May 2010 and expired after its 24-month term.

The Company will determine, at its sole discretion, the timing, the dollar amount and the price per share of each draw under this facility, subject to certain conditions. When the Company elects to utilize the facility by delivery of a draw down notice to Azimuth, the Company will issue shares to Azimuth at a discount of 5% to the volume weighted average price of the Company's common stock over a preceding period of trading days (a "Draw Down Period"). The Purchase Agreement also provides that from time to time, at the Company's sole discretion, it may grant Azimuth an option to purchase additional shares of the Company's common stock during each Draw Down Period for an amount of shares specified by the Company based on the trading price of its common stock. Upon

Azimuth's exercise of such an option, the Company will sell to Azimuth the shares subject to the option at a price equal to the greater of (i) the daily volume weighted average price of the Company's common stock on the day Azimuth notifies the Company of its election to exercise its option or (ii) the threshold price for the option determined by the Company, in each case less a discount of 5%.

Azimuth is not required to purchase any shares at a pre-discounted purchase price below $2.00 per share, and any shares sold under this facility will be sold pursuant to a shelf registration statement declared effective by the Securities and Exchange Commission on July 3, 2012. The Purchase Agreement will terminate on August 1, 2014.

During the three months ended September 30, 2012, the Company raised $13.4 million in net proceeds pursuant to draw downs made under the Purchase Agreement.

- On August 10, 2012, the Company settled with Azimuth on the purchase of 1,035,813 shares of the Company's common stock under the Purchase Agreement at a price of $2.99 per share for an aggregate purchase price of $3.1 million. The Company received $3.0 million in net proceeds from the sale of these shares after deducting offering expenses.
- On August 24, 2012, the Company settled with Azimuth on the purchase of 1,274,998 shares of the Company's common stock under the Purchase Agreement at a price of $3.89 per share for an aggregate purchase price of $5.0 million. The Company received $4.9 million in net proceeds from the sale of these shares after deducting offering expenses.
- On September 25, 2012, the Company settled with Azimuth on the purchase of 1,179,049 shares of the Company's common stock under the Purchase Agreement at a price of $4.66 per share for an aggregate purchase price of $5.5 million. The Company received $5.4 million in net proceeds from the sale of these shares after deducting offering expenses.

As of September 30, 2012, the Company had $6.4 million available for future draw downs under the Purchase Agreement.

3. Fair Value Accounting

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Three levels of inputs, of which the first two are considered observable and the last unobservable, may be used to measure fair value. The three levels are:

- Level 1 — Quoted prices in active markets for identical assets or liabilities.
- Level 2 — Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The following table represents the Company's fair value hierarchy for its financial assets (cash equivalents and marketable securities) by major security type and liability measured at fair value on a recurring basis as of September 30, 2012 and December 31, 2011 (in thousands):

September 30, 2012	Level 1	Level 2	Level 3	Total
Assets				
Money market funds	$24,807	$ —	$ —	$24,807
Liabilities				
Contingent consideration liability	$ —	$ —	$10,500	$10,500
Total liabilities	$ —	$ —	$10,500	$10,500

December 31, 2011	Level 1	Level 2	Level 3	Total
Assets				
Money market funds	$12,619	$ —	$ —	$12,619
Available for sale debt securities				
Corporate debt securities	$ —	$2,001	$ —	$ 2,001
Total available for sale debt securities	$ —	$2,001	$ —	$ 2,001
Total assets	$12,619	$2,001	$ —	$14,620
Liabilities				
Contingent consideration liability	$ —	$ —	$16,500	$16,500
Total liabilities	$ —	$ —	$16,500	$16,500

Cash equivalents and marketable securities

The following table outlines the amortized cost, fair value and unrealized gain/(loss) for the Company's financial assets by major security type as of September 30, 2012 and December 31, 2011 (in thousands):

September 30, 2012	Amortized Cost	Fair Value	Unrealized Gain/(Loss)
Money market funds	$ 24,807	$ 24,807	$ —
Less amounts classified as cash equivalents	(24,807)	(24,807)	—
Total marketable securities	$ —	$ —	$ —

December 31, 2011	Amortized Cost	Fair Value	Unrealized Gain/(Loss)
Money market funds	$ 12,619	$ 12,619	$ —
Corporate debt securities	2,001	2,001	—
Total	14,620	14,620	—
Less amounts classified as cash equivalents	(12,619)	(12,619)	—
Total marketable securities	$ 2,001	$ 2,001	$ —

The Company had no sales of marketable securities during the three or nine months ended September 30, 2012 or 2011. As of September 30, 2012, all of the Company's marketable securities have a maturity of less than one year.

The Company's available-for-sale debt securities are valued utilizing a multi-dimensional relational model. Inputs, listed in approximate order of priority for use when available, include benchmark yields, reported trades, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids, offers and reference data.

Contingent Consideration Liability

In connection with the exercise of the Company's option to purchase all of the outstanding equity of Symphony Allegro, Inc. ("Allegro"), the Company is obligated to make contingent cash payments to the former Allegro stockholders related to certain payments received by the Company from future partnering agreements pertaining to ADASUVE (*Staccato* loxapine), AZ-104 (*Staccato* loxapine, low-dose) or AZ-002 (*Staccato* alprazolam). In order to estimate the fair value of the liability associated with the contingent cash payments, the Company prepared several cash flow scenarios for ADASUVE, AZ-104 and AZ-002, which are subject to the contingent payment obligation. Each potential cash flow scenario consisted of assumptions of the range of estimated milestone and license payments potentially receivable from such partnerships and assumed royalties received from future product sales. Based on these estimates, the Company computed the estimated payments to be made to the former Allegro stockholders. Payments were assumed to terminate upon the expiration of the related patents.

The projected cash flow assumptions for ADASUVE in the United States ("U.S.") and Canada continue to be based on the terms of the agreements with Biovail Laboratories International SRL ("Biovail") signed in February 2010 and multiple internal product sales forecasts, as the Company expects that any potential partnership agreement for ADASUVE in the U.S. and Canada would have similar terms to that of the Biovail agreements, despite these agreements being terminated in October 2010. The timing and extent of the projected cash flows for ADASUVE for the territories licensed to Grupo Ferrer are based on the Grupo Ferrer agreement, as amended (see Note 9). The timing and extent of the projected cash flows for the remaining territories for ADASUVE and worldwide territories for AZ-002 and AZ-104 were based on internal estimates for potential milestones and multiple product royalty scenarios and are also consistent in structure to the Biovail agreements as the Company expects future partnerships for these products and product candidates to have similar structures.

The Company then assigned a probability to each of the cash flow scenarios based on several factors, including: the product candidate's stage of development, preclinical and clinical results, technological risk related to the successful development of the different drug candidates, estimated market size, market risk and potential partnership interest to determine a risk adjusted weighted average cash flow based on all of these scenarios. These probability and risk adjusted weighted average cash flows were then discounted utilizing the Company's estimated weighted average cost of capital ("WACC"). The Company's WACC considered the Company's cash position, competition, risk of substitute products, and risk associated with the financing of the development projects. The Company determined the discount rate to be 18% and applied this rate to the probability adjusted cash flow scenarios.

This fair value measurement is based on significant inputs not observed in the market and thus represents a Level 3 measurement. Level 3 measurements are valued based on unobservable inputs that are supported by little or no market activity and reflect the Company's assumptions in measuring fair value.

The Company records any changes in the fair value of the contingent consideration liability in earnings in the period of the change. Certain events including, but not limited to, clinical trial results, U.S. Food and Drug Administration ("FDA") approval or non-approval of the Company's submissions, European Medicines Agency approval or non-approval of the Company's submissions, the timing and terms of any strategic partnership agreement, and the commercial success of ADASUVE, AZ-104 or AZ-002 could have a material impact on the fair value of the contingent consideration liability, and as a result, the Company's results of operations and financial position.

During the three and nine months ended September 30, 2011, the Company modified the assumptions regarding the timing and/or probability of certain cash flows to reflect the completion of the Grupo Ferrer licensing agreement (see Note 9). The changes in these assumptions and the effect of the passage of three and nine months on the present value computation resulted in an increase to the net loss of $3,000,000, or $0.42 per share, for the three months ended September 30, 2011 and an increase to the net loss of $3,300,000 or $0.50 per share for the nine months ended September 30, 2011.

During the three and nine months ended September 30, 2012, the Company modified the assumptions regarding the timing and extent of certain cash flows primarily to reflect the three month extension of the FDA's review of the Company's ADASUVE New Drug Application ("NDA") from February 4, 2012 to May 4, 2012 and the receipt of the CRL for the ADASUVE NDA in May 2012. This change in assumptions and the effects of the passage of time on the present value computation resulted in an increase to the net loss of $200,000, or $0.02 per share, for the three months ended September 30, 2012 and a decrease to the net loss of $1,000,000 or $0.09 per share for the nine months ended September 30, 2012.

The following table represents a reconciliation of the change in the fair value measurement of the contingent consideration liability for the three and nine months ended September 30, 2012 and 2011 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Beginning balance	$10,300	$12,800	$16,500	$12,500
Payments made		—	(5,000)	—
Adjustments to fair value measurement	200	3,000	(1,000)	3,300
Ending balance	$10,500	$15,800	$10,500	$15,800

Financing Obligations

The Company has estimated the fair value of its financing obligations (see Note 7) using the net present value of the payments discounted at an interest rate that is consistent with its estimated current borrowing rate for similar long-term debt. The Company believes the estimates used to measure the fair value of the financing obligations constitute Level 3 inputs.

At September 30, 2012 and December 31, 2011, the estimated fair value of our financing obligations was $7,713,000 and $11,720,000, respectively and had book values of $7,994,000 and $12,280,000, respectively. Our payment commitments associated with these debt instruments may vary with changes in interest rates and are comprised of interest payments and principal payments. The fair value of our debt will fluctuate with movements of interest rates, increasing in periods of declining rates of interest and declining in periods of increasing rates of interest.

4. Share-Based Compensation Plans

2005 Equity Incentive Plan

In December 2005, the Company's Board of Directors adopted the 2005 Equity Incentive Plan (the "2005 Plan"). The 2005 Plan is an amendment and restatement of the Company's previous equity incentive plans. New grants of stock options and restricted stock units issued under the 2005 Plan that are not subject to performance-based vesting conditions generally vest over four years, based on service time, or upon the accomplishment of certain milestones and have a maximum contractual term of 10 years. Prior to vesting, restricted stock units do not have dividend equivalent rights, do not have voting rights and the shares underlying the restricted units are not considered issued and outstanding. Shares are issued upon vesting of the restricted stock units.

The 2005 Plan provides for annual reserve increases on the first day of each year commencing on January 1, 2007 and ending on January 1, 2015. The annual reserve increases will be equal to the lesser of (i) 2% of the total number of shares of the Company's common stock outstanding on December 31 of the preceding calendar year, or (ii) 100,000 shares of common stock. The Company's Board of Directors has the authority to designate a smaller number of shares by which the authorized number of shares of common stock will be increased prior to the last day of any calendar year. On each of January 1, 2012 and 2011 an additional 100,000 shares of the Company's common stock were reserved for issuance under this provision.

2005 Non-Employee Directors' Stock Option Plan

In December 2005, the Company's Board of Directors adopted the 2005 Non-Employee Directors' Stock Option Plan (the "Directors' Plan"). The Directors' Plan provides for the automatic grant of nonstatutory stock options to purchase shares of common stock to the Company's non-employee directors, which vest over four years and have a term of 10 years. The Directors' Plan provides for an annual reserve increase to be added on the first day of each fiscal year, commencing on January 1, 2007 and ending on January 1, 2015. The annual reserve increases will be equal to the number of shares subject to options granted during the preceding fiscal year less the number of shares that revert back to the share reserve during the preceding fiscal year. The Company's Board of Directors has the authority to designate a smaller number of shares by which the authorized number of shares of common stock will be increased prior to the last day of any calendar year. On January 1, 2012 and 2011 an additional 20,000 and 7,500 shares, respectively, of the Company's common stock were reserved for issuance under this provision.

2011 Employee Stock Option Exchange Program

On January 21, 2011, the Company commenced a voluntary employee stock option exchange program (the "Exchange Program") to permit the Company's eligible employees to exchange some or all of their eligible outstanding options ("Original Options") to purchase the Company's common stock with an exercise price greater than or equal to $23.70 per share, whether vested or unvested, for a lesser number of new stock options ("New Options"). In accordance with the terms and conditions of the Exchange Program, on February 22, 2011 (the "Grant Date"), the Company accepted outstanding options to purchase an aggregate of 212,843 shares of the Company's common stock, with exercise prices ranging from $23.80 to $117.00, and issued, in exchange, an aggregate of 80,890 New Options with an exercise price of $12.30. The New Options vested 33% on February 22, 2012 with the balance of the shares vesting in a series of twenty-four successive equal monthly installments thereafter, and have a term of five years. The exchange resulted in a decrease in the Company's common stock subject to outstanding stock options by 131,953 shares, which increased the number of shares available to be issued under the 2005 Plan.

The following table sets forth the summary of option activity under the Company's share-based compensation plans for the nine months ended September 30, 2012:

	Outstanding Options	
	Number of Shares	Weighted Average Exercise Price
Outstanding at January 1, 2012	845,787	$ 19.07
Options granted	477,837	3.52
Options exercised	—	—
Options canceled	(271,108)	18.44
Outstanding at September 30, 2012	1,052,516	12.17

The following table sets forth the summary of restricted stock unit activity under the Company's equity incentive plans for the nine months ended September 30, 2012:

	Number Of Shares	Weighted Average Grant-Date Fair Value
Outstanding at January 1, 2012	117,218	$ 11.77
Granted	278,032	4.96
Released	(259,707)	5.05
Forfeited	(66,660)	19.54
Outstanding at September 30, 2012	68,883	22.33

As of September 30, 2012, 196,681 and 5,188 shares remained available for issuance under the 2005 Plan and the Directors' Plan, respectively.

2005 Employee Stock Purchase Plan

In December 2005, the Company's Board of Directors adopted the 2005 Employee Stock Purchase Plan ("ESPP"). The ESPP allows eligible employee participants to purchase shares of the Company's common stock at a discount through payroll deductions. The ESPP consists of a fixed offering period, historically 24 months with four purchase periods within each offering period, and currently offering periods of six months. Purchases are generally made on the last trading day of each October and April. Employees purchase shares at each purchase date at 85% of the market value of the Company's common stock on their enrollment date or the end of the purchase period, whichever price is lower.

The ESPP provides for annual reserve increases on the first day of each fiscal year commencing on January 1, 2007 and ending on January 1, 2015. The annual reserve increases are equal to the least of (i) 1% of the total number of shares of the Company's common stock outstanding on December 31 st of the preceding calendar year, (ii) 75,000 shares of common stock, or (iii) a lesser amount determined by the Company's Board of Directors.

In May 2011, the Company's Compensation Committee terminated the then current offering period under the ESPP and resolved to begin a new offering period in August 2011 and also amended the ESPP to reduce the time period of each future offering period from twenty-four to six months. The new offering period under the ESPP began on August 15, 2011 and the related purchase occurred on April 30, 2012.

Pursuant to the ESPP, an additional 72,136 and 25,000 shares were reserved for issuance on January 1, 2012 and 2011, respectively. The Company issued 2,978 shares at a weighted average price of $5.30 under the ESPP during the nine months ended September 30, 2012 and 24,962 shares at a weighted average price of $8.10 under the ESPP during the nine months ended September 30, 2011. The Company did not issue shares under the ESPP during the three months ended September 30, 2012 or 2011. At September 30, 2012, 69,557 shares were available for issuance under the ESPP.

5. Share-Based Compensation

Employee Share-Based Awards

Compensation cost for employee share-based awards is based on the grant-date fair value and is recognized over the vesting period of the applicable award on a straight-line basis. The Company issues employee share-based awards in the form of stock options and restricted stock units under the Company's equity incentive plans, and stock purchase rights under the ESPP.

Valuation of Stock Options, Stock Purchase Rights and Restricted Stock Units

During the three and nine months ended September 30, 2012 and 2011, the weighted average fair value of share-based awards granted (excluding options issued in the Exchange Program) was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Stock Options	$ 2.57	$ 10.60	$ 2.58	$ 10.60
RSUs	—	—	4.90	13.30
Stock Purchase Rights	3.31	4.80	4.23	8.20

The estimated grant date fair values of the stock options, excluding the options issued in the Exchange Program in 2011, and stock purchase rights were calculated using the Black-Scholes valuation model, and the following weighted average assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Stock Option Plans				
Expected term	5.0 years	5.0 years	5.0 years	5.0 years
Expected volatility	98%	90%	98%	90%
Risk-free interest rate	0.62%	1.51%	0.63%	1.51%
Dividend yield	0%	0%	0%	0%
Employee Stock Purchase Plan				
Expected term	0.5 years	0.7 years	0.63 years	1.45 years
Expected volatility	135%	73%	96%	87%
Risk-free interest rate	0.15%	0.12%	0.13%	0.59%
Dividend yield	0%	0%	0%	0%

The Exchange Program described in Note 4 did not result in incremental expense, as the fair value of the New Options granted was equal to or less than the fair values of the Original Options measured immediately prior to being replaced on the date the New Options were granted and the Original Options were cancelled. The estimated grant date fair value of the New Options was calculated using the Black-Sholes valuation model. At the time of exchange, the exercise price of the Original Options was in excess of the market price, therefore the expected term of the Original Options granted was determined using the Monte Carlo Simulation method. The expected term of New Options granted was determined using the "shortcut" method, as illustrated in the Securities and Exchange Commission's Staff Accounting Bulletin No. 107, because the terms of the New Options are unique as compared to the existing awards and the Company does not have historical experience under the New Options terms. Under this approach, the expected term is estimated to be the average of the vesting term and the contractual term of the option. All other assumptions have been calculated using the historical methodologies applied by the Company to all other stock option awards. The number of shares underlying the options included in the Exchange Program and the weighted average assumptions utilized in the Black-Scholes valuation model were:

	Original Options	New Options
Number of shares	212,843	80,890
Expected term	4.7 years	3.4 years
Expected volatility	94%	98%
Risk-free interest rate	1.96%	1.38%
Dividend yield	0%	0%

The estimated fair value of restricted stock units awards is calculated based on the market price of Alexza's common stock on the date of grant, reduced by the present value of dividends expected to be paid on Alexza common stock prior to vesting of the restricted stock unit. The Company's estimate assumes no dividends will be paid prior to the vesting of the restricted stock unit.

As of September 30, 2012, there were $4,200,000 and $9,000 of total unrecognized compensation expense related to unvested stock option awards and stock purchase rights, respectively, which are expected to be recognized over a weighted average period of 1.6 years and 0.1 years, respectively. There was no unrecognized compensation expense related to unvested restricted stock units expected to be recognized at September 30, 2012.

There was no share-based compensation capitalized at September 30, 2012.

6. Net Loss per Share Attributable to Alexza Common Stockholders

Historical basic and diluted net loss per share attributable to Alexza common stockholders is calculated by dividing the net loss attributable to Alexza common stockholders by the weighted-average number of common shares outstanding for the period. The following items were excluded in the net loss per share attributable to Alexza common stockholders calculation for the three and nine months ended September 30, 2012 and 2011 because the inclusion of such items would have had an anti-dilutive effect:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Stock options	834,463	601,600	790,892	492,153
Restricted stock units	150,274	131,501	150,609	137,343
Warrants to purchase common stock	6,462,066	2,062,099	5,362,082	1,853,376

7. Financing Obligations

Hercules Technology Growth Capital

In May 2010, the Company entered into a Loan and Security Agreement ("Loan Agreement") with Hercules Technology Growth Capital, Inc. ("Hercules"). Under the terms of the Loan Agreement, the Company borrowed $15,000,000 at an interest rate of the higher of (i) 10.75% or (ii) 6.5% plus the prime rate as reported in the Wall Street Journal, with a maximum interest rate of 14% and issued to Hercules a secured term promissory note evidencing the loan. The Company made interest only payments through January 2011 and beginning in February 2011 the loan is being repaid in 33 equal monthly installments.

The Loan Agreement limits both the seniority and amount of future debt the Company may incur. The Company may be required to prepay the loan in the event of a change in control. In conjunction with the loan, the Company issued to Hercules a five-year warrant to purchase 37,639 shares of the Company's common stock at a price of $26.90 per share. The warrant is immediately exercisable and expires in May 2015. The Company estimated the fair value of this warrant as of the issuance date to be $921,000 which was recorded as a debt discount to the loan and consequently a reduction to the carrying value of the loan. The fair value of the warrant was calculated using the Black-Scholes option valuation model, and was based on the contractual term of the warrant of five years, a risk-free interest rate of 2.31%, expected volatility of 84% and a 0% expected dividend yield. The Company also recorded fees paid to Hercules as a debt discount, which further reduced the carrying value of the loan. The debt discount is being amortized to interest expense.

As of September 30, 2012, the Company has classified $6,469,000 as restricted cash in current assets. In January 2012, the Company and Hercules amended the Loan Agreement to require the Company to maintain an amount equal to the outstanding principal balance of the loan in a restricted account. Upon an event of default, as defined in the Loan Agreement, Hercules has the ability to access the funds. The restricted account will terminate upon the earlier to occur of (i) the mutual agreement of the Company and Hercules or (ii) the satisfaction in full of all of the Company's obligations under the Loan Agreement, at which time the remaining funds, if any, will be transferred to the Company's operating account.

Autoliv ASP, Inc.

In June 2010, in return for transfer to the Company of all right, title and interest in a production line for the commercial manufacture of chemical heat packages completed or to be completed by Autoliv ASP, Inc ("Autoliv") on behalf of the Company, the Company paid Autoliv $4.0 million in cash and issued Autoliv a $4.0 million unsecured promissory note. In February 2011, the Company entered into an agreement to amend the terms of the unsecured promissory note. Under the terms of that amendment, the original $4.0 million note was cancelled and a new unsecured promissory note was issued with a reduced principal amount of $2.8 million (the "New Note").

The New Note bears interest beginning on January 1, 2011 at 8% per annum and is being paid in 48 consecutive and equal installments of approximately $68,000.

Future scheduled principal payments under the Hercules and Autoliv financing obligations as of September 30, 2012 are as follows (in thousands):

	Total
2012 - remaining 3 months	1,589
2013	5,773
2014	781
Total	$8,143

8. Facility Leases

The Company leased two buildings, at 2023 Stierlin Court and 2091 Stierlin Court, in Mountain View, California, referred to herein as the "2023 Building" and the "2091 Building", respectively, which the Company began to occupy in the fourth quarter of 2007. The Company recognizes rental expense on the facilities on a straight-line basis over the initial term of the lease. Differences between the straight line rent expense and rent payments are classified as deferred rent liability on the balance sheet. The lease for the 2091 Building expires on March 31, 2018, and the Company has two options to extend the lease for five years each.

Effective March 30, 2012, the Company terminated the lease for the 2023 Building, totaling 41,290 square feet, and concurrently cancelled the two subleases associated with the 2023 Building. At the time of the termination, the Company recorded a non-cash contra-expense of $1,421,000 in general and administrative expenses, which is the net effect of reversing the deferred rent liability associated with the 2023 Building lease and subleases and the accelerated depreciation of fixed assets associated with the 2023 Building.

9. License Agreements

Cypress Bioscience, Inc.

In August 2010, the Company entered into a license and development agreement with Cypress Bioscience, Inc. ("Cypress") for *Staccato* nicotine (the "Cypress Agreement"). According to the terms of the Cypress Agreement, Cypress paid the Company a non-refundable upfront payment of $5 million to acquire the worldwide license for the *Staccato* nicotine technology.

Following the completion of certain preclinical and clinical milestones relating to the *Staccato* nicotine technology, if Cypress elects to continue the development of *Staccato* nicotine, Cypress will be obligated to pay the Company an additional technology transfer payment of $1 million. The Company has a carried interest of 50% prior to the technology transfer payment, and 10% after the completion of certain development activities and receipt of the technology transfer payment, subject to adjustment in certain circumstances, in the net proceeds of any sale or license by Cypress of the *Staccato* nicotine assets and the carried interest will be subject to put and call rights in certain circumstances.

Cypress has the responsibility for preclinical, clinical and regulatory aspects of the development of *Staccato* nicotine, along with the commercialization of the product. Cypress paid the Company a total of $3.9 million in research and development funding for the Company's efforts to execute a development plan culminating with the delivery of clinical trial materials for a Phase 1 study with *Staccato* nicotine.

Additionally, Cypress and the Company entered into an agreement to sublease approximately 2,500 square feet of the Company's premises and to provide certain administrative, facility and information technology support for a period of 12 months for $11,000 per month. Beginning in September 2011, the space became subleased on a month-to-month basis.

For revenue recognition purposes, the Company viewed the Cypress Agreement as a multiple element arrangement. Multiple element arrangements are analyzed to determine whether the various performance obligations, or elements, can be separated or whether they must be accounted for as a single unit of accounting. The Company evaluated whether the delivered elements under the arrangement

have value on a stand-alone basis and whether objective and reliable evidence of fair value of the undelivered items exist. Deliverables that do not meet these criteria are not evaluated separately for the purpose of revenue recognition. For a single unit of accounting, payments received are recognized in a manner consistent with the final deliverable. The Company was unable to allocate a fair value to each of the deliverables outlined in the Cypress Agreement and therefore accounted for the deliverables as a single unit of accounting. The Company recognized revenue ratably over the estimated performance period of the agreement. Amounts received prior to recognition as revenues were classified as deferred revenue in the balance sheet. The Company recognized $0 and $1,259,000 of revenue under the Cypress Agreement in the three and nine months ended September 30, 2012, respectively and $1,259,000 and $3,776,000 in the same periods in 2011, respectively. At September 30, 2012, the Company had no deferred revenues or further performance obligations related to the Cypress Agreement. In January 2011, Cypress was acquired by Ramius Value and Opportunity Advisors LLC; Royalty Pharma, US Partner, LP; Royalty Pharma US Partners 2008, LP; and RP Investment Corporation.

Grupo Ferrer Internacional, S.A.

On October 5, 2011, the Company and Grupo Ferrer entered into the Ferrer Agreement to commercialize ADASUVE in Europe, Latin America, Russia and the Commonwealth of Independent States countries (the "Ferrer Territories"). Under the terms of the Ferrer Agreement, the Company received an upfront cash payment of $10 million, of which $5 million was paid to the former Allegro stockholders (see above in Note 3), and the Company is eligible to receive additional milestone payments, contingent on individual country commercial sales initiation and royalty payments based on cumulative net sales targets. The Company will be responsible for filing and obtaining approval of the ADASUVE Marketing Authorization Application ("MAA") submitted to the European Medicines Agency for an opinion regarding the potential approval of ADASUVE and subsequent decision by the European Commission. Grupo Ferrer will be responsible for satisfaction of all other regulatory and pricing requirements to market and sell ADASUVE in the Ferrer Territories. Grupo Ferrer will have the exclusive rights to commercialize the product in the Ferrer Territories. The Company will supply ADASUVE to Grupo Ferrer for all of its commercial sales, and will receive a specified per-unit transfer price paid in Euros. Either party may terminate the Ferrer Agreement for the other party's uncured material breach or bankruptcy. The Ferrer Agreement continues in effect on a country-by-country basis until the later of the last to expire patent covering ADASUVE in such country or 12 years after first commercial sale. The Ferrer Agreement is subject to earlier termination in the event the parties mutually agree, by a party in the event of an uncured material breach by the other party or upon the bankruptcy or insolvency of either party.

In March 2012, the Company entered into an amendment to the Ferrer Agreement. Grupo Ferrer and the Company eliminated a future potential milestone payment in exchange for Grupo Ferrer's purchase of 241,936 shares of the Company's common stock for $12.40 per share, which reflected a premium on the fair value of the Company's common stock of approximately $1,452,000. During 2012, up to an additional $8 million of the Company's common stock may be purchased by Grupo Ferrer, upon a request by the Company and subject to acceptance by Grupo Ferrer, in exchange for the elimination of additional milestones at a price per share that will be a premium to the market price on the date of purchase.

The Company recognized revenue related to the Ferrer Agreement under the guidance of Accounting Standards Codification 605-25 and ASU 2009-13. The Company evaluated whether the delivered elements under the arrangement have value on a stand-alone basis and whether objective and reliable evidence of fair value of the undelivered items exist. Deliverables that do not meet these criteria are not evaluated separately for the purpose of revenue recognition. For a single unit of accounting, payments received are recognized in a manner consistent with the final deliverable. The Company determined that the license and the development and regulatory services are a single unit of accounting as the licenses were determined to not have stand-alone value. The Company has begun to deliver all elements of the arrangement and is recognizing the $10 million upfront payment as revenue ratably over the estimated performance period of the agreement of four years. The $1,452,000 premium received from the sale of common stock to Grupo Ferrer is additional consideration received pursuant to the Ferrer Agreement and does not pertain to a separate deliverable or element of the arrangement, and thus is being deferred and recognized as revenue in a manner consistent with the $10 million upfront payment.

The Company recognizes milestone payments utilizing the milestone method of revenue recognition. The Company is eligible to receive up to $8.0 million of milestone payments from Grupo Ferrer. The Company will recognize milestone revenue upon first commercial sales in each of nine (9) identified countries. The Company believes each of these milestones are substantive as there is uncertainty that the milestones will be met, the milestone can only be achieved with the Company's past and current performance and the achievement of the milestone will result in additional payment to the Company. The Company will record royalty revenues in the period certain cumulative sales targets are met by Grupo Ferrer.

During the three and nine months ended September 30, 2012, the Company recognized $729,000 and $2,082,000 in revenues, respectively, and at September 30, 2012 had deferred revenue of $8,744,000 related to the Ferrer Agreement.

10. Autoliv Manufacturing and Supply Agreement

In November 2007, the Company entered into a Manufacturing and Supply Agreement (the "Manufacture Agreement") with Autoliv relating to the commercial supply of chemical heat packages that can be incorporated into the Company's *Staccato* device (the "Chemical Heat Packages"). Autoliv had developed these Chemical Heat Packages for the Company pursuant to a development agreement between Autoliv and the Company. Under the terms of the Manufacture Agreement, Autoliv agreed to develop a manufacturing line capable of producing 10 million Chemical Heat Packages a year.

In June 2010 and February 2011, the Company entered into agreements to amend the terms of the Manufacture Agreement (together the "Amendments"). Under the terms of the first of the Amendments, the Company paid Autoliv $4.0 million and issued Autoliv a $4.0 million unsecured promissory note in return for a production line for the commercial manufacture of Chemical Heat Packages. A production line is comprised of two identical and self-sustaining "cells," and the first such cell has been completed, installed and qualified. Under the terms of the Second Amendment, the original $4.0 million note was cancelled and the New Note was issued with a reduced principal amount of $2.8 million, and production on the second cell halted. The New Note is payable in 48 equal monthly installments of approximately $68,000, with the last payment scheduled for December 2014. In the event that the Company requests completion of the second cell of the first production line for the commercial manufacture of Chemical Heat Packages, Autoliv will complete, install and fully qualify such second cell for a cost to the Company of $1.2 million and Autoliv will transfer ownership of such cell to the Company upon the payment in full of such $1.2 million and the New Note.

The provisions of the Amendments supersede (a) the Company's obligation set forth in the Manufacture Agreement to reimburse Autoliv for certain expenses related to the equipment and tooling used in production and testing of the Chemical Heat Packages in an amount of up to $12 million upon the earliest of December 31, 2011, 60 days after the termination of the Manufacture Agreement or 60 days after approval by the FDA of an NDA filed by the Company, and (b) the obligation of Autoliv to transfer possession of such equipment and tooling.

Subject to certain exceptions, Autoliv has agreed to manufacture, assemble and test the Chemical Heat Packages solely for the Company in conformance with the Company's specifications. The Company will pay Autoliv a specified purchase price, which varies based on annual quantities ordered by the Company, per Chemical Heat Package delivered. The initial term of the Manufacture Agreement expires on December 31, 2012, at which time the Manufacture Agreement will automatically renew for successive five-year renewal terms unless the Company or Autoliv notifies the other party no less than 36 months prior to the end of the initial term or the then-current renewal term that such party wishes to terminate the Manufacture Agreement. The Manufacture Agreement provides that during the term of the Manufacture Agreement, Autoliv will be the Company's exclusive supplier of the Chemical Heat Packages. In addition, the Manufacture Agreement grants Autoliv the right to negotiate for the right to supply commercially any second generation Chemical Heat Package (a "Second Generation Product") and provides that the Company will pay Autoliv certain royalty payments if the Company manufactures Second Generation Products itself or if the Company obtains Second Generation Products from a third party manufacturer. Upon the termination of the Manufacture Agreement, the Company will be required, on an ongoing basis, to pay Autoliv certain royalty payments related to the manufacture of the Chemical Heat Packages by the Company or third party manufacturers.

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

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, which are subject to the "safe harbor" created by those sections. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. In some cases, you can identify forward-looking statements by the following words: "may," "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue," "ongoing" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. Examples of these statements include, but are not limited to, statements regarding: the prospects of us receiving approval to market ADASUVE in the United States or other countries, the adequacy of our capital to support our operations, our ability to raise additional funds and the potential terms of such potential financings, the implications of interim or final results of our clinical trials, the progress and timing of our research programs, including clinical testing, the extent to which our issued and pending patents may protect our products and technology, the potential of our product candidates to lead to the development of safe or effective therapies, our ability to enter into collaborations, our future operating expenses, our future losses, our future expenditures and the sufficiency of our cash resources. Our actual results could differ materially from those discussed in our forward-looking statements for many reasons, including the risks faced by us and described in Part II, Item 1A of this Quarterly Report on Form 10-Q and our other filings with the Securities and Exchange Commission, or SEC. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this Quarterly Report on Form 10-Q. You should read this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results may be materially different from what we expect. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

The following discussion and analysis should be read in conjunction with the unaudited financial statements and notes thereto included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

The names "Alexza Pharmaceuticals, Inc.," "Alexza," "*Staccato*" and "ADASUVE" are trademarks of Alexza Pharmaceuticals, Inc. We have registered these trademarks with the U.S. Patent and Trademark Office and other international trademark offices. All other trademarks, trade names and service marks appearing in this Quarterly Report on Form 10-Q are the property of their respective owners.

We are a pharmaceutical company focused on the research, development, and commercialization of novel proprietary products for the acute treatment of central nervous system conditions. All of our product candidates are based on our proprietary technology, the *Staccato* system. The *Staccato* system vaporizes an excipient-free drug to form a condensation aerosol that, when inhaled, allows for rapid systemic drug delivery. Because of the particle size of the aerosol, the drug is quickly absorbed through the deep lung into the bloodstream, providing speed of therapeutic onset that is comparable to intravenous, or IV, administration but with greater ease, patient comfort and convenience.

Lead product candidate update

Our lead product candidate is Adasuve ™ (*Staccato* loxapine), or ADASUVE, which is being developed for the acute treatment of agitation associated with schizophrenia or bipolar I disorder in adults. In December 2009, we submitted a New Drug Application, or NDA, for ADASUVE with the U.S. Food and Drug Administration, or the FDA. In October 2010, we received a Complete Response Letter, or CRL, from the FDA regarding our NDA for ADASUVE. In August 2011, we resubmitted the ADASUVE NDA, which was accepted for filing by the FDA as a complete, class 2 response to the FDA's CRL. The FDA indicated a Prescription Drug User Fee Act, or PDUFA, goal date for the ADASUVE NDA of February 4, 2012. In December 2011, the ADASUVE NDA was reviewed by the Psychopharmacologic Drugs Advisory Committee, or PDAC, and at the end of the meeting, the PDAC voted to recommend that ADASUVE be approved for use as a single dose in 24 hours when used with the FDA recommended Risk Evaluation and Mitigation Strategy, or REMS, for the treatment for agitation in patients with schizophrenia or bipolar mania. The vote on this question was 9/8/1 (yes/no/abstain). In a notice received from the FDA in January 2012, the PDUFA goal date for the ADASUVE NDA was extended 90 days from February 4, 2012 to May 4, 2012. In May 2012, we received a second CRL from the FDA regarding our NDA for ADASUVE. In June 2012, we resubmitted our ADASUVE NDA to the FDA in response to the CRL received in May 2012. In July 2012 the FDA notified us the resubmitted ADASUVE NDA had been accepted as a complete, class 2 response to the FDA's CRL with an indicated PDUFA goal date of December 21, 2012.

A CRL is issued by the FDA indicating that an NDA review cycle is complete and the application is not ready for approval in its present form. In the first CRL, the FDA stated that its primary clinical safety concern was related to data from the three Phase 1 pulmonary safety studies with ADASUVE. This concern was primarily based on observed, dose-related post-dose decreases in forced expiratory volume in one second, or FEV1, a standard measure of lung function, in healthy subjects and in subjects with asthma or chronic obstructive pulmonary disease, or COPD. The FDA also noted that decreases in FEV1 were recorded in subjects who were administered device-only, placebo versions of ADASUVE. In the information package submitted to the FDA in response to the first CRL and in preparation for the End-of-Review meeting, we presented evidence that we believe demonstrates the placebo device is

safe, including a blinded expert review of the flow-volume loops data from the healthy subject study as further evidence that there appears to be no consistent pattern suggestive of airway obstruction in these subjects. We also provided an analysis that we believe shows that there is no meaningful temporal relationship between placebo administration and decreases in FEV1. We believe this evidence and analysis confirm that the changes seen were likely background events in the population studied, where the repeated and extensive pulmonary function testing may have contributed to some of the observations. Additionally, we believe we showed that the aerosol characterization does not indicate a basis for concern. We reiterated these arguments in our August 2011 NDA resubmission.

In December 2011, the ADASUVE NDA was the subject of a PDAC meeting. At the end of the meeting, the PDAC voted to recommend that ADASUVE be approved for use as a single dose in 24 hours when used with the FDA recommended REMS for the treatment for agitation in patients with schizophrenia or bipolar mania. The vote on this question was 9/8/1 (yes/no/abstain).

The FDA takes an advisory committee's advice into consideration as part of its review of an NDA, but is not bound by an advisory committee's recommendations. After reviewing and discussing the ADASUVE data and the FDA proposed REMS, the committee voted on the following additional questions:

- Does the committee conclude that ADASUVE (loxapine) inhalation powder has been shown to be effective as a treatment for agitation in patients with schizophrenia or bipolar mania? The resulting vote was: 17/1/0 (yes/no/abstain).
- Does the committee conclude that ADASUVE (loxapine) inhalation powder has been shown to be acceptably safe for use as a treatment for agitation in patients with schizophrenia or bipolar mania:
    a. When used in conjunction with the REMS proposed by the sponsor? The resulting vote was: 1/17/0 (yes/no/abstain).
    b. When used in conjunction with the REMS proposed by the FDA? The resulting vote was: 5/12/1 (yes/no/abstain).
- Does the committee conclude that ADASUVE (loxapine) inhalation powder would be acceptably safe for use as a single dose in 24 hours as a treatment for agitation in patients with schizophrenia or bipolar mania when used in conjunction with the REMS proposed by FDA? The resulting vote was: 11/5/2 (yes/no/abstain).

In May 2012, we received a second CRL from the FDA. In the CRL, the FDA noted, "During a recent inspection of the Mountain View, CA manufacturing facility for this application, our field investigator conveyed deficiencies to the representative of the facility. Satisfactory resolution of these deficiencies is required before this application may be approved." We stated that we believed the deficiencies were medical device specific and readily addressable. Since the receipt of the CRL, we received further clarification of the specific deficiencies from the FDA and have made submissions directly to the Center for Devices and Radiological Health Office of Compliance and the San Francisco FDA District Office, intended to fully address the deficiencies. The May 2012 CRL also contained comments on the product's draft product labeling. We believe that there is substantial agreement between us and the FDA on product labeling. In the ADASUVE NDA resubmission, we submitted updated draft labeling which is intended to be responsive to the comments provided by the FDA in the May 2012 CRL. There were no new clinical or safety issues identified and there were no other deficiencies outlined in the CRL. With respect to the ADASUVE REMS, the CRL stated that discussions can continue on the proposed REMS after the response to the CRL has been submitted. We believe that there is substantial agreement between us and the FDA on the proposed REMS. In June 2012, we resubmitted the ADASUVE NDA and were notified by the FDA that our resubmitted ADASUVE NDA has a PDUFA goal date of December 21, 2012.

In October 2010, we were notified that ADASUVE was eligible for submission to the European Medicines Agency, or EMA, for an opinion regarding the potential approval of ADASUVE through the centralized marketing authorization procedure. Marketing authorization granted by the European Commission on the basis of the opinion issued by the EMA are valid in all of the European Union member states. We also have been notified that ADASUVE is acceptable for submission as a trade name and have completed work on the Pediatric Investigation Plan for the Marketing Authorization Application, or MAA, submission. On October 26, 2011, the EMA accepted the submission of our ADASUVE MAA. In March 2012, we received the Committee for Medicinal Products for Human Use, or CHMP, Consolidated List of Questions, or the Day 120 List of Questions, regarding our ADASUVE MAA. The Day 120 List of Questions included "major objections," including objections pertaining to the extrapolation of the Phase 3 clinical efficacy data, aspects of the risk management plan, and the need to obtain an EU Good Manufacturing Practices certificate for our Mountain View, California manufacturing facility and commercial manufacturing process. In May 2012, we and our European corporate partner, Grupo Ferrer, met with the EMA, and the Rapporteur and Co-Rapporteur appointed for ADASUVE, to further understand specifics of the major objections raised in the Day 120 List of Questions. In July 2012, we submitted our responses to the EMA, which were intended to address the questions outlined in the Day 120 List of Questions.

In July 2012, we completed the follow-up activities resulting from the May 2012 EU pre approval inspection. Based upon the outcome from this inspection of our Mountain View, California facility and our responses, the Spanish authorities, on behalf of the European Union, determined that our facility complied with the principles and guidelines of Good Manufacturing Practice set forth in Directive 2003/94/EC and in August 2012 issued us an EU Certificate of Good Manufacturing Practices Compliance of a Manufacturer. The initial certificate is valid for three years, through May 15, 2015. The receipt of this certificate resolved one of the major objections outlined in the Day 120 List of Questions.

In September 2012, we received the Day 180 List of Outstanding Issues from the CHMP regarding our ADASUVE MAA. However, the Day 180 List of Outstanding Issues included two "major objections," which preclude a recommendation for marketing authorization at the present time. The first major objection states that the CHMP does not believe that our data supports the broad indication as submitted, and that we should justify that the benefit/risk is positive in this group or identify a group of patients in whom the benefit/risk would be positive. The second major objection is that to limit the risk for, among other risks, bronchospasm and an effect on cardiac rhythms, or QT time, we proposed to limit the use of ADASUVE to a single dose per 24 hours, however, a "considerable proportion," as described by the CHMP, of patients in the efficacy studies did not respond to a single dose at the 4 hours time point and needed subsequent doses. Therefore, it remains uncertain whether in clinical practice it will be feasible to avoid dose-repetition.

During the fourth quarter of 2012, we plan to submit additional analyses and responses to the EMA in response to the Day 180 List of Outstanding Issues, including the two major objections. We also anticipate a face-to-face meeting with the CHMP during the same time period.

In October 2011, we entered into a commercial partnership with Grupo Ferrer pursuant to a Collaboration, License and Supply Agreement, or the Ferrer Agreement, to commercialize ADASUVE in Europe, Latin America, Russia and the Commonwealth of Independent States countries, or the Ferrer Territories. Under the terms of the Ferrer Agreement, we received an up-front cash payment of $10 million, $5 million of which was paid to the former Symphony Allegro stock holders, or the Allegro Investors. We are eligible to receive additional milestone payments contingent on individual country commercial sales initiation and cumulative net sales targets. We will be responsible for filing and obtaining marketing authorization from the European Commission on the basis of the ADASUVE Marketing Authorization Application, or MAA, submitted to the EMA. Grupo Ferrer will be responsible for satisfaction of all other regulatory and pricing reimbursement requirements to market and sell ADASUVE in the Ferrer Territories. Grupo Ferrer will have the exclusive rights to commercialize ADASUVE in the Ferrer Territories. We will supply ADASUVE to Grupo Ferrer for all of its commercial sales, and will receive a specified per-unit transfer price. Either party may terminate the Ferrer Agreement for the other party's uncured material breach or bankruptcy. The Ferrer Agreement continues in effect on a country-by-country basis until the later of the last to expire patent covering ADASUVE in such country or 12 years after first commercial sale. The Ferrer Agreement is subject to earlier termination in the event the parties mutually agree, by a party in the event of an uncured material breach by the other party or upon the bankruptcy or insolvency of either party.

In March 2012, we entered into an amendment to the Ferrer Agreement. Grupo Ferrer and Alexza agreed to eliminate a future potential milestone payment in exchange for Grupo Ferrer's purchase of $3 million of our common stock and Grupo Ferrer purchased approximately 241,936 shares of our common stock for $12.40 per share. During 2012, up to an additional $8 million of our common stock may be purchased by Grupo Ferrer, upon a request by us and subject to acceptance by Grupo Ferrer, in exchange for the elimination of additional milestones at a price per share that will be a premium to the market price on the date of purchase.

We believe that, based on our cash, cash equivalents, marketable securities and restricted cash balance at September 30, 2012, we have sufficient capital resources to meet our anticipated cash needs, at our current cost levels, into the second quarter of 2013. We are unable to assert that our financial position is sufficient to fund operations beyond the second quarter of 2013, and as a result, there is substantial doubt about our ability to continue as a going concern. We may not be able to raise sufficient capital on acceptable terms, or at all, to continue to pursue approval to commercialize ADASUVE in the United States or other countries, to continue development of our other product candidates or to continue operations.

On June 12, 2012, we effected a 1-for-10 reverse stock split of our outstanding common stock. The reverse stock split affected all stockholders of our common stock uniformly and did not materially affect any stockholder's percentage of ownership interest. The par value of our common stock remains unchanged at $0.0001 per share and the number of authorized shares of common stock remains the same after the reverse stock split.

On July 20, 2012, we entered into a committed equity line of credit with Azimuth Opportunity, L.P., or Azimuth, under which we may sell up to the lesser of $20 million of common stock over an approximately 24-month period pursuant to a Common Stock Purchase Agreement, or the Purchase Agreement. We are not obligated to utilize any of the facility and we remain free to enter into and consummate other equity and debt financing transactions. We will determine, at our sole discretion, the timing, the dollar amount and the price per share of each draw under this facility, subject to certain conditions. When we elect to use the facility, we will issue shares to Azimuth at a discount of 5% to the volume weighted average price of our common stock over a preceding period of trading days. Azimuth is not required to purchase any shares at a pre-discounted purchase price below $2.00 per share. Any shares sold under this facility will be sold pursuant to a shelf registration statement declared effective by the Securities and Exchange Commission on July 3, 2012. This facility replaces a similar facility that was established in May 2010 and expired after its 24-month term. During the third

quarter of 2012, we settled with Azimuth on the purchase of a total of 3,489,860 shares of our common stock under the Purchase Agreement at an aggregate purchase price of $13.6 million. The Company received $13.4 million in net proceeds from the sale of these shares after deducting offering expenses.

On February 23, 2012, we issued an aggregate of 4,400,000 shares of our common stock and warrants to purchase up to an additional 4,400,000 shares of our common stock in an underwritten public offering. Net proceeds from the offering were $20.2 million, after deducting offering expenses. The warrants are exercisable beginning February 24, 2013 at $5.00 per share and will expire on February 23, 2017. The shares of common stock and warrants were sold pursuant to a shelf registration statement declared effective by the SEC on May 20, 2010. We agreed to customary obligations, including indemnification.

Other than those licensed to Grupo Ferrer for our ADASUVE product candidate and Cypress Biosciences, Inc., or Cypress, for our *Staccato* nicotine product candidate, we have retained all rights to our product candidates and the *Staccato* system. We intend to capitalize on our internal resources to develop certain product candidates and to identify routes to utilize external resources to develop and commercialize other product candidates.

We were incorporated December 19, 2000. We have funded our operations primarily through the sale of equity securities, equipment financings, debt financings and government grants. We have generated $68.8 million in revenues from inception through September 30, 2012, primarily through license and development agreements and to a lesser extent United States Small Business Innovation Research grants and drug compound feasibility studies. Prior to 2007, we recognized governmental grant revenue and drug compound feasibility revenue. However, we expect no grant revenue or drug compound feasibility screening revenue in 2012. We do not expect any product revenue until at least mid-2013.

We have incurred significant losses since our inception. As of September 30, 2012, our deficit accumulated during development stage was $324.3 million and total stockholders' equity was $10.3 million. We recognized net losses of $17.7 million in the nine months ended September 30, 2012 and $40.5 million, $1.5 million and $56.1 million in the years ended December 31, 2011, 2010 and 2009, respectively, and $369.4 million in the period from December 19, 2000 (Inception) to September 30, 2012. In February 2012, we reduced our workforce by 29, or 38% of our employees. We expect our operating expenses to increase in the fourth quarter of 2012 as we initiate our commercialization and manufacturing efforts in anticipation of the potential approvals of our ADASUVE NDA and MAA.

The process of conducting preclinical studies and clinical trials necessary to obtain FDA approval is costly and time consuming. We consider the development of our product candidates to be crucial to our long-term success. If we do not complete development of our product candidates and obtain regulatory approval to market one or more of these product candidates, we may be forced to cease operations. The probability of success for each product candidate may be impacted by numerous factors, including preclinical data, clinical data, competition, device development, manufacturing capability, regulatory approval and commercial viability. Our strategy is to focus our resources on ADASUVE. In addition, we plan to seek additional commercial partners for the worldwide development and commercialization for all of our product candidates. If in the future we enter into additional partnerships, third parties could have control over preclinical development, clinical trials or the regulatory process for some of our product candidates. Accordingly, the progress of such product candidates would not be under our control. We cannot forecast with any degree of certainty which of our product candidates, if any, will be subject to any future partnerships or how such arrangements would affect our development plans or capital requirements.

As a result of the uncertainties discussed above, the uncertainty associated with clinical trial enrollments, and the risks inherent in the development process, we are unable to determine the duration and completion costs of the current or future clinical stages of our product candidates or when, or to what extent, we will generate revenues from the commercialization and sale of any of our product candidates. Development timelines, probability of success and development costs vary widely. While we are currently focused on developing our product candidates, we anticipate that we and our partners will make determinations as to which programs to pursue and how much funding to direct to each program on an ongoing basis in response to the scientific and clinical success of each product candidate, as well as an ongoing assessment as to the product candidate's commercial potential. We do not expect any of our current product candidates to be commercially available before mid-2013, if at all.

Results of Operations

Comparison of Three and Nine Months Ended September 30, 2012 and 2011

Revenue

Revenues for the three and nine months ended September 30, 2012 were $729,000 and $3,341,000, respectively, and $1,259,000 and $3,776,000 in the same periods in 2011, respectively. We recognized revenues related to our license and development agreement with Cypress, or the Cypress Agreement, signed in August 2010 in the nine months ended September 30, 2012 and both the three and nine months ended September 30, 2011. There was no revenue recognized from the Cypress Agreement in the three months ended September 30, 2012. Revenues in the three and nine months ended September 30, 2012 also included amounts related to our commercial partnership with Grupo Ferrer signed in October 2011. We do not anticipate product revenues until at least mid-2013.

Research and Development Expenses

Research and development costs are identified as either directly attributable to one of our product candidates or as general research. Direct costs consist of personnel costs directly associated with a candidate, preclinical study costs, clinical trial costs, related clinical drug and device development and manufacturing costs, contract services and other research expenditures. Overhead, facility costs and other support service expenses are allocated to each candidate or to general research, and the allocation is based on employee time spent on each program.

The following table allocates our expenditures between product candidate costs or general research, based on our internal records and estimated allocations of employee time and related expenses (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Product candidate expenses	$ 4,254	$ 7,777	$12,864	$19,365
General research	530	274	1,962	1,612
Total research and development expenses	$ 4,784	$ 8,051	$14,826	$20,977

Research and development expenses were $4.8 million and $14.8 million during the three and nine months ended September 30, 2012, respectively, and $8.1 million and $21.0 million in the same periods in 2011, respectively. The decrease in research and development expenses was a result of the suspension of development of our AZ-007 and *Staccato* nicotine product candidates as well as our efforts to conserve cash resources, including a 38% Company mandated reduction in our workforce in February 2012 and an additional net reduction of 18%of our workforce due to employees who have since voluntarily resigned. Due to the Company mandated reduction in our workforce, we recorded a reversal of share-based compensation for unvested stock options, expensed in earlier periods that resulted in a reduction of research and development costs of $431,000 during the three months ended March 31, 2012.

We expect research and development non-share based compensation expenses in the fourth quarter of 2012 will increase as we initiate some pre-commercialization and commercial manufacturing efforts in anticipation of the potential approvals of our ADASUVE NDA and MAA.

General and Administrative Expenses

General and administrative expenses were $2.3 million and $6.5 million during the three and nine months ended September 30, 2012, respectively, and $3.1 million and $8.7 million in the same periods in 2011, respectively. During the three months ended March 31, 2012, the Company recorded a non-cash contra expense of $1.4 million related to the termination of our lease and associated subleases of one of our Mountain View facilities. This non-cash contra expense was a result of the reversal of deferred rent liability, net of the accelerated depreciation of the fixed assets, related to the facility. The decreases from 2011 levels were also a result of our efforts to conserve cash resources, including the reductions in our workforce as described above.

Excluding the one-time contra expense related to the lease termination, we expect general and administrative expenses to increase in the fourth quarter of 2012 to support some pre-commercialization and commercial manufacturing efforts in anticipation of the potential approvals of our ADASUVE NDA and MAA.

In addition, we have not recognized cash bonuses under our 2012 cash bonus plan and expenses associated with certain share-based awards that will vest upon the approval of the ADASUVE NDA. If the NDA is approved in the fourth quarter of 2012, we will recognize operating expenses of approximately $1.8 million related to the 2012 cash bonus plan and $1.9 million of share-based compensation.

Change in the Fair Value of Contingent Consideration Liability

In connection with our acquisition of all of the outstanding equity of Symphony Allegro, Inc., or Allegro, in the third quarter of 2009, we are obligated to pay Symphony Allegro Holdings LLC, or Holdings, certain percentages of cash receipts that may be generated from future collaboration transactions for ADASUVE, AZ-104 and/or AZ-002. We measure the fair value of this contingent consideration liability on a recurring basis. Any changes in the fair value of this contingent consideration liability are recognized in earnings in the period of the change. Certain events, including, but not limited to, clinical trial results, regulatory approval or nonapproval of our submissions, such as our ADASUVE NDA we filed with the FDA in July 2012 and our ADASUVE MAA filed with the EMA in October 2011, the timing and terms of a strategic partnership, and the commercial success of ADASUVE, AZ-104, and/or AZ-002, could have a material impact on the fair value of the contingent consideration liability, and as a result, our results of

operations. During the three months ended September 30, 2012, we updated the contingent liability fair value model primarily to reflect the present value impact of the passage of three months on our discounted cash flow model. During the three and nine months ended September 30, 2012, we updated the contingent liability fair value model primarily to reflect the timing of certain cash flows as a result of the delay in our ADASUVE PDUFA goal date and the receipt of the CRL for the ADASUVE NDA in May 2012. This update resulted in a non-operating, non-cash loss of $0.2 million during the three months ended September 30, 2012 and an non-operating, non-cash gain of $1.0 million during the nine months ended September 30, 2012.

Interest and Other Income/(Expense), Net

Interest and other income/(expense), net, was $5,000 and $413,000 for the three and nine months ended September 30, 2012, respectively, and $13,000 and $30,000 in the same periods in 2011, respectively. In 2012, the amount primarily consists of gains on the retirement of fixed assets as the Company sold certain equipment no longer being utilized. We expect interest income to continue to remain nominal through 2012 as we expect the low interest rate environment to continue.

Interest Expense

Interest expense was $333,000 and $1,146,000 for the three and nine months ended September 30, 2012, respectively, and $529,000 and $1,703,000 in the same periods in 2011, respectively. The amounts represent interest on our equipment financing obligations and term loan agreements. Interest expense decreased due to a reduction in our outstanding debt balances as we continue to make our scheduled payments. We expect interest expense to continue to decrease from current levels as we decrease our outstanding debt balances as we make our monthly payments.

Liquidity and Capital Resources

Since inception, we have financed our operations primarily through private placements and public offerings of equity securities, revenues primarily from licensing and development agreements, government grants and payments from Allegro. We have received additional funding from financing obligations, interest earned on investments, as described below, and funds received upon exercises of stock options and exercises of purchase rights under our 2005 Employee Stock Purchase Plan, or ESPP. As of September 30, 2012, we had $32.0 million in cash, cash equivalents, marketable securities and restricted cash. Our cash and marketable security balances are held in a variety of interest bearing instruments, including obligations of U.S. government agencies, high credit rating corporate borrowers and money market accounts. Cash in excess of immediate requirements is invested with regard to liquidity, capital preservation and yield.

Cash Flows from Operating Activities. Net cash used in operating activities was $11.0 million and $24.6 million during the nine months ended September 30, 2012 and 2011, respectively. The net cash used in operating activities in the nine months ended September 30, 2012 primarily reflects the net loss of $17.7 million offset by the non-cash charges of: (i) depreciation of $3.5 million; (ii) share-based compensation expense of $2.5 million; and (iii) the change in fair value of the contingent consideration liability of $1.0 million. Cash flows from operating activities were also impacted by the reduction in: (i) other liabilities of $3.7 million; (ii) deferred revenues of $1.9 million; and (iii) accounts payable of $1.8 million partially offset by the collection of the accounts receivables of $10.0 million.

The net cash used in operating activities in the nine months ended September 30, 2011 primarily reflects the net loss of $30.8 million offset by the non-cash charges of: (i) share-based compensation expense of $1.5 million; (ii) depreciation of $3.4 million; and (iii) the change in fair value of the contingent consideration liability of $3.3 million. Cash flows from operating activities were also impacted by the reduction in deferred revenues of $1.8 million and other liabilities of $1.7 million partially offset by the increase in accrued clinical and other accrued liabilities of $0.8 million.

Cash Flows from Investing Activities. Net cash provided by investing activities was $2.4 million and $9.4 million during the nine months ended September 30, 2012 and 2011, respectively. Investing activities consist primarily of purchases and maturities of marketable securities and capital purchases. During the nine months ended September 30, 2012, we had maturities of marketable securities, net of purchases, of $2.0 million, proceeds from the disposal of the property and equipment of $0.4 million and purchases of property and equipment of $0.2 million, primarily consisting of equipment purchases.

During the nine months ended September 30, 2011, we had maturities of marketable securities, net of purchases, of $9.8 million, and purchases of property and equipment of $0.4 million, primarily consisting of equipment purchases.

Cash Flows from Financing Activities . Net cash provided by financing activities was $19.2 million and $12.0 million during the nine months ended September 30, 2012 and 2011, respectively. Cash flows from financing activities have generally consisted of proceeds from the issuance of our common stock and net cash flows from our equipment financing agreements. In the nine months ended September 30, 2012, we raised net proceeds of $20.2 million from a public offering, $13.4 million from the utilization of our equity line of credit and $1.5 million from the sale of common stock to Grupo Ferrer. In the nine months ended September 30, 2011, we had net proceeds of $15.9 million from our registered direct offering in May 2011.

During the nine months ended September 30, 2012, we made a payment of $5.0 million to Holdings as a result of our receipt of the $10 million Grupo Ferrer upfront payment and we entered into an agreement with Hercules Technology Growth Capital, Inc., or Hercules, to establish a restricted cash account impacting cash flows by $6.5 million. In the nine months ended September 30, 2012 and 2011, principal payments on our financing obligations were $4.5 million and $4.1 million, respectively.

We believe that, based on our cash, cash equivalents, marketable securities and restricted cash balance at September 30, 2012, we have sufficient capital resources to meet our anticipated cash needs, at our current cost levels, into the second quarter of 2013. Changing circumstances may cause us to consume capital significantly faster or slower than we currently anticipate or to alter our operations. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available financial resources sooner than we currently expect. The key assumptions underlying these estimates include:

- expenditures related to continued preclinical and clinical development of our lead product candidates during this period within budgeted levels;
- no unexpected costs related to the development of our manufacturing capability;
- no unexpected costs related to the our response to the CRL issued by the FDA related to the ADASUVE NDA;
- no unexpected costs related to the EMA review of our ADASUVE MAA; and
- no unbudgeted growth in the number of our employees during this period.

Our forecast of the period of time that our financial resources will be adequate to support operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed in “Risk Factors.” In light of the numerous risks and uncertainties associated with the development and commercialization of our product candidates and the extent to which we enter into additional strategic partnerships with third parties to participate in development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials. Our future funding requirements will depend on many factors, including:

- the cost, timing and outcomes of regulatory approvals or non-approvals;
- the scope, rate of progress, results and costs of our preclinical studies, clinical trials and other research and development activities;
- the terms and timing of any additional distribution, strategic partnership or licensing agreements that we may establish;
- the number and characteristics of product candidates that we pursue;
- the cost and timing of establishing manufacturing, marketing and sales capabilities;
- the cost of establishing clinical and commercial supplies of our product candidates;
- the cost of preparing, filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and
- the extent to which we acquire or invest in businesses, products or technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

We will need to raise additional funds to support our operations, and such funding may not be available to us on acceptable terms, or at all. If we are unable to raise additional funds when needed, we may not be able to continue development of our product candidates or we could be required to delay, scale back or eliminate some or all of our development programs, or reduce our efforts to build our commercial manufacturing, marketing and sales capacity, and other operations. We may seek to raise additional funds through public or private financing, strategic partnerships or other arrangements. Any additional equity financing may be dilutive to stockholders and debt financing, if available, may involve restrictive covenants. Applicable listing standards may affect our ability to consummate certain types of offerings of our securities in the future. Given the limited number of additional authorized shares of our common stock, we may not be able to raise significant proceeds through the sale of our equity securities. If we raise funds through additional collaborative or licensing arrangements, we may be required to relinquish, on terms that are not favorable to us, rights to some of our technologies, product candidates that we would otherwise seek to develop or commercialize ourselves. Our failure to raise capital when needed may harm our business, financial condition, results of operations, and prospects.

Contractual Obligations

We lease a 64,104 square foot manufacturing, office and laboratory facility in Mountain View, California, which we began to occupy in the fourth quarter of 2007. The lease expires on March 31, 2018, and we have two options to extend the lease for five years each. We sublease 2,500 square feet on a month-to-month basis. We believe that the Mountain View facility is sufficient for our office, manufacturing and laboratory needs for at least the next three years.

On May 4, 2010, we entered into a Loan and Security Agreement, or the Loan Agreement, with Hercules. Under the terms of the Loan Agreement, we borrowed $15,000,000 at an interest rate equal to the higher of (i) 10.75% or (ii) 6.5% plus the prime rate as reported in the Wall Street Journal, with a maximum interest rate of 14%, and issued to Hercules a secured term promissory note evidencing the loan. We made interest only payments through January 2011 and beginning in February 2011 the loan began to be repaid in 33 equal monthly installments.

On November 2, 2007, we entered into a manufacturing and supply agreement, or the manufacture agreement, with Autoliv ASP, Inc., or Autoliv, relating to the commercial supply of chemical heat packages that can be incorporated into our *Staccato* device. Autoliv had developed these chemical heat packages for us pursuant to a development agreement between Autoliv and us executed in October 2005.

In June 2010 and February 2011, we entered into agreements to amend the terms of the manufacture agreement, or the amendments. Under the terms of the first of the amendments, we paid Autoliv $4 million and issued Autoliv a $4 million unsecured promissory note in return for a production line for the commercial manufacture of chemical heat packages. A production line is comprised of two identical and self-sustaining "cells," and the first such cell has been completed, installed and qualified. Under the terms of the second of the amendments, the original $4 million note was cancelled and a new unsecured promissory note was issued with a reduced principal amount of $2.8 million, or the second note, and production on the second cell halted. The second note is payable in 48 equal monthly installments of approximately $68,000 and the last payment is scheduled for December 2014.

In the event that we request completion of the second cell of the first production line for the commercial manufacture of chemical heat packages, Autoliv will complete, install and fully qualify such second cell for a cost to us of $1.2 million and Autoliv will transfer ownership of such cell to us upon the payment in full of such $1.2 million and the second note. At our request, Autoliv will manufacture up to two additional production lines for the commercial manufacture of chemical heat packages at a cost not to exceed $2,400,000 for each additional line.

We will pay Autoliv a specified purchase price, which varies based on annual quantities ordered by us, per chemical heat package delivered. The initial term of the manufacture agreement expires on December 31, 2012, at which time the manufacture agreement will automatically renew for successive five-year renewal terms unless we or Autoliv notify the other party no less than 36 months prior to the end of the initial term or the then-current renewal term that such party wishes to terminate the manufacture agreement.

Our scheduled future minimum contractual payments, net of sublease income, including interest at September 30, 2012, are as follows (in thousands):

	Operating Lease Agreements	Financing Obligations	Total
2012 - remaining 3 months	1,001	1,785	2,786
2013	3,542	6,124	9,666
2014	3,502	815	4,317
2015	3,197	—	3,197
2016	3,287	—	3,287
Thereafter	4,240	—	4,240
Total	$ 18,769	$ 8,724	$27,493

As part of our purchase of all of the outstanding equity of Allegro in August 2009, we agreed to pay to Holdings certain percentages of cash payments that may be generated from future partnering transactions pertaining to ADASUVE (*Staccato* loxapine), AZ-104 (*Staccato* loxapine, low-dose) or AZ-002 (*Staccato* alprazolam). In January 2012, we made a payment to Holdings of $5 million as a result of the $10 million upfront payment we received from Grupo Ferrer.

Critical Accounting Policies, Estimates and Judgments

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments related to development costs. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making assumptions about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 3 of the notes to the consolidated financial statements in our Annual Report on Form 10-K as filed with the SEC on March 12, 2012, we believe the following accounting policies are critical to the process of making significant estimates and judgments in preparation of our financial statements.

Share-Based Compensation

We use the Black-Scholes option pricing model to determine the fair value of stock options and purchase rights issued under our ESPP. The determination of the fair value of share-based payment awards on the date of grant using an option-pricing model is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. These variables include our expected stock price volatility over the term of the awards, actual and projected employee stock option exercise behaviors, risk-free interest rates and expected dividends.

We estimated the expected term of options based on the historical term periods of options that have been granted but are no longer outstanding and the estimated terms of outstanding options. We estimated the volatility of our stock based on our actual historical volatility since our initial public offering. We base the risk-free interest rate that we use in the option pricing model on U.S. Treasury zero-coupon issues with remaining terms similar to the expected term on the options. We do not anticipate paying any cash dividends in the foreseeable future and therefore use an expected dividend yield of zero in the option pricing model.

We are required to estimate forfeitures at the time of grant and revise those estimates in subsequent periods if actual forfeitures differ from those estimates. We use historical data to estimate pre-vesting option forfeitures and record share-based compensation expense only for those awards that are expected to vest. All share-based payment awards are amortized on a straight-line basis over the requisite service periods of the awards, which are generally the vesting periods.

The estimated fair value of restricted stock unit awards is calculated based on the market price of our common stock on the date of grant, reduced by the present value of dividends expected to be paid on our common stock prior to vesting of the restricted stock unit. Our current estimate assumes no dividends will be paid prior to the vesting of the restricted stock unit. If factors change and we employ different assumptions for estimating share-based compensation expense in future periods or if we decide to use a different valuation model, the expenses in future periods may differ significantly from what we have recorded in the current period and could materially affect our operating loss, net loss and net loss per share.

See Note 5 to the condensed consolidated financial statements in this Quarterly Report on this Form 10-Q for further information regarding ASC 718 option valuation disclosures.

Contingent Consideration Liability

In August 2009, we completed our purchase of all of the outstanding equity of Allegro, and in exchange we: (i) issued to the former Allegro stockholders, or the Allegro Investors, 1,000,000 shares of our common stock; (ii) issued to the Allegro Investors five-year warrants to purchase 500,000 shares of our common stock with an exercise price of $22.60 per share; and (iii) will pay to the Allegro Investors certain percentages of cash payments that may be generated from future partnering transactions pertaining to ADASUVE/AZ-104 (*Staccato* loxapine) or AZ-002 (*Staccato* alprazolam).

We estimate the fair value of the liability associated with the contingent cash payments to the Allegro Investors, or contingent consideration liability, on a quarterly basis using a probability-weighted discounted cash flow model. We derive multiple cash flow scenarios for each product candidates subject to the cash payments and apply a probability to each of the scenarios. These probability and risk adjusted weighted average cash flows are then discounted utilizing our estimated weighted average cost of capital, or WACC. Our WACC considers our cash position, competition, risk of substitute products, and risk associated with the financing of the development projects. We determined the discount rate to be 18% and applied this rate to the probability adjusted cash flow scenarios.

We record any changes in the fair value of the contingent consideration liability in earnings in the period of the change. Certain events including, but not limited to, clinical trial results, FDA or EMA approval or non-approval of our submissions, the timing and terms of any strategic partnership agreement, the commercial success of ADASUVE, AZ-104 or AZ-002 and the discount rate assumption could have a material impact on the fair value of the contingent consideration liability, and as a result, our results of operations and financial position.

Revenue Recognition

We recognize revenue in accordance with the SEC Staff Accounting Bulletin, No. 101, *Revenue Recognition in Financial* Statements, as amended by Staff Accounting Bulletin No. 104, *Revision of Topic 13.* In determining the accounting for collaboration agreements, we determine whether an arrangement involves multiple revenue-generating deliverables that should be accounted for as a single unit of accounting or divided into separate units of accounting for revenue recognition purposes and, if this division is required, how the arrangement consideration should be allocated among the separate units of accounting. If the arrangement represents a single unit of

accounting, the revenue recognition policy and the performance obligation period must be determined, if not already contractually defined, for the entire arrangement. If the arrangement represents separate units of accounting, a revenue recognition policy must be determined for each unit.

For collaborations entered into prior to January 1, 2011 we followed the guidelines of Accounting Standards Codification, or ASC, 605-25 *Revenue Recognition Multiple-Element Arrangement* . For collaboration agreements entered into or significantly modified on or subsequent to January 1, 2011, we followed the guidelines of Accounting Standards Update, or ASU, 2009-13, which amends the criteria to identify separate units of accounting within ASC 605-25. The revised guidance eliminated the residual method of allocation, and instead requires companies to use the relative selling price method when allocating revenue in a multiple deliverable arrangement. When applying the relative selling price method, the selling price for each deliverable is determined using vendor specific objective evidence of selling price, if it exists, otherwise using third-party evidence of selling price. If neither vendor specific objective evidence nor third-party evidence of selling price exists for a deliverable, companies shall use their best estimate of the selling price for that deliverable when applying the relative selling price method.

For milestone payments, the Company follows the guidance of ASU 2010-17, " *Milestone Method of Revenue Recognition a consensus of the FASB Emerging Issues Task Force* ." ASU 2010-17 provides guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research and development transactions. A vendor can recognize consideration in its entirety as revenue in the period in which the milestone is achieved only if the milestone meets all criteria to be considered substantive. A milestone is considered substantive if; (i) there is uncertainty that the milestones will be met, (ii) the milestone can be achieved only with our past and current performance and (iii) the achievement of the milestone will result in additional payment.

Revenues for non-refundable upfront license fee payments, where we continue to have obligations, will be recognized as performance occurs and obligations are completed.

Recently Adopted Accounting Standards

In June 2011, the Financial Accounting Standards Board, or FASB, issued ASU 2011-05, " *Presentation of Comprehensive Income.* " ASU 2011-15 requires the presentation of total comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. We adopted these disclosure requirements in this first quarter of 2012.

On May 12, 2011, the FASB issued ASU 2011-04, " *Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs.* " ASU 2011-04 is the result of joint efforts by the FASB and the International Accounting Standards Board to develop a single, converged fair value framework. There are few differences between ASU 2011-04 and its international counterpart, IFRS 13. ASU 2011-04 is largely consistent with existing fair value measurement principles in U.S. GAAP; however it expands ASC 820's existing disclosure requirements for fair value measurements and makes other amendments. The adoption of ASU 2011-04 did not have a material effect on our financial position, results of operations or cash flows.

Off Balance Sheet Arrangements

None.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our exposure to market risk is confined to our cash, cash equivalents, marketable securities and restricted cash. The primary objective of our investment activities is to preserve our capital to fund operations. We also seek to maximize income from our investments without assuming significant risk. To achieve our objectives, we maintain a portfolio of cash equivalents and marketable securities in a variety of securities of high credit quality. As of September 30, 2012, we had cash, cash equivalents, marketable securities and restricted cash of $32.0 million. The securities in our investment portfolio are not leveraged, are classified as available-for-sale and are, due to their very short-term nature, subject to minimal interest rate risk. We currently do not hedge interest rate exposure. Because of the short-term maturities of our investments, we do not believe that an increase in market rates would have a material negative impact on the realized value of our investment portfolio. We actively monitor changes in interest rates. We perform quarterly reviews of our investment portfolio and believe we have minimal exposure related to mortgage and other asset-backed securities. We have no exposure to auction rate securities.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures.

Our management (with the participation of our chief executive officer, principal financial officer and outside counsel) has reviewed our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended). Based on that evaluation, our chief executive officer and chief financial officer have concluded that, as of September 30, 2012, our internal disclosure controls and procedures were effective.

Changes in Internal Controls over Financial Reporting

There has been no change in our internal control over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls.

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within a company have been detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met and, as set forth above, our chief executive officer and principal financial officer have concluded, based on their evaluation as of the end of the period covered by this report, that our disclosure controls and procedures were sufficiently effective to provide reasonable assurance that the objectives of our disclosure control system were met.

PART II. OTHER INFORMATION

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, together with all of the other information included in this Quarterly Report, before deciding whether to invest in shares of our common stock. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. The occurrence of any of the following risks could harm our business, financial condition or results of operations. In such case, the trading price of our common stock could decline, and you may lose all or part of your investment.

Risks Relating to Our Business

Our management concluded that due to our need for additional capital, and the uncertainties surrounding our ability to raise such funding, substantial doubt exists as to our ability to continue as a going concern.

Our audited financial statements for the fiscal year ended December 31, 2011 were prepared on a going concern basis in accordance with United States generally accepted accounting principles. The going concern basis of presentation assumes that we will continue in operation for the next twelve months and will be able to realize our assets and discharge our liabilities and commitments in the normal course of business and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from our inability to continue as a going concern. Our operating and capital plans for the next twelve months call for cash expenditure to exceed our cash, cash equivalents, marketable securities, restricted cash and working capital. Our management concluded that due to our need for additional capital, and the uncertainties surrounding our ability to raise such funding, substantial doubt exists as to our ability to continue as a going concern. We may be forced to reduce our operating expenses, raise additional funds, principally through the additional sales of our securities or debt financings, or enter into an additional corporate partnership to meet our working capital needs. However, we cannot guarantee that we will be able to obtain sufficient additional funds when needed or that such funds, if available, will be obtainable on terms satisfactory to us. If we are unable to raise sufficient additional capital or complete a strategic transaction, we may be unable to continue to fund our operations, develop our product candidates or realize value from our assets and discharge our liabilities in the normal course of business. These uncertainties raise substantial doubt about our ability to continue as a going concern. If we become unable to continue as a going concern, we may have to liquidate our assets, and might realize significantly less than the values at which they are carried on our financial statements, and stockholders may lose all or part of their investment in our common stock.

We have a history of net losses. We expect to continue to incur substantial and increasing net losses for the foreseeable future, and we may never achieve or maintain profitability.

We are not profitable and have incurred significant net losses in each year since our inception, including net losses of $17.7 million, $40.5 million, $1.5 million, and $56.1 million for the nine months ended September 30, 2012, and the years ended December 31, 2011, 2010 and 2009, respectively, and $369.4 million for the period from December 19, 2000 (inception) to September 30, 2012. As of September 30, 2012, we had a deficit accumulated during development stage of $324.3 million and stockholders' equity of $10.3 million. We expect to continue to incur substantial net losses and negative cash flow for the foreseeable future. These losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital.

Because of the numerous risks and uncertainties associated with pharmaceutical product development and commercialization, we are unable to accurately predict the timing or amount of future expenses or when, or if, we will be able to achieve or maintain profitability. Currently, we have no products approved for commercial sale, and to date we have not generated any product revenue. We have financed our operations primarily through the sale of equity securities, equipment financing, debt financing, collaboration

and licensing agreements, and government grants. The size of our future net losses will depend, in part, on the rate of growth or contraction of our expenses and the level and rate of growth, if any, of our revenues. Revenues from strategic partnerships are uncertain because we may not enter into any additional strategic partnerships. If we are unable to develop and commercialize one or more of our product candidates or if sales revenue from any product candidate that receives marketing approval is insufficient, we will not achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability.

We are a development stage company. Our success depends substantially on our lead product candidates. If we do not develop commercially successful products, we may be forced to cease operations.

You must evaluate us in light of the uncertainties and complexities affecting a development stage pharmaceutical company. We have not completed clinical development for any of our product candidates. In May 2012, we received a second CRL from the FDA regarding our NDA for our ADASUVE product candidate. A CRL is issued by the FDA indicating that the NDA review cycle is complete and the application is not ready for approval in its present form. In the May 2012 CRL, the FDA noted, "During a recent inspection of the Mountain View, CA manufacturing facility for this application, our field investigator conveyed deficiencies to the representative of the facility. Satisfactory resolution of these deficiencies is required before this application may be approved." With respect to the ADASUVE REMS, the CRL stated that discussions can continue on the proposed REMS after the response to the action letter has been submitted. The CRL also contained FDA comments on draft product labeling. We resubmitted our NDA for ADASUVE in June 2012 and the PDUFA goal date for the ADASUVE NDA is December 21, 2012. We may be unsuccessful in resolving the concerns raised in the CRL and we may never receive marketing approval for ADASUVE or any of our other product candidates. On October 26, 2011, the EMA accepted the submission of our ADASUVE MAA. In March 2012, we received the Day 120 List of Questions regarding our ADASUVE MAA. The Day 120 List of Questions included major objections pertaining to the extrapolation of the Phase 3 study population to the intended patient population, pulmonary safety in patients with active airways disease and recommendations to address this issue via the risk management plan and other aspects of the risk management plan. In May 2012, the EMA performed a pre-approval inspection and in August 2012, we received our EU Good Manufacturing Practices Certificate for our Mountain View, California. We submitted our response to the Day 120 List of Questions in July 2012. In September 2012, we received the Day 180 List of Outstanding Issues for the ADASUVE MAA. The Day 180 List of Outstanding Issues included two "major objections," which preclude a recommendation for marketing authorization at the present time. The first major objection states that the CHMP does not believe that our data supports the broad indication as submitted, and that we should justify that the benefit/risk is positive in this group, or identify a group of patients in whom the benefit/risk would be positive. The second major objection is that to limit the risk for, among other risks, bronchospasm and an effect on QT time, we proposed to limit the use of ADASUVE to a single dose per 24 hours, however, a "considerable proportion," as described by the CHMP, of patients in the efficacy studies did not respond to a single dose at the 4 hours time point and needed subsequent doses. Therefore, it remains uncertain whether in clinical practice it will be feasible to avoid dose-repetition. Each of our other product candidates is at an earlier stage of development and may be affected by concerns expressed in the CRL and/or the Day 180 List of Outstanding Issues. Each of our product candidates will be unsuccessful if it:

- does not demonstrate acceptable quality, safety and efficacy in preclinical studies and clinical trials or otherwise does not meet applicable regulatory standards for approval;
- does not offer therapeutic or other improvements over existing or future drugs used to treat the same or similar conditions;
- is not capable of being produced in commercial quantities at an acceptable cost, or at all; or
- is not accepted by patients, the medical community or third party payors.

Our ability to generate product revenue in the future is dependent on the successful development and commercialization of our product candidates. We have not proven our ability to develop and commercialize products. Problems frequently encountered in connection with the development and utilization of new and unproven technologies and the competitive environment in which we operate might limit our ability to develop commercially successful products. We do not expect any of our current product candidates to be commercially available before at least mid-2013, if at all. If we are unable to make our product candidates commercially available, we will not generate product revenues, and we will not be successful.

We will need substantial additional capital in the future. If additional capital is not available, we will have to delay, reduce or cease operations.

We will need to raise additional capital to fund our operations, to develop our product candidates and to develop our manufacturing capabilities. Our future capital requirements will be substantial and will depend on many factors including:

- our response to the CRL and interactions with the FDA regarding the issues raised therein;
- the cost and outcomes of other regulatory proceedings, such as the EMA review of the MAA for ADASUVE;
- the scope, rate of progress, results and costs of our preclinical studies, clinical trials and other research and development activities, and our manufacturing development and commercial manufacturing activities;

- the cost and timing of developing manufacturing capacity;
- the cost and timing of developing sales and marketing capabilities prior to receipt of any regulatory approval of our product candidates;
- revenues received from any existing or future products;
- payments received under our collaboration with Cypress and Grupo Ferrer and any future strategic partnerships;
- the availability of authorized shares of our common stock to issue to potential investors;
- the filing, prosecution and enforcement of patent claims; and
- the costs associated with commercializing our product candidates, if they receive regulatory approval.

We believe that with current cash, cash equivalents, marketable securities and restricted cash and our current expected cash usage, we have sufficient capital resources to meet our anticipated cash needs, at our current cost levels, into the second quarter of 2013. In February 2012, we reduced our workforce by 29 employees or 38% of our workforce in an effort to preserve cash balances. Changing circumstances may cause us to consume capital significantly faster or slower than we currently anticipate, or to alter our operations. We have based these estimates on assumptions that may prove to be wrong, and we could exhaust our available financial resources sooner than we currently expect. The key assumptions underlying these estimates include:

- expenditures related to continued preclinical and clinical development of our product candidates during this period within budgeted levels;
- no unexpected costs related to the development of our manufacturing capability;
- no unexpected costs related to our response to the CRL and interactions with the FDA regarding the issues raised therein;
- no unexpected costs related to the EMA review of our ADASUVE MAA; and
- no unbudgeted growth in the number of our employees during this period.

We may never be able to generate a sufficient amount of product revenue to cover our expenses. Until we do, we expect to finance our future cash needs through public or private equity offerings, debt financings, strategic partnerships or licensing arrangements. Any financing transaction may contain unfavorable terms. For example, the terms of certain warrants we have issued in previous financings could require us to pay warrant holders a significant portion of the proceeds in a change of control transaction, potentially materially reducing the proceeds available to holders of our common stock. If we raise additional funds by issuing equity securities, such as our February 2012 public stock offering or draw downs under the Purchase Agreement with Azimuth, our stockholders' equity will be diluted and debt financing, if available, may involve restrictive covenants. If we raise additional funds through strategic partnerships, we may be required to relinquish rights to our product candidates or technologies, or to grant licenses on terms that are not favorable to us. Complying with the terms of the foregoing rights and restrictions may make it more difficult to complete certain types of transactions and result in delays to our fundraising efforts.

The process for obtaining approval of an NDA is time consuming, subject to unanticipated delays and costs, and requires the commitment of substantial resources. We received a second CRL for our ADASUVE NDA in May 2012.

In May 2012, we received a second CRL from the FDA regarding our ADASUVE NDA. A CRL is issued by the FDA indicating that the NDA review cycle is complete and the application is not ready for approval in its present form. In the May 2012 CRL, the FDA noted, "During a recent inspection of the Mountain View, CA manufacturing facility for this application, our field investigator conveyed deficiencies to the representative of the facility. Satisfactory resolution of these deficiencies is required before this application may be approved." With respect to the ADASUVE REMS, the CRL stated that discussions can continue on the proposed REMS after the response to the action letter has been submitted. The CRL also contained FDA comments on draft product labeling. We may be unsuccessful in resolving these issues and we may never receive marketing approval for ADASUVE or any of our other product candidates.

The FDA will conduct an in-depth review of our June 2012 resubmission of the NDA for ADASUVE to determine whether to approve ADASUVE for commercial marketing for the indications we have proposed. If the FDA is not satisfied with the information we provide, the FDA may refuse to approve our NDA or may require us to perform additional studies or provide other information in order to secure approval. The FDA may delay, limit or refuse to approve the NDA we plan to resubmit if we do not sufficiently address the issues raised in the CRL.

If the FDA determines that the clinical trials submitted for a product candidate in support of an NDA are not conducted in full compliance with the applicable protocols for these studies, as well as with applicable regulations and standards, or if the FDA does not agree with a company's interpretation of the results of such studies, the FDA may reject the data that resulted from such studies. The rejection of data from clinical trials required to support an NDA could negatively impact a company's ability to obtain marketing authorization for a product candidate and would have a material adverse effect on a company's business and financial condition.

In addition, an NDA may not be approved, or approval may be delayed, as a result of changes in FDA policies for drug approval during the review period. For example, although many products have been approved by the FDA in recent years under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, or FDCA, objections have been raised to the FDA's interpretation of Section 505(b)(2). If challenges to the FDA's interpretation of Section 505(b)(2) are successful, the FDA may be required to change its interpretation, which could delay or prevent the approval of an NDA. Any significant delay in the review or approval of our resubmitted NDA would have a material adverse effect on our business and financial condition.

On October 26, 2011, the EMA accepted the submission of our ADASUVE MAA for an opinion regarding the potential approval of ADASUVE prior to potential grant of marketing authorization by the European Commission. In March 2012, we received the Day 120 List of Questions regarding our ADASUVE MAA. The Day 120 List of Questions included major objections pertaining to the extrapolation of the Phase 3 study population to the intended patient population, pulmonary safety in patients with active airways disease and recommendations to address this issue via the risk management plan and other aspects of the risk management plan. We submitted out response to the questions in the Day 120 List of Questions in July 2012. In September 2012, we received the Day 180 List of Outstanding Issues for the ADASUVE MAA. The Day 180 List of Outstanding Issues outlined major objections pertaining to the relative benefits and risks of ADASUVE for the intended patient population and the feasibility of limiting the number of doses of ADASUVE administered once in a twenty-four hour period and the associated pulmonary safety risks of additional doses. Any significant delay in the review of approval of our application for marketing authorization following response to these questions may harm the chances for approval of our MAA, and would have a material adverse effect on our business and financial condition.

Unstable market conditions may have serious adverse consequences on our business.

The recent economic downturn and market instability has made the business climate more volatile and more costly. Our general business strategy may be adversely affected by unpredictable and unstable market conditions. If the current equity and credit markets deteriorate further, or do not improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. While we believe that with current cash, cash equivalents, marketable securities, restricted cash and our current expected cash usage, we have sufficient capital resources to meet our anticipated cash needs, at our current cost levels, into the second quarter of 2013, we may obtain additional financing on less than attractive rates or on terms that are extremely dilutive to existing stockholders, such as our February 2012 underwritten public offering. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our business, financial condition and stock price and could require us to delay or abandon clinical development plans or alter our operations. There is a risk that one or more of our current component manufacturers and partners may encounter difficulties during challenging economic times, which would directly affect our ability to attain our operating goals on schedule and on budget.

Unless our preclinical studies demonstrate the safety of our product candidates, we will not be able to commercialize our product candidates.

To obtain regulatory approval to market and sell any of our product candidates, we must satisfy the FDA and other regulatory authorities abroad, through extensive preclinical studies, that our product candidates are safe. Our *Staccato* system creates condensation aerosol from drug compounds, and there currently are no approved products that use a similar method of drug delivery. Companies developing other inhalation products have not defined or successfully completed the types of preclinical studies we believe will be required for submission to regulatory authorities as we seek approval to conduct our clinical trials. We may not have conducted or may not conduct in the future the types of preclinical testing ultimately required by regulatory authorities, or future preclinical tests may indicate that our product candidates are not safe for use in humans. Preclinical testing is expensive, can take many years and have an uncertain outcome. In addition, success in initial preclinical testing does not ensure that later preclinical testing will be successful.

We may experience numerous unforeseen events during, or as a result of, the preclinical testing process, which could delay or prevent our ability to develop or commercialize our product candidates, including:

- our preclinical testing may produce inconclusive or negative safety results, which may require us to conduct additional preclinical testing or to abandon product candidates that we believed to be promising;
- our product candidates may have unfavorable pharmacology, toxicology or carcinogenicity; and
- our product candidates may cause undesirable side effects.

Any such events would increase our costs and could delay or prevent our ability to commercialize our product candidates, which could adversely impact our business, financial condition and results of operations.

Failure or delay in commencing or completing clinical trials for our product candidates could harm our business.

We have not completed all the clinical trials necessary to support an application with the FDA or other regulatory authorities abroad for approval to market any of our product candidates other than what we believe to be adequate clinical trials to support the marketing approval for ADASUVE in the United States. Future clinical trials may be delayed or terminated as a result of many factors, including:

- insufficient financial resources to fund such trials;

- delays or failure in reaching agreement on acceptable clinical trial contracts or clinical trial protocols with prospective sites;
- regulators or institutional review boards may not authorize us to commence a clinical trial;
- regulators or institutional review boards may suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or concerns about patient safety;
- we may suspend or terminate our clinical trials if we believe that they expose the participating patients to unacceptable health risks;
- we may experience slower than expected patient enrollment or lack of a sufficient number of patients that meet the enrollment criteria for our clinical trials;
- patients may not complete clinical trials due to safety issues, side effects, dissatisfaction with the product candidate, or other reasons;
- we may have difficulty in maintaining contact with patients after treatment, preventing us from collecting the data required by our study protocol;
- product candidates may demonstrate a lack of efficacy during clinical trials;
- we may experience governmental or regulatory delays, failure to obtain regulatory approval or changes in regulatory requirements, policy and guidelines; and
- we may experience delays in our ability to manufacture clinical trial materials in a timely manner as a result of ongoing process and design enhancements to our *Staccato* system.

Any delay in commencing or completing clinical trials for our product candidates would delay commercialization of our product candidates and harm our business, financial condition and results of operations. It is possible that none of our product candidates will successfully complete clinical trials or receive regulatory approval, which would severely harm our business, financial condition and results of operations.

If our product candidates do not meet safety and efficacy endpoints in clinical trials, they will not receive regulatory approval, and we will be unable to market them.

We have not yet received regulatory approval from the FDA or any foreign regulatory authority to market any of our product candidates. The clinical development and regulatory approval process is extremely expensive and takes many years. The timing of any approval cannot be accurately predicted. If we fail to obtain regulatory approval for our product candidates, we will be unable to market and sell them and therefore we may never be profitable. In May 2012, the FDA issued a second CRL regarding our NDA for ADASUVE. In the May 2012 CRL, the FDA noted, “During a recent inspection of the Mountain View, CA manufacturing facility for this application, our field investigator conveyed deficiencies to the representative of the facility. Satisfactory resolution of these deficiencies is required before this application may be approved.” With respect to the ADASUVE REMS, the CRL stated that discussions can continue on the proposed REMS after the response to the action letter has been submitted. The CRL also contained FDA comments on draft product labeling. We may be unsuccessful in resolving these issues and we may never receive marketing approval for ADASUVE or any of our other product candidates.

In March 2012, we received the Day 120 List of Questions regarding our ADASUVE MAA. The Day 120 List of Questions included major objections pertaining to the extrapolation of the Phase 3 study population to the intended patient population, pulmonary safety in patients with active airways disease and recommendations to address this issue via the risk management plan and other aspects of the risk management plan. In July 2012, we submitted our responses to the Day 120 List of Questions. In September 2012, we received the Day 180 List of Outstanding Issues for the ADASUVE MAA. The Day 180 List of Outstanding Issues outlined major objections pertaining to the relative benefits and risks of ADASUVE for the intended patient population and the feasibility of limiting the number of doses of ADASUVE administered once in a twenty-four hour period and the associated pulmonary safety risks of additional doses We may never receive marketing approval for ADASUVE or any of our other product candidates as a result of the issues raised in the Day 180 List of Outstanding Issues.

As part of the regulatory process, we must conduct clinical trials for each product candidate to demonstrate safety and efficacy to the satisfaction of the FDA and other regulatory authorities abroad. The number and design of clinical trials that will be required varies depending on the product candidate, the condition being evaluated, the trial results and regulations applicable to any particular product candidate. In June 2008, we announced that our Phase 2a proof-of-concept clinical trial of AZ-002 (*Staccato* alprazolam) did not meet either of its two primary endpoints. In September 2009, we announced that our Phase 2b clinical trial of AZ-104 (*Staccato* loxapine, low-dose) for the treatment of migraine did not meet its primary endpoint.

Prior clinical trial program designs and results are not necessarily predictive of future clinical trial designs or results. Initial results may not be confirmed upon full analysis of the detailed results of a trial. Product candidates in later stage clinical trials may fail to show the desired safety and efficacy despite having progressed through initial clinical trials with acceptable endpoints.

If our product candidates fail to show a clinically significant benefit compared to placebo, they will not be approved for marketing.

The design of our clinical trials is based on many assumptions about the expected effect of our product candidates, and if those assumptions prove incorrect, the clinical trials may not produce statistically significant results. Our *Staccato* system is not similar to other approved drug delivery methods, and there is no precedent for the application of detailed regulatory requirements to our product candidates. We cannot assure you that the design of, or data collected from, the clinical trials of our product candidates will be sufficient to support the FDA and foreign regulatory approvals.

Regulatory authorities may not approve our product candidates even if they meet safety and efficacy endpoints in clinical trials.

The FDA and other foreign regulatory agencies, such as the EMA, can delay, limit or deny marketing approval for many reasons, including:

- a product candidate may not be considered safe or effective;
- the manufacturing processes or facilities we have selected may not meet the applicable requirements; and
- changes in their approval policies or adoption of new regulations may require additional work on our part.

Part of the regulatory approval process includes compliance inspections of manufacturing facilities to ensure adherence to applicable regulations and guidelines. The regulatory agency may delay, limit or deny marketing approval of our other product candidates as a result of such inspections. In the fourth quarter of 2011, the FDA completed its second pre-approval inspection, or PAI, of our facility in Mountain View, California. In the May 2012 CRL, the FDA noted, “During a recent inspection of the Mountain View, CA manufacturing facility for this application, our field investigator conveyed deficiencies to the representative of the facility. Satisfactory resolution of these deficiencies is required before this application may be approved.” We may be unable to address these deficiencies and we may never receive marketing approval for ADASUVE or any of our other product candidates.

Any delay in, or failure to receive or maintain, approval for any of our product candidates could prevent us from ever generating meaningful revenues or achieving profitability. The Day 120 List of Questions that we received from the CHMP in March 2012 outlined major objections pertaining to the extrapolation of the Phase 3 study population to the intended patient population, pulmonary safety in patients with active airways disease and recommendations to address this issue via the risk management plan and other aspects of the risk management plan. In July 2012, we submitted our responses to the Day 120 List of Questions. In September 2012, we received the Day 180 List of Outstanding Issues for the ADASUVE MAA. The Day 180 List of Outstanding Issues outlined major objections pertaining to the relative benefits and risks of ADASUVE for the intended patient population and the feasibility of limiting the number of doses of ADASUVE administered once in a twenty-four hour period and the associated pulmonary safety risks of additional doses. We may never receive marketing approval for ADASUVE or any of our other product candidates as a result of the issues raised in the Day 180 List of Outstanding Issues.

Our product candidates may not be approved even if they achieve their endpoints in clinical trials. Regulatory agencies, including the FDA, or their advisors may disagree with our trial design and our interpretations of data from preclinical studies and clinical trials. Regulatory agencies may change requirements for approval even after a clinical trial design has been approved. For example, ADASUVE and our other product candidates combine drug and device components in a manner that the FDA considers to meet the definition of a combination product under FDA regulations. The FDA exercises significant discretion over the regulation of combination products, including the discretion to require separate marketing applications for the drug and device components in a combination product. To date, our products are being regulated as drug products under the new drug application process administered by the FDA. The FDA could in the future require additional regulation of our products under the medical device provisions of the FDCA. Our systems are designed to comply with Quality Systems Regulation, or QSR, which sets forth the FDA’s current good manufacturing practice requirements for medical devices, and other applicable government regulations and corresponding foreign standards. If we fail to comply with these regulations, it could have a material adverse effect on our business and financial condition.

Regulatory agencies also may approve a product candidate for fewer or more limited indications than requested or may grant approval subject to the performance of post-marketing studies. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates.

Our product candidates will remain subject to ongoing regulatory review even if they receive marketing approval in the United States or in other countries. If we fail to comply with continuing regulations, we could lose these approvals, and the sale of any future products could be suspended. If approval is denied or limited in a country, or if a country imposes post-marketing requirements, that decision could affect our ability to market ADASUVE in such countries.

Even if we receive regulatory approval to market a particular product candidate, the FDA or a foreign regulatory authority could condition approval on conducting additional costly post-approval studies or trials or could limit the scope of our approved labeling or could impose burdensome post-approval obligations, such as those required under a REMS. Moreover, the product may later cause adverse effects that limit or prevent its widespread use, force us to withdraw it from the market, cause the FDA or a foreign regulatory authority to impose additional obligations or restrictions on marketing, or impede or delay our ability to obtain regulatory approvals in additional countries. In addition, we will continue to be subject to FDA and foreign regulatory authority review and periodic inspections to ensure adherence to applicable regulations. After receiving marketing approval, the FDA and foreign regulatory authorities could impose extensive regulatory requirements on the manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, distribution and record keeping related to the product.

We have filed an MAA with the EMA for ADASUVE for the rapid control of agitation in adult patients with schizophrenia or bipolar disorder and plan to seek approval to market ADASUVE in other countries. In March 2012, we received the Day 120 List of Questions that outlined major objections to our ADASUVE MAA. In July 2012, we submitted our responses to the Day 120 List of Questions. In September 2012, we received the Day 180 List of Outstanding Issues for the ADASUVE MAA. The Day 180 List of Outstanding Issues outlined major objections pertaining to the relative benefits and risks of ADASUVE for the intended patient population and the feasibility of limiting the number of doses of ADASUVE administered once in a twenty-four hour period and the associated pulmonary safety risks of additional doses. Because of these and any other major objections that may be raised during the review procedure, we may not receive marketing authorization from the European Commission and would be unable to commercialize ADASUVE in the European Union. Alternatively, any marketing authorizations may be subject to conditions for approval or post-approval obligations. Such conditions or obligations may be costly and time consuming to fulfill and may affect our operations. For example, additional clinical data may be required to confirm the safety or efficacy profile of ADASUVE in the target patient population. In addition, marketing authorizations are subject to periodic reviews, which, if negative, could affect our ability to commercialize ADASUVE in the European Union.

If we fail to comply with the regulatory requirements of the FDA and other applicable U.S. and foreign regulatory authorities, including the EMA, or previously unknown problems with any future products, suppliers or manufacturing processes are discovered, we could be subject to administrative or judicially imposed sanctions, including:

- restrictions on the products, suppliers or manufacturing processes;
- warning letters or untitled letters;
- injunctions, consent decrees, or the imposition of civil or criminal penalties against us;
- fines against us;
- product seizures, detentions or import or export bans;
- voluntary or mandatory product recalls and publicity requirements;
- suspension or withdrawal of regulatory approvals;
- suspension or termination of any clinical trials of the products;
- total or partial suspension of production;
- our partner, Grupo Ferrer, could terminate our arrangement to commercialize ADASUVE in the Ferrer Territories, which would delay the development and may increase the cost of developing and commercializing ADASUVE;
- refusal to approve pending applications for marketing approval of new drugs or supplements to approved applications; and
- denial of permission to file an application or supplement in a jurisdiction.

A REMS may impose regulatory burdens on our products or on healthcare providers that may make the marketing or use of our products commercially unattractive or impractical.

We expect that the FDA will impose a REMS on ADASUVE, and may impose a REMS on any other product candidates we may develop, as a condition of approval, or any time after approval if the FDA becomes aware of new safety information and determines that a REMS is necessary to ensure that the benefits of the drug outweigh the risks of the drug. A REMS may include various elements, such as distribution of a medication guide or a patient package insert; implementation of a communication plan to educate healthcare providers of the drug's risks; imposition of limitations on who may prescribe or dispense the drug, including training and certification requirements; or other measures that the FDA deems necessary to assure the safe use of the drug. The FDA has a wide degree of discretion in deciding which elements are necessary, and it may impose elements that significantly burden our ability to market the product, or that burden healthcare providers to the extent that use of the product is severely curtailed.

For ADASUVE, the FDA recommended that the REMS contain measures to ensure that the product is only available in certified healthcare facilities that have ready access to albuterol and immediate access to advanced airway management capabilities. We may never reach agreement on terms that will both satisfy the FDA and permit marketing and use of ADASUVE in a commercially feasible manner. Even if we do reach agreement with the FDA about elements in a REMS for ADASUVE that permit commercially viable marketing, in the future the FDA could impose additional REMS elements that substantially burden or even eliminate that viability.

If we do not produce our commercial devices cost effectively, we will never be profitable.

Our *Staccato* system based product candidates contain electronic and other components in addition to the active pharmaceutical ingredients. As a result of the cost of developing and producing these components, the cost to produce our product candidates, and any approved products, will likely be higher per dose than the cost to produce intravenous or oral tablet products. This increased cost of goods may prevent us from ever selling any products at a profit. In October 2011, we committed to sell ADASUVE to Grupo Ferrer for a fixed transfer price. If we are unable to manufacture ADASUVE at a price lower than the fixed transfer price, we will incur losses on sales to Grupo Ferrer. Our future manufacturing costs per unit will be dependent on future demand of ADASUVE. If we do not generate sufficient demand, our manufacturing costs will exceed the Grupo Ferrer fixed transfer price. The development and production of our technology entail a number of technical challenges, including achieving adequate dependability, that may be expensive or time consuming to solve. Any delay in or failure to develop and manufacture any future products in a cost effective way could prevent us from generating any meaningful revenues and prevent us from becoming profitable.

We rely on third parties to conduct our preclinical studies and our clinical trials. If these third parties do not perform as contractually required or expected, we may not be able to obtain regulatory approval for our product candidates, or we may be delayed in doing so.

We do not have the ability to conduct preclinical studies or clinical trials independently for our product candidates. We must rely on third parties, such as contract research organizations, medical institutions, academic institutions, clinical investigators and contract laboratories, to conduct our preclinical studies and clinical trials. We are responsible for confirming that our preclinical studies are conducted in accordance with applicable regulations and that each of our clinical trials is conducted in accordance with its general investigational plan and protocol. The FDA requires us to comply with regulations and standards, commonly referred to as good laboratory practices for conducting and recording the results of our preclinical studies and good clinical practices for conducting, monitoring, recording and reporting the results of clinical trials, to assure that data and reported results are accurate and that the clinical trial participants are adequately protected. Our reliance on third parties does not relieve us of these responsibilities. If the third parties conducting our clinical trials do not perform their contractual duties or obligations, do not meet expected deadlines, fail to comply with the FDA's good clinical practice regulations, do not adhere to our clinical trial protocols or otherwise fail to generate reliable clinical data, we may need to enter into new arrangements with alternative third parties and our clinical trials may be extended, delayed or terminated or may need to be repeated, and we may not be able to obtain regulatory approval for or commercialize the product candidate being tested in such trials.

Problems with the third parties that manufacture the active pharmaceutical ingredients in our product candidates may delay our clinical trials or subject us to liability.

We do not currently own or operate manufacturing facilities for clinical or commercial production of the active pharmaceutical ingredient, or API, used in any of our product candidates. We have no experience in drug manufacturing, and we lack the resources and the capability to manufacture any of the APIs used in our product candidates, on either a clinical or commercial scale. As a result, we rely on third parties to supply the API used in each of our product candidates. We expect to continue to depend on third parties to supply the API for our product candidates and any additional product candidates we develop in the foreseeable future.

An API manufacturer must meet high precision and quality standards for that API to meet regulatory specifications and comply with regulatory requirements. A contract manufacturer is subject to ongoing periodic unannounced inspection by the FDA and corresponding state and foreign authorities to ensure strict compliance with current good manufacturing practice, or cGMP, and other applicable government regulations and corresponding foreign standards. Additionally, a contract manufacturer must pass a PAI by the FDA to ensure strict compliance with cGMP prior to the FDA's approval of any product candidate for marketing. A contract manufacturer's failure to conform with cGMP could result in the FDA's refusal to approve or a delay in the FDA's approval of a product candidate for marketing. We are ultimately responsible for confirming that the APIs used in our product candidates are manufactured in accordance with applicable regulations.

Our third party suppliers may not carry out their contractual obligations or meet our deadlines. In addition, the API they supply to us may not meet our specifications and quality policies and procedures. If we need to find alternative suppliers of the API used in any of our product candidates, we may not be able to contract for such supplies on acceptable terms, if at all. Any such failure to supply or delay caused by such contract manufacturers would have an adverse effect on our ability to continue clinical development of our product candidates or commercialize any future products.

If our third party drug suppliers fail to achieve and maintain high manufacturing standards in compliance with cGMP regulations, we could be subject to certain product liability claims in the event such failure to comply resulted in defective products that caused injury or harm.

If we experience problems with the manufacturers of components of our product candidates, our development programs may be delayed and we may be subject to liability.

We outsource the manufacturing of the components of our *Staccato* system, including the printed circuit boards, the plastic airways, and the chemical heat packages to be used in our commercial single dose device. We have no experience in the manufacturing of components, other than our chemical heat packages, and we currently lack the resources and the capability to manufacture them, on either a clinical or commercial scale. As a result, we rely on third parties to supply these components. We expect to continue to depend on third parties to supply these components for our current product candidates and any devices based on the *Staccato* system we develop in the foreseeable future.

The third-party suppliers of the components of our *Staccato* system must meet high precision and quality standards for our finished devices to comply with regulatory requirements. A contract manufacturer is subject to ongoing periodic unannounced inspection by the FDA and corresponding state and foreign authorities to ensure that our finished devices remain in strict compliance with the QSR, which sets forth the FDA's cGMP requirements for medical devices, and other applicable government regulations and corresponding foreign standards. We are ultimately responsible for confirming that the components used in the *Staccato* system are manufactured in accordance with specifications, standards and procedures necessary to ensure that our finished devices comply with the QSR or other applicable regulations.

Our third party suppliers may not comply with their contractual obligations or meet our deadlines, or the components they supply to us may not meet our specifications and quality policies and procedures. If we need to find alternative suppliers of the components used in the *Staccato* system, we may not be able to contract for such components on acceptable terms, if at all. Any such failure to supply or delay caused by such contract manufacturers would have an adverse effect on our ability to continue clinical development of our product candidates or commercialize any future products.

In addition, the heat packages used in the single dose version of our *Staccato* system are manufactured using certain energetic, or highly combustible, materials that are used to generate the rapid heating necessary for vaporizing the drug compound while avoiding degradation. Manufacture of products containing energetic materials is regulated by the U.S. government. We have entered into a manufacture agreement with Autoliv for the manufacture of the heat packages in the commercial design of our single dose version of our *Staccato* system. If Autoliv fails to manufacture the heat packages to the necessary specifications, or does not carry out its contractual obligations to supply our heat packages to us, or if the FDA requires different manufacturing or quality standards than those set forth in our manufacture agreement, our clinical trials or commercialization efforts may be delayed, suspended or terminated while we seek additional suitable manufacturers of our heat packages, which may prevent us from commercializing our product candidates that utilize the single dose version of the *Staccato* system.

If we do not establish additional strategic partnerships, we will have to undertake development and commercialization efforts on our own, which would be costly and delay our ability to commercialize any future products.

A key element of our business strategy is our intent to selectively partner with pharmaceutical, biotechnology and other companies to obtain assistance for the development and potential commercialization of our product candidates. In December 2006, we entered into such a development relationship with Allegro and in December 2007 we entered into a strategic relationship with Endo Pharmaceuticals, Inc., or Endo, for the development of AZ-003, or the Endo license agreement. In January 2009, we mutually agreed with Endo to terminate the Endo license agreement. In June 2009, we amended the terms of our option agreement with Allegro, resulting in our acquisition of Allegro and the termination of the agreement in August 2009. In February 2010, we entered into a collaboration with Biovail Laboratories International SRL, or Biovail, for the commercialization of ADASUVE in the United States and Canada. In October 2010, Biovail gave us notice that it was terminating the collaboration and the collaboration terminated in January 2011. In August 2010, we entered into a license and development agreement with Cypress for *Staccato* nicotine. In October 2011, we entered into the Ferrer Agreement with Grupo Ferrer for the commercialization of ADASUVE in the Ferrer Territories. We intend to enter into additional strategic partnerships with third parties to develop and commercialize our product candidates. Other than Cypress and Grupo Ferrer, we do not currently have any strategic partnerships for any of our product candidates. We face significant competition in seeking appropriate strategic partners, and these strategic partnerships can be intricate and time consuming to negotiate and document. We may not be able to negotiate additional strategic partnerships on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any additional strategic partnerships because of the numerous risks and uncertainties associated with establishing strategic partnerships. If we are unable to negotiate additional strategic partnerships for our product candidates we may be forced to curtail the development of a particular candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization, reduce the scope of our sales or marketing activities

or undertake development or commercialization activities at our own expense. In addition, we will bear all the risk related to the development of a product candidate. If we elect to increase our expenditures to fund development or commercialization activities on our own, we will need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we will not be able to bring our product candidates to market and generate product revenue.

If we enter into additional strategic partnerships, we may be required to relinquish important rights to and control over the development of our product candidates or otherwise be subject to terms unfavorable to us.

Our relationships with Cypress and Grupo Ferrer are, and any other strategic partnerships or collaborations with pharmaceutical or biotechnology companies we may establish will be, subject to a number of risks including:

- business combinations or significant changes in a strategic partner's business strategy may adversely affect a strategic partner's willingness or ability to complete its obligations under any arrangement;
- we may not be able to control the amount and timing of resources that our strategic partners devote to the development or commercialization of product candidates;
- strategic partners may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new version of a product candidate for clinical testing;
- strategic partners may not pursue further development and commercialization of products resulting from the strategic partnering arrangement or may elect to discontinue research and development programs;
- strategic partners may not commit adequate resources to the marketing and distribution of any future products, limiting our potential revenues from these products;
- disputes may arise between us and our strategic partners that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and consumes resources;
- strategic partners may experience financial difficulties;
- strategic partners may not properly maintain or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- strategic partners could independently move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- strategic partners could terminate the arrangement or allow it to expire, which would delay the development and may increase the cost of developing our product candidates.

If we fail to gain market acceptance among physicians, patients, third-party payors and the medical community, we will not become profitable.

The *Staccato* system is a fundamentally new method of drug delivery. Any future product based on our *Staccato* system may not gain market acceptance among physicians, patients, third-party payors and the medical community. If these products do not achieve an adequate level of acceptance, we will not generate sufficient product revenues to become profitable. The degree of market acceptance of any of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- demonstration of acceptable quality, safety and efficacy in clinical trials and meeting applicable regulatory standards for approval;
- the existence, prevalence and severity of any side effects;
- potential or perceived advantages or disadvantages compared to alternative treatments;
- offering therapeutic or other improvements over existing or future drugs used to treat the same or similar conditions;
- perceptions about the relationship or similarity between our product candidates and the parent drug compound upon which each product candidate is based;
- the timing of market entry relative to competitive treatments;
- the ability to offer any future products for sale at competitive prices;
- relative convenience, product dependability and ease of administration;
- the restrictions imposed on ADASUVE by any REMS program and labeling requirements the FDA may require;
- the strength of marketing and distribution support;
- acceptance by patients, the medical community or third-party payors, if ADASUVE is approved;

- the sufficiency of coverage and reimbursement of our product candidates by governmental and other third-party payors; and
- the product labeling, including the package insert, and the marketing restrictions required by the FDA or regulatory authorities in other countries.

Our product candidates that we may develop may require expensive carcinogenicity tests.

We combine small molecule drugs with our *Staccato* system to create proprietary product candidates. Some of these drugs may not have previously undergone carcinogenicity testing that is now generally required for marketing approval. We may be required to perform carcinogenicity testing with product candidates incorporating drugs that have not undergone carcinogenicity testing or may be required to do additional carcinogenicity testing for drugs that have undergone such testing. Any carcinogenicity testing we are required to complete will increase the costs to develop a particular product candidate and may delay or halt the development of such product candidate.

If some or all of our patents expire, are invalidated or are unenforceable, or if some or all of our patent applications do not yield issued patents or yield patents with narrow claims, competitors may develop competing products using our or similar intellectual property and our business will suffer.

Our success will depend in part on our ability to obtain and maintain patent and trade secret protection for our technologies and product candidates both in the United States and other countries. We do not know whether any patents will issue from any of our pending or future patent applications. In addition, a third party may successfully circumvent our patents. Our rights under any issued patents may not provide us with sufficient protection against competitive products or otherwise cover commercially valuable products or processes.

The degree of protection for our proprietary technologies and product candidates is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- we might not have been the first to make the inventions covered by each of our pending patent applications and issued patents;
- we might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- the claims of our issued patents may be narrower than as filed and not sufficiently broad to prevent third parties from circumventing them;
- it is possible that none of our pending patent applications will result in issued patents;
- we may not develop additional proprietary technologies or drug candidates that are patentable;
- our patent applications or patents may be subject to interference, opposition or similar administrative proceedings;
- any patents issued to us or our potential strategic partners may not provide a basis for commercially viable products or may be challenged by third parties in the course of litigation or administrative proceedings such as reexaminations or interferences; and
- the patents of others may have an adverse effect on our ability to do business.

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The United States Patent and Trademark Office is currently developing regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act will not become effective until one year or 18 months after its enactment. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Even if valid and enforceable patents cover our product candidates and technologies, the patents will provide protection only for a limited amount of time.

Our potential strategic partners' ability to obtain patents is uncertain because, to date, some legal principles remain unresolved, there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the United States, and the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific and factual issues. Furthermore, the policies governing pharmaceutical and medical device patents outside the United States may be even more uncertain. Changes in either patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

Our current patents or any future patents that may be issued regarding our product candidates or methods of using them, can be challenged by our competitors who can argue that our patents are invalid and/or unenforceable. Third parties may challenge our rights to, or the scope or validity of, our patents. Patents also may not protect our product candidates if competitors devise ways of making these or similar product candidates without legally infringing our patents. The FDCA and the FDA regulations and policies provide incentives to manufacturers to challenge patent validity or create modified, non-infringing versions of a drug or device in order to facilitate the approval of generic substitutes. These same types of incentives encourage manufacturers to submit new drug applications that rely on literature and clinical data not prepared for or by the drug sponsor.

We also rely on trade secrets to protect our technology, especially where we do not believe that patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. The employees, consultants, contractors, outside scientific collaborators and other advisors of our company and our strategic partners may unintentionally or willfully disclose our confidential information to competitors. Enforcing a claim that a third party illegally obtained and is using our trade secrets is expensive and time consuming and the outcome is unpredictable. Failure to protect or maintain trade secret protection could adversely affect our competitive business position.

Our research and development collaborators may have rights to publish data and other information in which we have rights. In addition, we sometimes engage individuals or entities to conduct research that may be relevant to our business. The ability of these individuals or entities to publish or otherwise publicly disclose data and other information generated during the course of their research is subject to certain contractual limitations. These contractual provisions may be insufficient or inadequate to protect our trade secrets and may impair our patent rights. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our technology and other confidential information, then our ability to receive patent protection or protect our proprietary information may be jeopardized.

Litigation or other proceedings or third party claims of intellectual property infringement could require us to spend time and money and could shut down some of our operations.

Our commercial success depends in part on not infringing patents and proprietary rights of third parties. Others have filed, and in the future are likely to file, patent applications covering products that are similar to our product candidates, as well as methods of making or using similar or identical products. If these patent applications result in issued patents and we wish to use the claimed technology, we would need to obtain a license from the third party. We may not be able to obtain these licenses at a reasonable cost, if at all.

In addition, administrative proceedings, such as interferences and reexaminations before the U.S. Patent and Trademark Office, could limit the scope of our patent rights. We may incur substantial costs and diversion of management and technical personnel as a result of our involvement in such proceedings. In particular, our patents and patent applications may be subject to interferences in which the priority of invention may be awarded to a third party. We do not know whether our patents and patent applications would be entitled to priority over patents or patent applications held by such a third party. Our issued patents may also be subject to reexamination proceedings. We do not know whether our patents would survive reexamination in light of new questions of patentability that may be raised following their issuance.

Third parties may assert that we are employing their proprietary technology or their proprietary products without authorization. In addition, third parties may already have or may obtain patents in the future and claim that use of our technologies or our products infringes these patents. We could incur substantial costs and diversion of management and technical personnel in defending our self against any of these claims. Furthermore, parties making claims against us may be able to obtain injunctive or other equitable relief, which could effectively block our ability to further develop, commercialize and sell any future products and could result in the award of substantial damages against us. In the event of a successful claim of infringement against us, we may be required to pay damages and obtain one or more licenses from third parties. We may not be able to obtain these licenses at a reasonable cost, if at all. In that event, we could encounter delays in product introductions while we attempt to develop alternative methods or products. In the event we cannot develop alternative methods or products, we may be effectively blocked from developing, commercializing or selling any future products. Defense of any lawsuit or failure to obtain any of these licenses would be expensive and could prevent us from commercializing any future products.

We review from time to time publicly available information concerning the technological development efforts of other companies in our industry. If we determine that these efforts violate our intellectual property or other rights, we intend to take appropriate action, which could include litigation. Any action we take could result in substantial costs and diversion of management and technical personnel in enforcing our patents or other intellectual property rights against others. Furthermore, the outcome of any action we take to protect our rights may not be resolved in our favor.

Competition in the pharmaceutical industry is intense. If our competitors are able to develop and market products that are more effective, safer or less costly than any future products that we may develop, our commercial opportunity will be reduced or eliminated.

We face competition from established as well as emerging pharmaceutical and biotechnology companies, academic institutions, government agencies and private and public research institutions. Our commercial opportunity will be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects or are less expensive than any future products that we may develop and commercialize. In addition, significant delays in the development of our product candidates could allow our competitors to bring products to market before us and impair our ability to commercialize our product candidates.

We anticipate that, if approved, ADASUVE would compete with other available antipsychotic drugs for the treatment of agitation, such as intramuscular formulations, which are approved for the treatment of agitation, and oral tablets and oral solutions, which are not approved for the treatment of agitation.

We anticipate that, if approved, AZ-002 would compete with the oral tablet form of alprazolam and possibly IV and oral forms of other benzodiazepines.

We anticipate that, if approved, AZ-007 would compete with non-benzodiazepine GABA-A receptor agonists. We are aware of more than 13 approved generic versions of zolpidem, or zaleplon, oral tablets, as well as at least one insomnia product, a version of zolpidem intended to treat middle of the night awakening, that has been approved by the FDA. Additionally, we are aware of one product in Phase 3 development for the treatment of insomnia.

We anticipate that, if approved, AZ-104 would compete with currently marketed triptan drugs and with other migraine headache treatments. In addition, we are aware of at least one new migraine product under review by the FDA, which is an inhaled formulation, and at least four new product candidates in late-phase development for the treatment of migraines.

We anticipate that, if approved, AZ-003 would compete with some of the available forms of fentanyl, including injectable fentanyl, oral transmucosal and nasal fentanyl formulations and ionophoretic transdermal delivery of fentanyl. We are also aware of two fentanyl products approved by regulatory agencies in the United States or abroad, and at least four products in Phase 3 clinical trial development for acute pain. In addition, if approved, AZ-003 would compete with various generic opioid drugs, such as oxycodone, hydrocodone and morphine, or combination products including one or more of such drugs.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Established pharmaceutical companies may invest heavily to discover quickly and develop novel compounds or drug delivery technology that could make our product candidates obsolete. Smaller or early stage companies may also prove to be significant competitors, particularly through strategic partnerships with large and established companies. In addition, these third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA approval or discovering, developing and commercializing products before we do. If we are not able to compete effectively against our current and future competitors, our business will not grow and our financial condition will suffer.

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

We do not have an internal sales organization and we have no experience in the sales and distribution of pharmaceutical products. There are risks involved with establishing our own sales capabilities and increasing our marketing capabilities, as well as entering into arrangements with third parties to perform these services. Developing an internal sales force is expensive and time consuming and could delay any product launch. On the other hand, if we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenues or the profitability of these product revenues are likely to be lower than if we market and sell any products that we develop ourselves.

We may establish our own specialty sales force and/or engage additional pharmaceutical or other healthcare companies with an existing sales and marketing organization and distribution systems to sell, market and distribute any future products. We are currently seeking partners for the development and commercialization of ADASUVE in addition to the commercial partnership we entered into with Grupo Ferrer. We also intend to seek international distribution partners in addition to Grupo Ferrer for our product candidates. We may not be able to establish a specialty sales force or establish sales and distribution relationships on acceptable terms. Factors that may inhibit our efforts to commercialize any future products without strategic partners or licensees include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe any future products;

- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

Because the establishment of sales and marketing capabilities depends on the progress towards commercialization of our product candidates and because of the numerous risks and uncertainties involved with establishing our own sales and marketing capabilities, we are unable to predict when, if ever, we will establish our own sales and marketing capabilities. If we are not able to partner with additional third parties and are unsuccessful in recruiting sales and marketing personnel or in building a sales and marketing infrastructure, we will have difficulty commercializing our product candidates, which would adversely affect our business and financial condition.

If we lose our key personnel or are unable to attract and retain additional personnel, we may be unable to develop or commercialize our product candidates.

We are highly dependent on our President and Chief Executive Officer, Thomas B. King, the loss of whose services might adversely impact the achievement of our objectives. In addition, recruiting and retaining qualified clinical, scientific and engineering personnel to manage clinical trials of our product candidates and to perform future research and development work will be critical to our success. There is currently a shortage of skilled executives in our industry, which is likely to continue. As a result, competition for skilled personnel is intense and the turnover rate can be high. Although we believe we will be successful in attracting and retaining qualified personnel, competition for experienced management and clinical, scientific and engineering personnel from numerous companies and academic and other research institutions may limit our ability to do so on acceptable terms. In addition, we do not have employment agreements with any of our employees, and they could leave our employment at will. We have change of control agreements with our executive officers and vice presidents that provide for certain benefits upon termination or a change in role or responsibility in connection with a change of control of our company. We do not maintain life insurance policies on any employees. Failure to attract and retain personnel would prevent us from developing and commercializing our product candidates.

If plaintiffs bring product liability lawsuits against us, we may incur substantial liabilities and may be required to limit commercialization of the product candidates that we may develop.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates in clinical trials and will face an even greater risk if we or any partner we have or may obtain commercializes any products. We may be held liable if any product we develop causes injury or is found otherwise unsuitable during product testing, manufacturing, marketing or sale. Regardless of merit or eventual outcome, liability claims may result in decreased demand for any product candidates that we may develop, injury to our reputation, withdrawal of clinical trials, costs to defend litigation, substantial monetary awards to clinical trial participants or patients, loss of revenue and the inability to commercialize any products that we develop. We have product liability insurance that covers our clinical trials up to a $10 million aggregate annual limit. We intend to expand product liability insurance coverage to include the sale of commercial products if we obtain marketing approval for ADASUVE or any other products that we may develop. However, this insurance may be prohibitively expensive, or may not fully cover our potential liabilities. Inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or delay the commercialization of our product candidates. If we are sued for any injury caused by any future products, our liability could exceed our total assets.

Healthcare law and policy changes, based on recently enacted legislation, may have an adverse effect on us.

Healthcare costs have risen significantly over the past decade. In March 2010, President Obama signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or, collectively, the Healthcare Reform Act. This law substantially changes the way health care is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The Healthcare Reform Act contains a number of provisions that are expected to impact our business and operations, including provisions governing enrollment in federal healthcare programs, reimbursement and discount programs and fraud and abuse prevention and control, which will impact existing government healthcare programs and will result in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program. We anticipate that if we obtain approval for our product candidates, some of our revenue and the revenue from our collaborators may be derived from U.S. government healthcare programs, including Medicare. Additionally, in 2009, the Department of Defense implemented a program pursuant to the National Defense Authorization Act for Fiscal Year 2008 that requires rebates, based on Federal statutory pricing, from manufacturers of innovator drugs and biologics. Furthermore, the Healthcare Reform Act imposes a non-deductible fee treated as an excise tax on pharmaceutical manufacturers or importers who sell “branded prescription drugs,” which includes innovator drugs and biologics (excluding generics, over-the-counter drugs, and certain orphan drugs) to U.S. government programs. We expect that the Healthcare Reform Act and other healthcare reform measures that may be adopted in the future could have an adverse effect on our industry generally and our ability to successfully commercialize our product candidates or could limit or eliminate our spending on development projects.

In addition to this legislation, there will continue to be proposals by legislators at both the federal and state levels, regulators and third-party payors to keep these costs down while expanding individual healthcare benefits. Certain of these changes could impose limitations on the prices we will be able to charge for any product candidates that are approved or the amounts of reimbursement available for these products from governmental agencies or third-party payors, or may increase the tax obligations on life sciences companies such as ours. While it is too early to predict specifically what effect the Health Reform Act and its implementation or any future legislation or policies will have on our business, we believe that healthcare reform may have an adverse effect on our business and financial condition.

Our product candidates AZ-002, AZ-003 and AZ-007 contain drug substances that are regulated by the U.S. Drug Enforcement Administration. Failure to comply with applicable regulations and requirements could harm our business.

The Controlled Substances Act imposes various registration, recordkeeping and reporting requirements, procurement and manufacturing quotas, labeling and packaging requirements, security controls and a restriction on prescription refills on certain pharmaceutical products. A principal factor in determining the particular requirements, if any, applicable to a product is its actual or potential abuse profile. The U.S. Drug Enforcement Administration, or DEA, regulates chemical compounds as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. Alprazolam, the API in AZ-002, is regulated as a Schedule IV substance, fentanyl, the API in AZ-003, is regulated as a Schedule II substance, and zaleplon, the API in AZ-007, is regulated as a Schedule IV substance. Each of these product candidates is subject to DEA regulations relating to manufacture, storage, record keeping and reporting, distribution and physician prescription procedures, and DEA regulations may impact the amount of the scheduled substance that would be available for clinical trials and commercial distribution. As a Schedule II substance, fentanyl is subject to more stringent controls, including quotas on the amount of product that can be manufactured as well as a prohibition on the refilling of prescriptions without a new prescription from the physician. The DEA periodically inspects facilities for compliance with its rules and regulations. Failure to comply with current and future regulations of the DEA could lead to a variety of sanctions, including revocation, or denial of renewal, of DEA registrations, injunctions, or civil or criminal penalties and could harm our business, financial condition and results of operations.

The single dose version of our Staccato system contains materials that are regulated by the U.S. government, and failure to comply with applicable regulations could harm our business.

The single dose version of our *Staccato* system uses energetic materials to generate the rapid heating necessary for vaporizing the drug, while avoiding degradation. Manufacture of products containing energetic materials is controlled by the U.S. Bureau of Alcohol, Tobacco, Firearms and Explosives, or ATF. Technically, the energetic materials used in our *Staccato* system are classified as “low explosives,” and the ATF has granted us a license/permit for the manufacture of such low explosives. Additionally, due to inclusion of the energetic materials in our *Staccato* system, the U.S. Department of Transportation, or DOT, might regulate shipments of the single dose version of our *Staccato* system. However, the DOT has granted the single dose version of our *Staccato* system “Not Regulated as an Explosive” status. Failure to comply with the current and future regulations of the ATF or DOT could subject us to future liabilities and could harm our business, financial condition and results of operations. Furthermore, these regulations could restrict our ability to expand our facilities or construct new facilities or could require us to incur other significant expenses in order to maintain compliance.

We use hazardous chemicals and highly combustible materials in our business. Any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly.

Our research and development processes involve the controlled use of hazardous materials, including chemicals. We also use energetic materials in the manufacture of the chemical heat packages that are used in our single dose devices. Our operations produce hazardous waste. We cannot eliminate the risk of accidental contamination or discharge or injury from these materials. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of these materials. We could be subject to civil damages in the event of an improper or unauthorized release of, or exposure of individuals to, hazardous materials. In addition, claimants may sue us for injury or contamination that results from our use of these materials and our liability may exceed our total assets. Compliance with environmental and other laws and regulations may be expensive, and current or future regulations may impair our research, development or production efforts.

Certain of our suppliers are working with these types of hazardous and energetic materials in connection with our component manufacturing agreements. In the event of a lawsuit or investigation, we could be held responsible for any injury caused to persons or property by exposure to, or release of, these hazardous and energetic materials. Further, under certain circumstances, we have agreed to indemnify our suppliers against damages and other liabilities arising out of development activities or products produced in connection with these agreements.

We will need to implement additional finance and accounting systems, procedures and controls in the future as we grow and to satisfy new reporting requirements.

The laws and regulations affecting public companies, including the current provisions of the Sarbanes-Oxley Act of 2002, or Sarbanes-Oxley, and rules enacted and proposed by the SEC and by The NASDAQ Global Market, will result in increased costs to us as we continue to undertake efforts to comply with rules and respond to the requirements applicable to public companies. The rules make it more difficult and costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage as compared to the polices previously available to public companies. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or our board committees or as executive officers.

As a public company, we need to comply with Sarbanes-Oxley and the related rules and regulations of the SEC, including expanded disclosure, accelerated reporting requirements and more complex accounting rules. Compliance with Section 404 of Sarbanes-Oxley and other requirements will continue to increase our costs and require additional management resources. We will need to continue to implement additional finance and accounting systems, procedures and controls as we grow to satisfy new reporting requirements. We currently do not have an internal audit group. In addition, we may need to hire additional legal and accounting staff with appropriate experience and technical knowledge, and we cannot assure you that if additional staffing is necessary that we will be able to do so in a timely fashion.

Our business is subject to increasingly complex corporate governance, public disclosure and accounting requirements that could adversely affect our business and financial results.

We are subject to changing rules and regulations of federal and state government as well as the stock exchange on which our common stock is listed. These entities, including the Public Company Accounting Oversight Board, the SEC and The NASDAQ Global Market, have issued a significant number of new and increasingly complex requirements and regulations over the course of the last several years and continue to develop additional regulations and requirements in response to laws enacted by Congress. On July 21, 2010, the Dodd-Frank Wall Street Reform and Protection Act, or the Dodd-Frank Act, was enacted. The Dodd-Frank Act contains significant corporate governance and executive compensation-related provisions, some of which the Securities and Exchange Commission, or SEC, has implemented by adopting additional rules and regulations in areas such as the compensation of executives, referred to as “say-on-pay”. We cannot assure you that we are or will be in compliance with all potentially applicable regulations. If we fail to comply with the Sarbanes Oxley Act of 2002, the Dodd-Frank Act and associated SEC rules, or any other regulations, we could be subject to a range of consequences, including restrictions on our ability to sell equity securities or otherwise raise capital funds, the de-listing of our common stock from The NASDAQ Global Market, suspension or termination of our clinical trials, failure to obtain approval to market ADASUVE, restrictions on future products or our manufacturing processes, significant fines, or other sanctions or litigation. Our efforts to comply with these requirements have resulted in, and are likely to continue to result in, an increase in expenses and a diversion of management’s time from other business activities.

Our workforce reduction in February 2012 and any future workforce and expense reductions may have an adverse impact on our internal programs and may divert management attention.

In February 2012, we conducted a strategic reduction in our workforce of approximately 38% of our employees in order to preserve our capital resources and to manage our operating expenses. This and any other additional reductions in our workforce may limit our ability to complete all of our corporate objectives. We may be required to implement further workforce and expense reductions in the future. Further workforce and expense reductions could result in reduced progress on our internal programs. In addition, employees, whether or not directly affected by a reduction, may seek future employment with our business partners or our competitors. Although our employees are required to sign a confidentiality agreement at the time of hire, the confidential nature of certain proprietary information may not be maintained in the course of any such future employment. In addition, the implementation of expense reduction programs may result in the diversion of efforts of our executive management team and other key employees, which could adversely affect our business. In addition, the workforce reduction may make retaining and motivating the remaining workforce more difficult, causing us to lose the services of employees that we rely upon.

We could be adversely affected by violations of applicable anti-corruption laws such as the U.S. Foreign Corrupt Practices Act and the U.K. Bribery Act of 2010.

Anti-corruption laws, such as the U.S. Foreign Corrupt Practices Act and the U.K. Bribery Act of 2010, generally prohibit directly or indirectly giving, offering, or promising anything of value to improperly induce the recipient to act, or refrain from acting, in a manner that would confer a commercial advantage. The anti-bribery provisions of the U.S. Foreign Corrupt Practices Act generally prohibit directly or indirectly giving, offering or promising an inducement to a public official (broadly interpreted) to corruptly influence the official’s actions in order to obtain a commercial advantage. The U.K. Bribery Act of 2010 prohibits both domestic and international bribery, as well as bribery in both the private and public sectors. In addition, an organization that “fails to prevent bribery” by anyone associated with the organization may be charged under the U.K. Bribery Act unless the organization can establish the defense of having implemented “adequate procedures” to prevent bribery. If we receive approval to market ADASUVE,

we plan to adopt and implement policies and procedures to ensure that those involved in the marketing, sale, and distribution of our products are both aware of these legal requirements and committed to complying therewith. However, we cannot assure that these policies and procedures will protect us from potentially illegal acts committed by individual employees or agents. If we were found to be liable for anti-bribery law violations, we could be subject to criminal or civil penalties or other sanctions that could have a material adverse effect on our business and financial condition.

If ADASUVE is approved for marketing, we will be subject to significant ongoing regulatory obligations and oversight, which may result in significant additional expense and limit our ability to commercialize our products.

If ADASUVE or any of our other product candidates are approved for marketing, we will be subject to significant ongoing regulatory obligations, such as safety reporting requirements, periodic and annual reporting requirements, and additional post-marketing obligations, including regulatory oversight of the promotion and marketing of our products. In addition, the manufacture, labeling, packaging, distribution, import, export, adverse event reporting, storage, advertising, promotion and recordkeeping for any of our product candidates that may be approved by the FDA or foreign regulatory authorities will be subject to extensive and ongoing regulatory requirements. If we receive regulatory approvals to sell our products, the FDA and foreign regulatory authorities may impose significant restrictions on the indicated uses or marketing of our products, or impose requirements for burdensome post-approval study commitments. The terms of any product approval, including labeling, may be more restrictive than we desire and could affect the commercial potential of the product. If we become aware of previously unknown problems with any of our products in the United States or overseas or at our contract manufacturers' facilities, a regulatory agency may impose labeling changes or restrictions on our products, our strategic collaborators, our manufacturers or on us. In such an instance, we could experience a significant drop in the sales of the affected products, our product revenues and reputation in the marketplace may suffer, and we could become the target of lawsuits.

The FDA and other governmental authorities also actively enforce regulations prohibiting off-label promotion, and the government has levied large civil and criminal fines against companies for alleged improper promotion. The government has also required companies to enter into complex corporate integrity agreements and/or non-prosecution agreements that impose significant reporting and other burdens on the affected companies.

If we are approved for marketing, we will also be subject to regulation by regional, national, state and local agencies, including the DEA, the Department of Justice, the Federal Trade Commission, the Office of Inspector General of the U.S. Department of Health and Human Services and other regulatory bodies, as well as governmental authorities in those foreign countries in which we may in the future commercialize our products. The FDCA, the Public Health Service Act, the Social Security Act, and other federal and state statutes and regulations govern to varying degrees the research, development, manufacturing and commercial activities relating to prescription pharmaceutical products, including preclinical testing, approval, production, labeling, sale, distribution, import, export, post-market surveillance, advertising, dissemination of information, promotion, marketing, and pricing to government purchasers and government healthcare programs. Any manufacturing, licensing, or commercialization partners we have or may in the future have, including Grupo Ferrer, will be subject to many of the same requirements.

The Federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical companies on one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common manufacturer business arrangements and activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Many pharmaceutical and other healthcare companies have been investigated and have reached substantial financial settlements with the federal government under these laws for a variety of alleged marketing activities, including providing free product to customers with the expectation that the customers would bill federal programs for the product; providing consulting fees, grants, free travel, and other benefits to physicians to induce them to prescribe the company's products; and inflating prices reported to private price publication services, which are used to set drug payment rates under government healthcare programs. We intend to comply with the exemptions and safe harbors whenever possible, but our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability.

The Federal False Claims Act prohibits any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Although we will not directly file claims, companies have been prosecuted for causing false claims to be submitted because of the marketing of their products for unapproved, and thus non-reimbursable, uses. Pharmaceutical and other healthcare companies have also been prosecuted on other legal theories of Medicare and Medicaid fraud.

The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Several states now require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and to report gifts and payments to individual physicians in the states. Other states prohibit providing meals to prescribers or other marketing-related activities. In addition, California, Connecticut, Nevada, and Massachusetts require pharmaceutical companies to implement compliance programs or marketing codes. Currently, several additional states are considering similar proposals.

Compliance with various federal and state laws is difficult and time consuming, and companies that violate them may face substantial penalties. The potential sanctions include civil monetary penalties, exclusion of a company's products from reimbursement under government programs, criminal fines and imprisonment. Because of the breadth of these laws and the lack of extensive legal guidance in the form of regulations or court decisions, it is possible that some of our business activities could be subject to challenge under one or more of these laws if any of our product candidates are approved for marketing. Such a challenge could have a material adverse effect on our business and financial condition.

The number and complexity of both federal and state laws continues to increase, and additional governmental resources are being added to enforce these laws and to prosecute companies and individuals who are believed to be violating them. In particular, the Federal Anti-Kickback Statute and the Federal False Claims Act include a number of provisions aimed at strengthening the government's ability to pursue anti-kickback and false claims cases against pharmaceutical manufacturers and other healthcare entities, including substantially increased funding for healthcare fraud enforcement activities, enhanced investigative powers, amendments to the False Claims Act that make it easier for the government and whistleblowers to pursue cases for alleged kickback and false claim violations. While it is too early to predict what effect these changes will have on our business, we anticipate that government scrutiny of pharmaceutical sales and marketing practices will continue for the foreseeable future and subject us to the risk of government investigations and enforcement actions if any of our product candidates are approved for marketing. Responding to a government investigation or enforcement action would be expensive and time-consuming, and could have a material adverse effect on our business and financial condition. If we or any of our partners fail to comply with applicable federal, state, local, or foreign regulatory requirements, we or they could be subject to a range of regulatory actions that could affect our or our partners' ability to commercialize our products if any of our product candidates are approved for marketing and could harm or prevent sales of the affected products, or could substantially increase the costs and expenses of commercializing and marketing our products if any of our product candidates are approved for marketing. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business.

Our facility is located near known earthquake fault zones, and the occurrence of an earthquake or other catastrophic disaster could damage our facility and equipment, which could cause us to curtail or cease operations.

Our facility is located in the San Francisco Bay Area near known earthquake fault zones and, therefore, is vulnerable to damage from earthquakes. We are also vulnerable to damage from other types of disasters, such as power loss, fire, floods and similar events. If any disaster were to occur, our ability to operate our business could be seriously impaired. We currently may not have adequate insurance to cover our losses resulting from disasters or other similar significant business interruptions, and we do not plan to purchase additional insurance to cover such losses due to the cost of obtaining such coverage. Any significant losses that are not recoverable under our insurance policies could seriously impair our business, financial condition and results of operations.

Risks Relating to Owning Our Common Stock

Our stock price has been and may continue to be extremely volatile.

Our common stock price has experienced large fluctuations. In addition, the trading prices of life science and biotechnology company stocks in general have experienced extreme price fluctuations in recent years. The valuations of many life science companies without consistent product revenues and earnings are extraordinarily high based on conventional valuation standards, such as price to revenue ratios. These trading prices and valuations may not be sustained. Any negative change in the public's perception of the prospects of life science or biotechnology companies could depress our stock price regardless of our results of operations. Other broad market and industry factors may decrease the trading price of our common stock, regardless of our performance. Market fluctuations, as well as general political and economic conditions such as terrorism, military conflict, recession or interest rate or currency rate fluctuations, also may decrease the trading price of our common stock. In addition, our stock price could be subject to wide fluctuations in response to various factors, including:

- actual or anticipated regulatory approvals or non-approvals of our product candidates or competing products;
- actual or anticipated cash depletion of our financial resources;
- actual or anticipated results and timing of our clinical trials;
- changes in laws or regulations applicable to our product candidates;
- changes in the expected or actual timing of our development programs, including delays or cancellations of clinical trials for our product candidates;
- period to period fluctuations in our operating results;

- announcements of new technological innovations or new products by us or our competitors;
- changes in financial estimates or recommendations by securities analysts;
- sales results for ADASUVE, if it is approved for marketing;
- our ability to manufacture our product candidates at a cost effective price, if approved for marketing;
- conditions or trends in the life science and biotechnology industries;
- changes in the market valuations of other life science or biotechnology companies;
- developments in domestic and international governmental policy or regulations;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- additions or departures of key personnel;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- sales of our common stock (or other securities) by us; and
- sales and distributions of our common stock by our stockholders.

In the past, stockholders have often instituted securities class action litigation after periods of volatility in the market price of a company's securities. If a stockholder files a securities class action suit against us, we would incur substantial legal fees, and our management's attention and resources would be diverted from operating our business in order to respond to the litigation.

If we sell shares of our common stock in future financings, existing common stockholders will experience immediate dilution and, as a result, our stock price may go down.

We will need to raise additional capital to fund our operations, to develop our product candidates, to develop our commercialization plans, to expand our market knowledge and to continue the development of our commercial manufacturing capabilities. We may obtain such financing through the sale of our equity securities from time to time. As a result, our existing common stockholders will experience immediate dilution upon any such issuance. For example, in May 2011 we issued 1,192,703 shares of our common stock and warrants to purchase up to an additional 417,446 shares of our common stock in a registered direct offering, in February 2012, we issued 4,400,000 shares of our common stock and warrants to purchase up to an additional 4,400,000 shares of our common stock in an underwritten public offering, in March 2012, we issued 241,936 shares of our common stock in a private placement to Grupo Ferrer, in July 2012 we issued 80,429 shares of our common stock to Azimuth in consideration for its execution and delivery of the Purchase Agreement and in August and September 2012, we issued an aggregate of 3,489,860 shares of our common stock to Azimuth under the Purchase Agreement. If we enter into other financing transactions in which we issue equity securities in the future, our existing common stockholders will experience immediate dilution upon any such issuance.

If we fail to maintain compliance with the listing requirements of The NASDAQ Global Market, we may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.

Our common stock is currently listed on The NASDAQ Global Market. To maintain the listing of our common stock on The NASDAQ Global Market, we are required to meet certain listing requirements, including, among others, either: (i) a minimum closing bid price of $1.00 per share, a market value of publicly held shares (excluding shares held by our executive officers, directors and 10% or more stockholders) of at least $5 million and stockholders' equity of at least $10 million; or (ii) a minimum closing bid price of $1.00 per share, a market value of publicly held shares (excluding shares held by our executive officers, directors, affiliates and 10% or more stockholders) of at least $15 million and a total market value of listed securities of at least $50 million. On January 31, 2012, we received a notice from The NASDAQ Stock Market indicating that our common stock had not met the $1.00 per share minimum closing bid price requirement for 30 consecutive business days and that, if we were unable to demonstrate compliance with this requirement during the applicable grace periods, our common stock would be delisted after that time. We were notified that we had regained compliance with the minimum closing bid requirement on June 27, 2012 after our one for ten reverse stock split.

This reverse stock split may not prevent our common stock from dropping back down below The NASDAQ Global Market minimum closing bid price requirement in the future. It is also possible that we would otherwise fail to satisfy another NASDAQ Global Market requirement for continued listing of our common stock. As of October 26, 2012, the total market value of our publicly held shares of our common stock (excluding shares held by our executive officers, directors, affiliates and 10% or more stockholders) was $75.2 million and the total market value of our listed securities was $79.6 million and the closing bid price of our common stock was $5.07 per share. As of September 30, 2012, we had stockholders' equity of $10.3 million.

There can be no assurance that we will be successful in maintaining our listing of our common stock on The NASDAQ Global Market, or, if transferred, on The NASDAQ Capital Market, and could be subject to delisting. This could impair the liquidity and market price of our common stock. In addition, the delisting of our common stock from a national exchange could materially adversely affect our access to capital markets, and any limitation on market liquidity or reduction in the price of our common stock as a result of that delisting could adversely affect our ability to raise capital on terms acceptable to us, or at all.

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PART II. OTHER INFORMATION

Item 1. Legal Proceedings

None.

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

Recent Sales of Unregistered Equity Securities

None.

Use of Proceeds from the Sale of Registered Securities

Not applicable.

Issuer Purchases of Equity Securities

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

None.

Item 6. Exhibits

See the Exhibit Index following the signature page to this Quarterly Report on Form 10-Q for a list of exhibits filed or furnished with this report, which Exhibit Index is incorporated herein by reference.

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SIGNATURES

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

Alexza Pharmaceuticals, Inc.
(Registrant)

November 6, 2012

/s/ Thomas B. King
Thomas B. King
President and Chief Executive Officer
(principal executive officer)

November 6, 2012

/s/ Mark K. Oki
Mark K. Oki
Senior Vice President, Finance, Chief Financial Officer and Secretary
(principal financial officer and principal accounting officer)

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EXHIBIT INDEX

3.1	Restated Certificate of Incorporation. (1)
3.2	Certificate of Amendment to Restated Certificate of Incorporation. (1)
3.3	Certificate of Amendment to Restated Certificate of Incorporation. (1)
3.4	Amended and Restated Bylaws. (2)
3.5	Amendment to Amended and Restated Bylaws. (3)
4.1	Specimen Common Stock Certificate. (2)
4.2	Second Amended and Restated Investors' Right Agreement dated November 5, 2004, by and between Alexza and certain holders of Preferred Stock. (2)
10.1	Common Stock Purchase Agreement between Alexza and Azimuth Opportunity, L.P. dated July 20, 2012. (4)
10.2*	Form of Amended Change of Control Agreement between Alexza and each of its officers.
31.1	Certification required by Rule 13a-14(a) or Rule 15d-14(a).
31.2	Certification required by Rule 13a-14(a) or Rule 15d-14(a).
32.1	Certifications required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350).
101.INS‡	XBRL Instance Document (furnished electronically herewith).
101.SCH‡	XBRL Taxonomy Extension Schema Document (furnished electronically herewith).
101.CAL‡	XBRL Taxonomy Extension Calculation Linkbase Document (furnished electronically herewith).
101.LAB‡	XBRL Taxonomy Extension Label Linkbase Document (furnished electronically herewith).
101.PRE‡	XBRL Taxonomy Extension Presentation Linkbase Document (furnished electronically herewith).

* Management contract or compensation plan or arrangement.

‡ XBRL (Extensible Business Reporting Language) information is furnished and not filed or a part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections.

(1) Incorporated by reference to exhibits to our Registration Statement on Form S-3 filed on June 26, 2012 (File No. 333-182341).

(2) Incorporated by reference to exhibits to our Registration Statement on Form S-1 filed on December 22, 2005, as amended (File No. 333-130644).

(3) Incorporated by reference to our Annual Report on Form 10-K (File No. 000-51820) as filed with the SEC on March 17, 2008.

(4) Incorporated by reference to our Current Report on Form 8-K (File No. 000-51820) as filed with the SEC on July 23, 2012.

_____, 20 ____

V IA H AND D ELIVERY

_____
Alexza Pharmaceuticals, Inc.
2091 Stierlin Court
Mountain View, CA 94043

Re: Change of Control Agreement

Dear _____:

In consideration of your continued employment, Alexza Pharmaceuticals, Inc. (the " **Company** ") is pleased to offer you the following agreement regarding your severance benefits (the " **Agreement** "). This Agreement amends and supersedes any and all prior agreements with respect to your severance benefits and any such prior agreements are hereby expressly superseded and replaced in their entirety by this Agreement and shall have no further force or effect.

1. At-Will Employment. Nothing in this Agreement alters the at-will nature of your employment relationship with the Company. Subject to the terms of this Agreement, either you or the Company may terminate your employment relationship at any time, with or without Cause or advance notice. In particular, nothing expressed or implied in this Agreement will create any right or duty on the part of the Company to have you remain in the employment of the Company or any subsidiary prior to or following any Corporate Transaction.

2. Termination. You and the Company each acknowledge that either party has the right to terminate your employment with the Company at any time for any reason whatsoever, with or without cause or advance notice pursuant to the following:

(a) Termination by Death or Disability. In the event you shall die during the period of your employment hereunder or become permanently disabled, as evidenced by your inability to carry out your job responsibilities for a continuous period of six months, your employment and the Company's obligation to make payments hereunder shall terminate on the date of your death, or the date upon which, in the sole reasonable determination of the Board of Directors of the Company, you have failed to carry out your job responsibilities for six months, except the Company shall pay you (or your estate) (i) any salary earned but unpaid prior to such termination and all accrued but unused vacation, and (ii) any business expenses incurred by you in connection with your performance of your duties, according to the policies of the Company, that were incurred but not reimbursed as of the date of such termination. Vesting of any of your stock options outstanding on the date of termination shall cease on the date of termination. The Company's ability to terminate you as a result of any disability shall be to the extent permitted by state and/or federal law.

(b) Voluntary Resignation. In the event you voluntarily resign from your employment with the Company (other than for Good Reason as defined below), the Company's obligation to make payments hereunder shall cease upon such resignation, except the Company shall pay you (i) any salary earned but unpaid prior to the resignation and all accrued but unused vacation, and (ii) any business expenses incurred by you in connection with your performance of your duties, according to the policies of the Company, that were incurred but not reimbursed as of the date of resignation. Vesting of any of your stock options outstanding on the date of resignation shall cease on the date of resignation.

(c) Termination for Cause. In the event you are terminated by the Company for Cause (as defined below), the Company's obligation to make payments hereunder shall cease upon the date of receipt by you of written notice and explanation of such termination (the " **Date of Termination** " for purposes of this paragraph 2(c)), except the Company shall: pay you (i) any salary earned but unpaid prior to the Date of Termination, all accrued but unused vacation and (ii) any business expenses, incurred by you in connection with your performance of your duties, according to the policies of the Company, that were incurred but not reimbursed as of the Date of Termination. Vesting of any stock options outstanding on the Date of Termination shall cease on the Date of Termination.

(d) Termination by the Company Without Cause or Resignation for Good Reason in Connection with a Corporate Transaction. Subject to the terms and conditions of this Agreement, the Company will provide you with Severance Benefits (as defined in Section 3) if a Corporate Transaction occurs and as of, or within three (3) months prior to or twelve (12) months after, the effective time of such Corporate Transaction (i) the Company terminates your employment without Cause or (ii) you resign your employment for Good Reason. You will not be entitled to receive any Severance Benefits if (i) the Company terminates your employment for Cause, (ii) you resign from your employment with the Company other than for Good Reason, (iii) your employment with the Company terminates as a result of your death or disability or (iv) the Company terminates your employment without Cause or you resign your employment for Good Reason other than in connection with a Corporate Transaction as described in the preceding sentence. In addition, to the extent that any federal, state or local laws, including, without limitation, so-called "plant closing" laws, require the Company to give advance notice or make a payment of any kind to you because of your involuntary termination due to a layoff, reduction in force, plant or facility closing, sale of business, change of control, or any other similar event or reason, the Severance Benefits payable under this Agreement shall be reduced in an amount equal to any such payment received by you, such that the total amounts paid you do not exceed the Severance Benefits specified herein. The Severance Benefits provided under this Agreement are intended to satisfy any and all statutory obligations that may arise out of your involuntary termination of employment for the foregoing reasons.

3. Description of Severance Benefits. For purposes of this Agreement, " **Severance Benefits** " are defined as:

(a) severance pay (the " **Severance Pay** ") equivalent to twelve (12) months of your Base Salary (as defined below) plus an amount equal to the greater of (i) the annual bonus paid to you for the last completed fiscal year and (ii) the amount of your target bonus established for the fiscal year in which the Notice Date falls; provided that if no target bonus has been

established for the fiscal year in which the Notice Date falls, item (ii) shall be the amount of your target bonus established for the immediately preceding fiscal year. The date you are notified that your employment with the Company is being terminated without Cause or the date you notify the Company that you are terminating your employment for Good Reason, shall be referred to herein as the " **Notice Date** ." Subject to the final sentence of this Section 3, the Severance Pay will be paid in a single lump sum cash payment within seven days after the effective date of the release described below, and will be subject to standard payroll deductions and withholdings;

(b) all stock options, restricted stock units and other stock awards in the Company theretofore granted to you, and any restricted stock owned by you subject to a right of repurchase by the Company, shall vest immediately upon the Notice Date; *provided that*, the relevant stock option plan and such stock options, restricted stock units and other stock awards, as applicable, shall not have otherwise terminated in accordance with the terms thereof; and

(c) reimbursement of your out of pocket costs to continue your group health insurance benefits (and dependent coverage, if applicable) under COBRA at substantially the same level of coverage in effect immediately prior to the Notice Date for eighteen (18) months following the last day of the month in which your Notice Date occurs, payable in a single lump sum within seven days after the effective date of the release described below, subject to standard payroll deductions and withholdings; *provided, that* even if you do not elect or are not eligible to receive COBRA, you shall receive the equivalent of such out of pocket costs.

To receive any of the Severance Benefits, you must first sign, date and allow to become effective a general release of claims in favor of the Company in the form attached hereto as Exhibit A (the " **Release** "). Such Release shall not be signed or dated prior to the Notice Date.

To the extent Severance Benefits pursuant to Section 3 above (A) are paid from the date of termination of your employment through March 15 of the calendar year following such termination, such Severance Benefits are intended to constitute separate payments for purposes of Section 1.409A-2(b)(2) of the Treasury Regulations and thus payable pursuant to the "short-term deferral" rule set forth in Section 1.409A-1(b)(4) of the Treasury Regulations; (B) are paid following said March 15, such Severance Benefits are intended to constitute separate payments for purposes of Section 1.409A-2(b)(2) of the Treasury Regulations made upon an involuntary separation from service and payable pursuant to Section 1.409A-1(b)(9)(iii) of the Treasury Regulations, to the maximum extent permitted by said provision, and (C) are in excess of the amounts specified in clauses (A) and (B) of this paragraph, shall (unless otherwise exempt under Treasury Regulations) be considered separate payments subject to the distribution requirements of Section 409A(a)(2)(A) of the Internal Revenue Code of 1986, as amended (the "Code"), including, without limitation, the requirement of Section 409A(a)(2)(B)(i) of the Code that payments be delayed until 6 months after your separation from service if you are a "specified employee" within the meaning of the aforesaid section of the Code at the time of such separation from service.

4. Parachute Payments.

(a) If any Severance Benefits, payment, distribution or benefit you would receive pursuant to a Corporate Transaction from the Company or otherwise, but determined without regard to any additional payment required under this section 4(a), (" **Payment** ") would

(i) constitute a "parachute payment" within the meaning of Section 280G of the Internal Revenue Code of 1986, as amended (the " **Code** "), and (ii) be subject to the excise tax imposed by Section 4999 of the Code or any interest or penalties payable with respect to such excise tax (such excise tax, together with any such interest and penalties, are hereinafter collectively referred to as the " **Excise Tax** "), then you shall be entitled to receive from the Company an additional payment (the " **Gross-Up Payment** ") in an amount that shall fund the payment by you of any Excise Tax on the Payment as well as all income and employment taxes imposed on the Gross-Up Payment, any Excise Tax imposed on the Gross-Up Payment and any interest or penalties imposed with respect to income and employment taxes imposed on the Gross-Up Payment.

(b) The accounting firm engaged by the Company for general audit purposes as of the day prior to the effective date of the Corporate Transaction shall perform the foregoing calculations. If the accounting firm so engaged by the Company is serving as accountant or auditor for the individual, entity or group effecting the Corporate Transaction, the Company shall appoint a nationally recognized accounting firm to make the determinations required hereunder. The Company shall bear all expenses with respect to the determinations by such accounting firm required to be made hereunder.

(c) The accounting firm engaged to make the determinations hereunder shall provide its calculations, together with detailed supporting documentation, to the Company and you within fifteen calendar days after the date on which your right to a Payment is triggered (if requested at that time by the Company or you) or such other time as requested by the Company or you. If the accounting firm determines that no Excise Tax is payable with respect to a Payment, it shall furnish the Company and you with an opinion reasonably acceptable to you that no Excise Tax will be imposed with respect to such Payment. Any good faith determinations of the accounting firm made hereunder shall be final, binding and conclusive upon the Company and you.

5. Description of Corporate Transaction. For purposes of this Agreement, " **Corporate Transaction** " is defined as: (i) a sale of substantially all of the assets of the Company; (ii) a merger or consolidation in which the Company is not the surviving corporation if, immediately after the merger or consolidation, the stockholders of the Company immediately prior thereto do not beneficially own, directly or indirectly, either (A) outstanding voting securities representing more than fifty percent (50%) of the combined outstanding voting power of the surviving entity in such merger or consolidation, or (B) more than fifty percent (50%) of the combined outstanding voting power of the parent of the surviving entity in such merger or consolidation, in each case in substantially the same proportions as their ownership of the outstanding voting securities of the Company immediately prior to such transaction;; (iii) a reverse merger in which the Company is the surviving corporation but the shares of the Company's common stock outstanding immediately preceding the merger are converted by virtue of the merger into other property, whether in the form of securities, cash or otherwise if, immediately after the merger, the stockholders of the Company immediately prior thereto do not beneficially own, directly or indirectly, either (A) outstanding voting securities representing more than fifty percent (50%) of the combined outstanding voting power of the surviving entity in such merger or (B) more than fifty percent (50%) of the combined outstanding voting power of the parent of the surviving entity in such merger, in each case in substantially the same proportions as their ownership of the outstanding voting securities of the Company immediately

prior to such transaction; or (iv) any transaction or series of related transactions in which in excess of 50% of the Company's voting power is transferred, other than the sale by the Company of stock in transactions the primary purpose of which is to raise capital for the Company's operations and activities.

6. Definition of Base Salary. For purposes of this Agreement, " **Base Salary** " means your base salary as of the Notice Date, excluding the following: any type of bonus payments, commissions, incentive payments or any other similar remuneration paid directly to you, or any other income received in connection with stock options, contributions made by the Company under any employee benefit plan, or similar items of compensation.

7. Definition of Cause. For purposes of this Agreement, " **Cause** " means (i) your arrest for violation of a state or federal criminal law involving the commission of any felony against the Company; (ii) your intentional, material violation of any material written contract or agreement between you and the Company (which, if curable, is not cured within twenty (20) days after written notice thereof by the Company to you); (iii) your unauthorized use or disclosure of the Company's confidential information or trade secrets; or (iv) your continued gross misconduct (which, if curable, is not cured within twenty (20) days after written notice thereof by the Company to you). In the event you are terminated for Cause you will not be entitled to the Severance Benefits, pay in lieu of notice, vesting of any shares under any option plan, vesting of any unrestricted shares, or any other such compensation set forth herein, but you will be entitled to all compensation, benefits and unreimbursed expenses accrued through the date of termination. You and the Company acknowledge that this definition of " **Cause** " is not intended and does not apply to any aspect of the relationship between the Company and any of its employees, including you, beyond determining your eligibility for the Severance Benefits.

8. Definition of Good Reason. For purposes of this Agreement, " **Good Reason** " shall mean one or more of the following are undertaken by the Company or the surviving entity in the applicable Corporate Transaction without your express written consent: (i) relocation of your place of work greater than twenty-five miles from your current work location; (ii) a decrease in your base salary; (iii) a reduction in the amount of your annual target bonus opportunity as in effect prior to such decrease; or (iv) a significant diminution in your authority, duties or job responsibilities as in effect immediately prior to the first announcement relating to the Corporate Transaction. You and the Company acknowledge that this definition of Good Reason is not intended and does not apply to any aspect of the relationship between the Company and any of its employees, including you, beyond determining your eligibility for the Severance Benefits.

9. Miscellaneous. This Agreement constitutes the complete, final and exclusive embodiment of the entire agreement between you and the Company with regard to your Severance Benefits. It is entered into without reliance on any promise or representation, written or oral, other than those expressly contained herein, and it supersedes any prior or contemporaneous understandings, discussions, correspondence, agreements, promises, warranties or representations relating to Severance Benefits. This Agreement may not be modified or amended except in writing signed by you and a duly authorized officer of the Company. This Agreement will be deemed to have been entered into and will be construed and enforced in accordance with the laws of the State of California as applied to contracts made and

to be performed entirely within California. The parties agree that any action brought by either party to interpret or enforce any provision of this Agreement shall be brought in, and each party agrees to, and does hereby, submit to the jurisdiction and venue of, the appropriate state or federal court for the district encompassing the Company's principal place of business.

10. Successors and Binding Agreement . This Agreement will be binding upon and inure to the benefit of the Company and any successor to the Company, including without limitation any persons acquiring directly or indirectly all or substantially all of the business or assets of the Company whether or not through a Corporate Transaction (and such successor shall thereafter be deemed the "Company" for the purposes of this Agreement). This Agreement will inure to the benefit of and be enforceable by your personal or legal representatives, executors, administrators, successors, heirs, distributees and legatees.

11. Amendments. No provision of the Agreement may be amended, modified or waived unless such amendment, modification or waiver shall be agreed to in writing and signed by the Executive and a duly authorized officer of the Company.

12. Severability. If any provision of the Agreement shall be determined to be invalid or unenforceable by a court of competent jurisdiction, the remaining provisions of the Agreement shall be unaffected thereby and shall remain in full force and effect to the fullest extent permitted by law.

13. Independent Counsel. You acknowledge that this Agreement has been prepared on behalf of the Company by counsel to the Company and that this counsel does not represent, and is not acting on your behalf. You have been provided with an opportunity to consult with your own counsel with respect to this Agreement. You understand that the Company does not make any representation or warranty as to the tax treatment of your stock options.

14. Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed to be an original but all of which together will constitute one and the same agreement.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

The Company appreciates your continuing contributions to Alexza Pharmaceuticals, Inc. Please sign below to indicate your understanding and acceptance of this Agreement and return the signed original to me at your earliest convenience.

Very truly yours,

ALEXZA PHARMACEUTICALS, INC.

By: _____

Name: _____

Title: _____

UNDERSTOOD AND AGREED:

_____ _____

[_____] Date

E XHIBIT A

RELEASE

In exchange for the Severance Benefits provided under the foregoing Change of Control Agreement with Alexza Pharmaceuticals, Inc. (the " **Company** "), dated _____, 20__, and except as set forth in this release:

I agree to the terms in the foregoing Agreement.

In consideration of the payment to me of the Severance Benefits set forth in the Agreement, I hereby release, acquit and forever discharge the Company, its parents and subsidiaries, and their respective officers, directors, agents, servants, employees, attorneys, shareholders, successors, assigns and affiliates, of and from any and all claims, liabilities, demands, causes of action, costs, expenses, attorneys fees, damages, indemnities and obligations of every kind and nature, in law, equity, or otherwise, known and unknown, suspected and unsuspected, disclosed and undisclosed, arising out of or in any way related to agreements, events, acts or conduct at any time prior to and including the execution date of this release, including but not limited to: all such claims and demands directly or indirectly arising out of or in any way connected with my employment with the Company or the termination of that employment; claims or demands related to salary, bonuses, commissions, stock, stock options, or any other ownership interests in the Company, vacation pay, fringe benefits, expense reimbursements, severance pay, or any other form of compensation; claims pursuant to any federal, state or local law, statute, or cause of action including, but not limited to, the federal Civil Rights Act of 1964, as amended; the federal Americans with Disabilities Act of 1990; the federal Age Discrimination in Employment Act of 1967, as amended ("ADEA"); the California Fair Employment and Housing Act, as amended; tort law; contract law; wrongful discharge; discrimination; harassment; fraud; defamation; emotional distress; and breach of the implied covenant of good faith and fair dealing.

I acknowledge that I am knowingly and voluntarily waiving and releasing any rights I may have under the ADEA, as amended. I also acknowledge that the consideration given for the waiver and release in the preceding paragraph hereof is in addition to anything of value to which I was already entitled. I further acknowledge that I have been advised by this writing, as required by the ADEA, that: (a) my waiver and release do not apply to any rights or claims that may arise after the execution date of this release; (b) I have been advised hereby that I have the right to consult with an attorney prior to executing this release; (c) I have twenty-one (21) days to consider this release (although I may choose to voluntarily execute this release earlier); (d) I have seven (7) days following my execution of this release to revoke the release; and (e) this release will not be effective until the date upon which the revocation period has expired, which will be the eighth day after I execute this release.

I UNDERSTAND THAT THIS AGREEMENT INCLUDES A RELEASE OF ALL KNOWN AND UNKNOWN CLAIMS. In giving this release, which includes claims which may be unknown to me at present, I acknowledge that I have read and understand Section 1542 of the California Civil Code which reads as follows: **"A general release does not extend to claims**

which the creditor does not know or suspect to exist in his favor at the time of executing the release, which if known by him must have materially affected his settlement with the debtor." I hereby expressly waive and relinquish all rights and benefits under that section and any law of any jurisdiction of similar effect with respect to my release of any unknown or unsuspected claims I may have against the Company.

_____

[_____]

Date: _____

ALEXZA PHARMACEUTICALS, INC.

By: _____

Name: _____

Title: _____

Exhibit 31.1

CERTIFICATIONS

I, Thomas B. King certify that:

1. I have reviewed this quarterly report on Form 10-Q of Alexza 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(s) 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15 (f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) 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

d) 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(s) 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 6, 2012

/s/ Thomas B. King
Thomas B. King
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATIONS

I, Mark K. Oki, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Alexza 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(s) 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15 (f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) 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

d) 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(s) 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 6, 2012

/s/ Mark K. Oki
Mark K. Oki
Senior Vice President, Finance, Chief Financial Officer, Secretary, Principal Financial Officer and Principal Accounting Officer

Exhibit 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. § 1350), Thomas B. King, President and Chief Executive Officer of Alexza Pharmaceuticals, Inc. (the "Company"), and Mark K. Oki, the Senior Vice President, Finance, Chief Financial Officer and Secretary of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2012, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

In Witness Whereof , the undersigned have set their hands hereto as of the 6th day of November 2012.

/s/ Thomas B. King
Thomas B. King
President and Chief Executive Officer

/s/ Mark K. Oki
Mark K. Oki
Senior Vice President, Finance, Chief Financial Officer, Secretary, Principal Financial Officer and Principal Accounting Officer

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Alexza Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.