

TJX COMPANIES INC /DE/  
Form 4  
June 12, 2014

**FORM 4**

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

OMB APPROVAL

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**STATEMENT OF CHANGES IN BENEFICIAL OWNERSHIP OF SECURITIES**

Filed pursuant to Section 16(a) of the Securities Exchange Act of 1934, Section 17(a) of the Public Utility Holding Company Act of 1935 or Section 30(h) of the Investment Company Act of 1940

(Print or Type Responses)

1. Name and Address of Reporting Person \*  
**BENNETT ALAN M**

(Last) (First) (Middle)

**C/O THE TJX COMPANIES,  
INC., 770 COCHITUATE RD.**

(Street)

**FRAMINGHAM, MA 01701**

(City) (State) (Zip)

2. Issuer Name and Ticker or Trading Symbol  
**TJX COMPANIES INC /DE/ [TJX]**

3. Date of Earliest Transaction  
(Month/Day/Year)  
**06/10/2014**

4. If Amendment, Date Original Filed(Month/Day/Year)

5. Relationship of Reporting Person(s) to Issuer

(Check all applicable)

Director  10% Owner  
 Officer (give title below)  Other (specify below)

6. Individual or Joint/Group Filing(Check Applicable Line)  
 Form filed by One Reporting Person  
 Form filed by More than One Reporting Person

**Table I - Non-Derivative Securities Acquired, Disposed of, or Beneficially Owned**

1. Title of Security (Instr. 3)	2. Transaction Date (Month/Day/Year)	2A. Deemed Execution Date, if any (Month/Day/Year)	3. Transaction Code (Instr. 8)	4. Securities Acquired (A) or Disposed of (D) (Instr. 3, 4 and 5)	5. Amount of Securities Beneficially Owned Following Reported Transaction(s) (Instr. 3 and 4)	6. Ownership Form: Direct (D) or Indirect (I) (Instr. 4)	7. Nature of Beneficial Ownership (Instr. 4)
				(A) or (D)	Amount		
				Code	V		
					Amount		
				(D)	Price		

Reminder: Report on a separate line for each class of securities beneficially owned directly or indirectly.

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SEC 1474 (9-02)

**Table II - Derivative Securities Acquired, Disposed of, or Beneficially Owned (e.g., puts, calls, warrants, options, convertible securities)**

1. Title of Derivative Security	2. Conversion or Exercise	3. Transaction Date (Month/Day/Year)	3A. Deemed Execution Date, if any	4. Transaction Code	5. Number of Derivative Securities	6. Date Exercisable and Expiration Date (Month/Day/Year)	7. Title and Amount of Underlying Securities (Instr. 3 and 4)

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(Instr. 3)	Price of Derivative Security	(Month/Day/Year)	(Instr. 8) Acquired (A) or Disposed of (D) (Instr. 3, 4, and 5)	Code	V	(A)	(D)	Date Exercisable	Expiration Date	Title	Amount or Number of Shares
Deferred Stock Units	\$ 0	06/10/2014	A			1,248.66		(1)	(1)	Common Stock	1,248.66
Deferred Stock Units	\$ 0	06/10/2014	A			1,248.66		(2)	(2)	Common Stock	1,248.66
Deferred Stock Units	\$ 0	06/10/2014	A			186.33		(3)	(3)	Common Stock	186.33
Deferred Stock Units	\$ 0	06/10/2014	A			186.33		(4)	(4)	Common Stock	186.33

## Reporting Owners

Reporting Owner Name / Address	Relationships			
	Director	10% Owner	Officer	Other
BENNETT ALAN M C/O THE TJX COMPANIES, INC. 770 COCHITUATE RD. FRAMINGHAM, MA 01701	X			

## Signatures

Mary B. Reynolds, by Power of Attorney dated September 10,  
2007

06/12/2014

\_\_Signature of Reporting Person

Date

## Explanation of Responses:

- \* If the form is filed by more than one reporting person, *see* Instruction 4(b)(v).
- \*\* Intentional misstatements or omissions of facts constitute Federal Criminal Violations. *See* 18 U.S.C. 1001 and 15 U.S.C. 78ff(a).
- (1) Constitutes an award of deferred shares, under the Stock Incentive Plan, having a value of \$70,000. Shares will be delivered to each Director upon Director's retirement, under and subject to the terms of the Plan.  
  
Constitutes an award of deferred shares, under the Stock Incentive Plan, having a value of \$70,000. Shares vest on the date immediately preceding the date of the annual meeting next succeeding the date of grant of such shares, provided that the recipient is still a Director on
- (2) such date or, if earlier, immediately prior to a Change of Control. Vested shares will be delivered to each Director on the date of the annual meeting next succeeding the date of grant of such shares or upon the Director's retirement, in accordance with the Director's advance irrevocable election, if any, under and subject to the terms of the Plan.
- (3) Constitutes an award of deferred shares, under the Stock Incentive Plan, having a value equal to the aggregate dividends on previously granted deferred shares for which there has been a record date since June 11, 2013. Deferred shares will be delivered to each Director upon Director's retirement, under and subject to the terms of the Plan.

- (4) Constitutes an award of deferred shares, under the Stock Incentive Plan, having a value equal to the aggregate dividends on previously granted deferred shares for which there has been a record date since June 11, 2013. The previously granted deferred shares vest on the date immediately preceding the date of the annual meeting next succeeding the date of grant of such shares, provided that the recipient is still a Director on such date or, if earlier, immediately prior to a Change of Control. Vested shares will be delivered to each Director on the date of the annual meeting next succeeding the date of grant of such shares or upon the Director's retirement, in accordance with the Director's advance irrevocable election, if any, under and subject to the terms of the Plan.

Note: File three copies of this Form, one of which must be manually signed. If space is insufficient, *see* Instruction 6 for procedure. Potential persons who are to respond to the collection of information contained in this form are not required to respond unless the form displays a currently valid OMB number. of the underlying common stock on the NASDAQ Stock Market and the Investor's satisfaction, in its sole discretion, with the viability of certain undersea mining projects of the Company. This transaction received stockholders approval on June 9, 2015. Completion of the transaction requires amending the Company's articles of incorporation to (a) effect a reverse stock split, which was done on February 19, 2016, (b) adjusting the Company's authorized capitalization, which was also done on February 19, 2016, and (c) establishing a classified board of directors (collectively, the Amendments). The Amendments have been or will be set forth in certificates of amendment to the Company's articles of incorporation filed or to be filed with the Nevada Secretary of State.

### ***Series AA Convertible Preferred Stock Designation***

The Purchase Agreement provides for the issuance of up to 8,427,004 shares of Series AA-1 Convertible Preferred Stock, par value \$0.0001 per share (the Series AA-1 Preferred) and 7,223,145 shares of Series AA-2 Convertible Preferred Stock, par value \$0.0001 per share (the Series AA-2 Preferred), subject to stockholder approval which was received on June 9, 2015 and satisfaction of other conditions. Significant terms and conditions of the Series AA Preferred are as follows:

***Dividends.*** If and when the Company declares a dividend and any other distribution (including, without limitation, in cash, in capital stock (which shall include, without limitation, any options, warrants or other rights to acquire capital stock) of the Company, then the holders of each share of Series AA Preferred Stock are entitled to receive, a dividend or distribution in an amount equal to the amount of dividend or distribution received by the holders of common stock for which such share of Series AA Preferred Stock is convertible.

***Liquidation Preference.*** The Liquidation Preference on each share of Series AA Preferred Stock is its Stated Value plus accretion at the rate of 8% per annum compounded on each December 31 from the date of issue of such share until the date such share is converted. For any accretion period which is less than a full year, the Liquidation Preference shall accrete in an amount to be computed on the basis of a 360-day year of twelve 30-day months and the actual number of days elapsed.

***Voting Rights.*** The holders of Series AA Preferred will be entitled to one vote for each share of common stock into which the Series AA Preferred is convertible and will be entitled to notice of meetings of stockholders.

***Conversion Rights.*** At any time after the Preferred Shares have been issued, any holder of shares of Series AA Preferred may convert any or all of the shares of preferred stock into one fully paid and non-assessable share of Common Stock.

***Adjustments to Conversion Rights.*** If Odyssey pays a dividend or makes a distribution on its common stock in shares of common stock, subdivides its outstanding common stock into a greater number of shares, or combines its outstanding common stock into a smaller number of shares, or if there is a reorganization, or a merger or consolidation of Odyssey with or into any other entity which results in a conversion, exchange, or cancellation of the common stock, or a sale of all or substantially all of Odyssey's assets, then the conversion rights described above will be adjusted appropriately so that each holder of Series AA



Preferred will receive the securities or other consideration the holder would have received if the holder's Series AA Preferred had been converted before the happening of the event. The conversion price in effect from time to time is also subject to downward adjustment if we issue or sell shares of common stock for a purchase price less than the conversion price or if we issue or sell shares convertible into or exercisable for shares of common stock with a conversion price or exercise price less than the conversion price for the Series AA Preferred.

### ***Accounting considerations***

As stated above the issuance of the Series AA Convertible Preferred Stock is based on certain contingencies. No accounting treatment determination is required until these contingencies are met and the Series AA Convertible Preferred Stock has been issued. However, we have analyzed the instrument to determine the proper accounting treatment that will be necessary once the instruments have been issued.

ASC 480 generally requires liability classification for financial instruments that are certain to be redeemed, represent obligations to purchase shares of stock or represent obligations to issue a variable number of common shares. We concluded that the Series AA Preferred was not within the scope of ASC 480 because none of the three conditions for liability classification was present.

ASC 815 generally requires the analysis of embedded terms and features that have characteristics of derivatives to be evaluated for bifurcation and separate accounting in instances where their economic risks and characteristics are not clearly and closely related to the risks of the host contract. However, in order to perform this analysis we were first required to evaluate the economic risks and characteristics of the Series AA Convertible Preferred Stock in its entirety as being either akin to equity or akin to debt. Our evaluation concluded that the Series AA Convertible Preferred Stock was more akin to an equity-like contract largely due to the fact that most of its features were participatory in nature. As a result we concluded that the embedded conversion feature is clearly and closely related to the host equity contract and will not require bifurcation and liability classification.

The option to purchase the Series AA-2 Convertible Preferred Stock was analyzed as a freestanding financial instrument and has terms and features of derivative financial instruments. However, in analyzing this instrument under applicable guidance it was determined that it is both (i) indexed to the Company's stock and (ii) meet the conditions for equity classification.

### **Warrants**

Warrants to purchase 130,208 shares of common stock were attached to our formerly outstanding Senior Convertible debt. The exercise price on these warrants is \$43.20, and they expire on November 9, 2016.

### **Stock-Based Compensation**

We have two stock incentive plans. The first is the 2005 Stock Incentive Plan that expired in August 2015. After the expiration of this plan, equity instruments cannot be granted but this plan shall continue in effect until all outstanding awards have been exercised in full or are no longer exercisable and all equity instruments have vested or been forfeited.

On June 9, 2015, our shareholders approved our 2015 Stock Incentive Plan (the "Plan") that was adopted by our Board of Directors (the "Board") on January 2, 2015, which is the effective date. The plan expires on the tenth anniversary of the effective date. The Plan provides for the grant of incentive stock options, non-qualified stock options, restricted stock awards, restricted stock units and stock appreciation rights. This plan was initially capitalized with 450,000 shares that may be granted. The Plan is intended to comply with Section 162(m) of the Internal Revenue Code, which stipulates that the maximum aggregate number of Shares with respect to one or more Awards that may be granted to

any one person during any calendar year shall be 83,333, and the maximum aggregate amount of cash that may be paid in cash to any person during any calendar year with respect to one or more Awards payable in cash shall be \$2,000,000. The original maximum number of shares that were to be used for Incentive Stock Options ( ISO ) under the Plan shall be 450,000. During our June 2016 shareholder meeting, the shareholders elected to add 200,000 incremental shares to the Plan. With respect to each grant of an ISO to a Participant who is not a Ten Percent Stockholder, the Exercise Price shall not be less than the Fair Market Value of a Share on the date the ISO is granted. With respect to each grant of an ISO to a Participant who is a Ten Percent Stockholder, the Exercise Price shall not be less than one hundred ten percent (110%) of the Fair Market Value of a Share on the date the ISO is granted. If an Award is a Non-Qualifying Stock Option ( NQSO ), the Exercise Price for each Share shall be no less than (1) the minimum price required by applicable state law, or (2) the Fair Market Value of a Share on the date the NQSO is granted, whichever price is greatest. Any Award intended to meet the Performance Based Exception must be granted with an Exercise Price not less than the Fair Market Value of a Share determined as of the date of such grant.

Share-based compensation expense recognized during the period is based on the value of the portion of share-based payment awards that is ultimately expected to vest. As share-based compensation expense recognized in the statement of

operations is based on awards ultimately expected to vest, it can be reduced for estimated forfeitures. The ASC topic Stock Compensation requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The share based compensation charged against income for the three and six-month periods ended June 30, 2016 and 2015 was \$357,872 and \$798,773 and \$692,501 and \$1,393,379, respectively.

We did not grant stock options in the three-month periods ended June 30, 2015. We did grant stock options in the quarter ended June 30, 2016 to two independent directors in lieu of cash for services rendered to the Company as directors. The weighted average estimated fair value of these granted stock options was \$1.55. The weighted average fair value of stock options granted is determined using the Black-Scholes option-pricing model, which values options based on the stock price at the grant date, the expected life of the option, the estimated volatility of the stock, the expected dividend payments, and the risk-free interest rate over the life of the option. The Black-Scholes option valuation model was developed for estimating the fair value of traded options that have no vesting restrictions and are fully transferable. Because option valuation models require the use of subjective assumptions, changes in or variations from these assumptions can materially affect the fair value of the options.

	June 30, 2016	June 30, 2015
Risk-free interest rate	1.29%	
Expected volatility of common stock	80.87%	
Dividend yield	0%	
Expected life of options	8.2 years	

#### NOTE J CONCENTRATION OF CREDIT RISK

We maintain the majority of our cash at one financial institution. At June 30, 2016, our uninsured cash balance was approximately \$1,622,296.

At June 30, 2016, we do not have any debt obligations with variable interest rates.

#### NOTE K DERIVATIVE FINANCIAL INSTRUMENTS

The following tables summarize the components of our derivative liabilities and linked common shares as of June 30, 2016 and December 31, 2015 and the amounts that were reflected in our income related to our derivatives for the periods then ended:

	June 30, 2016	December 31, 2015
Derivative liabilities:		
Embedded derivatives derived from:		
2014 Convertible Promissory Notes	\$	\$ 3,396,191
		3,396,191
Warrant derivatives		
Senior Convertible Notes	3,891	6,225
Warrant derivatives	3,891	6,225

Explanation of Responses:

Total derivative liabilities	\$ 3,891	\$ 3,402,416
	<b>June 30, 2016</b>	<b>December 31, 2015</b>
Common shares linked to derivative liabilities:		
Embedded derivatives:		
2014 Convertible Promissory Notes*		3,174,604
		3,174,604
Warrant derivatives		
Senior Convertible Notes	130,208	130,208
	130,208	130,208
Total common shares linked to derivative liabilities	130,208	3,304,812

\* The common shares indexed to the 2014 Convertible Promissory Notes are shares indexed to Oceanica.



	Three months ended June 30,		Six months ended June 30,	
	2016	2015	2016	2015
Derivative income (expense):				
Unrealized gains (losses) from fair value changes:				
Senior Convertible Notes	\$	\$	\$	\$
2014 Convertible Promissory Notes		147,142	3,396,190	(331,984)
Warrant derivatives	61,051	64,748	2,335	80,971

We previously reported the Pathology Working Group's, or PWG, findings that only the high lorcaserin dose was associated with increased mammary adenocarcinoma aggressiveness, based on tumor incidence, multiplicity and time to onset, and that there were equivocal increases in lung metastases of mammary origin in the mid and high doses. Using the PWG's updated data set, we have now analyzed time to death due to mammary adenocarcinoma as an additional indicator of aggressiveness. This evaluation identified all animals for which the original pathologist named mammary tumor as cause of death. In some cases, the pathologist specifically named mammary adenocarcinoma as the cause of death; in other cases, animals had both mammary adenocarcinoma and fibroadenoma and neither was singled out as the cause of death. Therefore, we performed two survival analyses: The first was based upon death specifically attributed to adenocarcinoma, and the second assumed deaths due to unspecified mammary tumor in animals with both fibroadenoma and adenocarcinoma were also caused by adenocarcinoma. Time to death specifically attributed to adenocarcinoma was significantly decreased only in the high-dose group. In the second analysis, time to death due to unspecified mammary tumor was accelerated in the mid-dose group as well, although the incidence of adenocarcinoma was not increased over controls in the mid-dose group.

We have now completed many of the studies we plan to include in our response to the lorcaserin CRL. Certain studies are still ongoing, including a series of mechanistic studies that are intended to test whether there is a causal relationship between lorcaserin, prolactin and mammary tumor development in rats.

With regard to our planned marketing authorization application, or MAA, filing with the European Medicines Agency, or EMA, we have been granted eligibility for the centralized procedure and have been assigned the UK's Medicines and Healthcare products Regulatory Agency, or MHRA, as our application Rapporteur, and Sweden's Medical Products Agency, or MPA, as Co-rapporteur. We also received approval from the Pediatric Development Committee for our pediatric investigation plan application, which defers all pediatric studies until after EMA approval.

Our other recent developments include:

We entered into an equity line of credit agreement with Azimuth Opportunity, L.P., or Azimuth, that provides that, upon the terms and subject to the conditions and limitations set forth in the agreement, Azimuth is committed to purchase up to \$50 million worth of shares of our common stock over a 24-month term. We will determine, at our sole discretion, the timing and amount of any sales of our stock under the agreement, subject to certain conditions.

We presented three posters of new data analyses from the lorcaserin Phase 3 clinical trial program at Obesity 2011, the 29<sup>th</sup> Annual Scientific Meeting of The Obesity Society.

Robert E. Hoffman rejoined us as Vice President, Finance and Chief Financial Officer.

We refer you to our previously filed SEC reports for a more complete discussion of certain of these and related developments.

The drug development and approval process is long, uncertain and expensive, and our ability to achieve our goals, including obtaining regulatory approval for lorcaserin and other of our drug candidates, depends on numerous factors, many of which we do not control. We will continue to seek to balance the high costs of research, development and manufacturing against the need to sustain our operations long enough to commercialize the results of our efforts. We do not expect any of our drug candidates to be commercially available until at least late in 2012, if ever. We expect to continue to incur substantial losses, and do not expect to generate positive operating cash flows, for at least the short term.

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Accordingly, we will need to raise additional funds through equity, debt or other financing transactions or receive additional funds under our marketing and supply agreement with Eisai or under future collaborative agreements for one or more of our drug candidates or programs. Although we expect our cash used in operations to be significantly lower in 2011 compared to 2010 due to lower expected clinical trial expenses, cost savings from the workforce reduction we completed earlier this year and reduced research and development activities and expenses, we will continue to use substantial cash as we work to obtain regulatory approval of lorcaserin, continue advancing certain of our earlier-stage research and development programs and continue to incur general and administrative expenses.

### RESULTS OF OPERATIONS

We are providing the following summary of our revenues, research and development expenses and general and administrative expenses to supplement the more detailed discussion below. The dollar values in the following tables are in millions.

#### Revenues

Source of revenue	Three months ended		Nine months ended	
	September 30, 2011	September 30, 2010	September 30, 2011	September 30, 2010
Manufacturing services agreement	\$ 1.7	\$ 1.8	\$ 4.4	\$ 5.3
Collaborative agreements	1.8	5.8	6.2	7.3
<b>Total revenues</b>	<b>\$ 3.5</b>	<b>\$ 7.6</b>	<b>\$ 10.6</b>	<b>\$ 12.6</b>

#### Research and development expenses

Type of expense	Three months ended		Nine months ended	
	September 30, 2011	September 30, 2010	September 30, 2011	September 30, 2010
Salary and other personnel costs (excluding non-cash share-based compensation)	\$ 6.4	\$ 8.1	\$ 19.4	\$ 25.1
External clinical and preclinical study fees and expenses, including external manufacturing costs	1.7	4.3	5.4	10.0
Internal research and development manufacturing costs for Swiss facility	1.8	1.4	5.5	4.0
Facility and equipment costs	2.9	3.5	9.2	10.9
Research supplies	1.1	1.0	2.8	2.9
Non-cash share-based compensation	0.5	0.9	1.5	2.6
Other	0.6	1.0	1.8	3.5
<b>Total research and development expenses</b>	<b>\$ 15.0</b>	<b>\$ 20.2</b>	<b>\$ 45.6</b>	<b>\$ 59.0</b>

**Table of Contents****General and administrative expenses**

Type of expense	Three months ended		Nine months ended	
	September 30, 2011	September 30, 2010	September 30, 2011	September 30, 2010
Salary and other personnel costs (excluding non-cash share-based compensation)	\$ 2.5	\$ 2.3	\$ 6.9	\$ 7.0
Legal, accounting and other professional fees	1.6	2.7	6.1	7.0
Facility and equipment costs	1.1	1.0	3.2	2.8
Non-cash share-based compensation	0.3	0.4	1.4	1.7
Other	0.5	0.5	1.4	2.1
Total general and administrative expenses	\$ 6.0	\$ 6.9	\$ 19.0	\$ 20.6

**THREE MONTHS ENDED SEPTEMBER 30, 2011 AND 2010**

**Revenues.** We recognized revenues of \$3.5 million during the three months ended September 30, 2011, compared to \$7.6 million during the three months ended September 30, 2010. Our revenues for the three months ended September 30, 2011 included (i) \$1.7 million under our manufacturing services agreement with Siegfried Ltd, or Siegfried, (ii) \$1.0 million from amortization of the \$50.0 million non-refundable, upfront payment we received in July 2010 from Eisai and (iii) \$0.8 million under our marketing and supply agreement with Eisai in reimbursements for additional lorcaserin development work. Our revenues for the three months ended September 30, 2010 included (i) \$4.0 million of previously deferred non-cash revenues recognized under our license agreement with TaiGen Biotechnology Co., Ltd., or TaiGen, (ii) \$1.8 million under our manufacturing services agreement with Siegfried, (iii) \$1.0 million from amortization of the \$50.0 million non-refundable, upfront payment we received from Eisai and (iv) \$0.8 million for patent activities under our former collaboration with Ortho-McNeil-Janssen Pharmaceuticals, Inc., or Ortho-McNeil-Janssen, which was terminated effective December 28, 2010.

Absent any new collaborations, we expect our 2011 revenues will primarily consist of amortization of the \$50.0 million non-refundable, upfront payment we received from Eisai, research funding and reimbursement from Eisai for 50% of the cost of certain of the additional development expenses incurred in connection with responding to the lorcaserin CRL, and manufacturing services revenue under our agreement with Siegfried. We expect the revenues we recognize in 2011 under this manufacturing services agreement will be lower than in 2010.

Revenues for milestones that may be achieved in the future are difficult to predict, and our revenues may vary significantly from quarter to quarter and year to year. We expect that any significant revenues for at least the short term will depend on whether and when we enter into any agreements to commercialize lorcaserin outside of the United States, collaborate on or license any of our other drug candidates or intellectual property, and receive US marketing approval for lorcaserin, as well as revenues under our manufacturing services agreement with Siegfried and our marketing and supply agreement with Eisai.

**Cost of manufacturing services.** Cost of manufacturing services is comprised of direct costs associated with manufacturing drug products for Siegfried under our manufacturing services agreement, including related salaries, other personnel costs and machinery depreciation costs. We recognized cost of manufacturing services of \$1.6 million for the three months ended September 30, 2011, which included a \$0.2 million decrease in our contract loss provision for services expected to be rendered through June 30, 2012 under our manufacturing services agreement with Siegfried, which was amended effective January 1, 2011. We decreased the estimated contract loss provision primarily due to a change in the projected product mix expected to be manufactured. For the three months ended September 30, 2010, we recognized cost of manufacturing services of \$1.8 million.

**Research and development expenses.** Research and development expenses, which account for the majority of our expenses, consist primarily of salaries and other personnel costs, clinical trial costs (including payments to contract research organizations, or CROs), preclinical study fees, manufacturing costs for non-commercial products, costs for the development of our earlier-stage programs and technologies, research supply costs and facility and equipment costs. We expense research and development costs to operations as they are incurred when these expenditures relate to our research and development efforts and have no alternative future uses. We generally do not track our earlier-stage, internal research and development expenses by project; rather, we track such expenses by the type of cost incurred.

Research and development expenses decreased by \$5.2 million to \$15.0 million for the three months ended September 30, 2011, from \$20.2 million for the three months ended September 30, 2010. This was primarily due to decreases of (i) \$2.6 million in external clinical and

preclinical study fees and expenses due to a decrease in lorcaserin pre-launch production activities comparing these periods and (ii) \$1.7 million in salary and other personnel costs as a result of the reduction in our US workforce of approximately 25%, or 65 employees, we completed around the end of March 2011, which we refer to as the 2011 workforce reduction. Although we expect to continue to incur substantial research and development expenses in 2011, we expect our research and development expenses will be significantly lower than the 2010 level, primarily due to lower external clinical and preclinical study fees and expenses, including manufacturing costs, and cost savings from our 2011 workforce reduction. We expect to incur manufacturing costs for

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lorcaserin and that such costs will be substantial if the FDA approves our NDA for lorcaserin. However, if the NDA for lorcaserin is approved, we will begin to record our lorcaserin manufacturing costs as cost of goods sold as the related inventory is sold, instead of as part of our research and development expenses. Pre-launch inventory manufactured is being charged to expense until we believe that the likelihood of approval is such that we should begin recording the production costs related to the inventory produced as an asset.

Included in the \$1.7 million total external clinical and preclinical study fees and expenses noted in the table above for the three months ended September 30, 2011 was \$1.3 million related to our lorcaserin program and \$0.3 million related to our APD811 program for the potential treatment of pulmonary arterial hypertension. Substantially all of the \$4.3 million of total external clinical and preclinical study fees and expenses noted in the table above for the three months ended September 30, 2010 related to our lorcaserin program.

**General and administrative expenses.** General and administrative expenses decreased by \$0.9 million to \$6.0 million for the three months ended September 30, 2011, from \$6.9 million for the three months ended September 30, 2010. This was primarily due to a decrease of \$1.0 million in patent legal fees. We expect that our 2011 general and administrative expenses will be lower than in 2010, primarily as a result of our cost-containment efforts and lower legal fees.

**Amortization of acquired technology and other intangibles.** We recognized \$0.2 million for amortization of acquired technology and other intangibles for the three months ended September 30, 2011, compared to \$0.5 million for the three months ended September 30, 2010. This \$0.3 million decrease was primarily due to reaching the end of the 10-year estimated useful life of the Melanophore screening technology in the first quarter of 2011. The remaining amortization expense relates to the manufacturing facility production licenses we acquired in January 2008, which are being amortized over their estimated useful life of 20 years. Using the exchange rate in effect on September 30, 2011, we expect to record amortization expense of \$0.7 million per year through 2027 for the manufacturing facility production licenses.

**Interest and other expense, net.** Total interest and other expense, net, decreased by \$11.1 million to \$3.4 million for the three months ended September 30, 2011, from \$14.5 million for the three months ended September 30, 2010. Interest expense of \$1.3 million was recognized related to the Deerfield loan for the three months ended September 30, 2011, which included \$0.4 million we paid Deerfield in cash. For the three months ended September 30, 2010, interest expense of \$4.3 million was recognized on the Deerfield loan, which included \$1.5 million we paid Deerfield in cash. Although we expect the debt prepayments of \$20.0 million and \$17.7 million we made in the first quarter of 2011 to reduce our future interest payments by \$3.7 million, we expect that our interest expense will continue to be substantial due to both the \$22.3 million remaining principal balance and accretion on the Deerfield loan and payments on our lease financing obligations. At September 30, 2011, we expect interest expense of \$3.0 million to be paid in cash over the remaining term of the Deerfield loan.

**NINE MONTHS ENDED SEPTEMBER 30, 2011 AND 2010**

**Revenues.** We recognized revenues of \$10.6 million during the nine months ended September 30, 2011, compared to \$12.6 million during the nine months ended September 30, 2010. Our revenues for the nine months ended September 30, 2011 included (i) \$4.4 million under our manufacturing services agreement with Siegfried, which reflects a \$1.1 million reduction related to the loss incurred for services rendered under the agreement, (ii) \$2.9 million from amortization of the \$50.0 million non-refundable, upfront payment we received in July 2010 from Eisai, (iii) \$2.8 million under our marketing and supply agreement with Eisai in reimbursements for additional lorcaserin development work and (iv) \$0.5 million under our former collaboration with Ortho-McNeil-Janssen, primarily for patent activities. Our revenues for the nine months ended September 30, 2010 included (i) \$5.3 million under our manufacturing services agreement with Siegfried, (ii) \$4.0 million of previously deferred revenues under our license agreement with TaiGen, (iii) \$1.9 million for patent activities, primarily under our former collaboration with Ortho-McNeil-Janssen, (iv) \$1.0 million from amortization of the \$50.0 million non-refundable, upfront payment we received from Eisai and (v) \$0.4 million under a license agreement with GlaxoSmithKline LLC and GlaxoSmithKline Research & Development Limited for their use of our Melanophore screening technology.

**Cost of manufacturing services.** We recognized cost of manufacturing services of \$6.2 million and \$5.3 million for the nine months ended September 30, 2011 and 2010, respectively. The amount recognized for the nine months ended September 30, 2011 included \$0.9 million representing the estimated contract loss provision for services expected to be rendered through June 30, 2012 under the amended manufacturing services agreement with Siegfried.

**Research and development expenses.** Research and development expenses decreased \$13.4 million to \$45.6 million for the nine months ended September 30, 2011, from \$59.0 million for the nine months ended September 30, 2010. This was primarily due to decreases of (i) \$5.7 million in salary and personnel costs as a result of our 2011 workforce reduction, (ii) \$4.6 million in external clinical and preclinical study fees and expenses primarily due to completing our Phase 3 clinical trials for lorcaserin, (iii) \$1.7 million in facility and equipment costs, primarily depreciation expense, and (iv) \$1.2 million for use of consultants and contractors. These decreases were partially offset by a \$1.5 million increase in internal research and development manufacturing costs for our Swiss facility due to a decrease in manufacturing services under our agreement with Siegfried that resulted in an increase in our unused manufacturing capacity. Our internal research and development

manufacturing costs include costs related to lorcasein activities as

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well as unused manufacturing capacity. Included in the \$5.4 million of total external clinical and preclinical study fees and expenses for the nine months ended September 30, 2011 was \$2.5 million related to lorcaserin activities, \$1.7 million related to our APD811 program and \$0.7 million related to our APD334 program for the potential treatment of autoimmune diseases, including multiple sclerosis. Included in the \$10.0 million of total external clinical and preclinical study fees and expenses for the nine months ended September 30, 2010 was \$8.8 million related to our lorcaserin program, \$0.5 million related to our APD916 program (which we formerly studied for the potential treatment of narcolepsy with cataplexy and have since abandoned) and \$0.4 million related to our APD811 program.

**General and administrative expenses.** General and administrative expenses decreased \$1.6 million to \$19.0 million for the nine months ended September 30, 2011, from \$20.6 million for the nine months ended September 30, 2010. This was primarily due to decreases of \$0.8 million in legal fees and \$0.6 million in marketing research expenses.

**Restructuring charges.** We recognized \$3.5 million of restructuring charges for the nine months ended September 30, 2011 in connection with one-time employee termination costs, including severance and other benefits related to our 2011 workforce reduction.

**Amortization of acquired technology and other intangibles.** We recognized \$0.8 million for amortization of acquired technology and other intangibles for the nine months ended September 30, 2011, compared to \$1.6 million for the nine months ended September 30, 2010. This was primarily due to reaching the end of the 10-year estimated useful life of the Melanophore screening technology in the first quarter of 2011.

**Interest and other expense, net.** Total interest and other expense, net, decreased by \$1.3 million to \$21.1 million for the nine months ended September 30, 2011, from \$22.4 million for the nine months ended September 30, 2010. This was primarily due a \$5.1 million decrease in interest expense primarily related to the Deerfield loan as a result of principal repayments totaling \$67.7 million that we made since the beginning of 2010. Such decrease was partially offset by a \$4.5 million reduction in the non-cash gain from revaluation of our derivative liabilities. The interest expense recognized in the nine months ended September 30, 2010 included the non-cash correction of prior period errors which resulted in a \$3.0 million decrease to interest expense. The interest expense recognized for the nine months ended September 30, 2011 included \$1.9 million we paid Deerfield in cash, compared to \$5.0 million paid for the nine months ended September 30, 2010.

**Deemed dividend related to beneficial conversion feature of convertible preferred stock.** We recorded a deemed dividend of \$2.3 million in the nine months ended September 30, 2011 upon the issuance of our formerly outstanding Series C Convertible Preferred Stock, or Series C Preferred, related to the beneficial conversion feature of the Series C Preferred. We did not record any such dividends for the nine months ended September 30, 2010, and we do not expect to record any in the future.

## **LIQUIDITY AND CAPITAL RESOURCES**

### *Short term*

As of September 30, 2011, we had \$77.9 million in cash and cash equivalents, which we believe will be sufficient to fund our operations for at least the next 12 months. Other potential sources of liquidity in the short term include (i) entering into collaborative, licensing or commercial agreements for one or more of our drug candidates or programs or our patent portfolios, (ii) equity, debt or other financing, (iii) the sale of facilities we own and (iv) payments from collaborators.

To date, we have obtained cash and funded our operations primarily through the sale of equity, the issuance of debt and related financial instruments, payments from collaborators and sale leaseback transactions. We will continue to be opportunistic in our efforts to obtain cash, and expect to evaluate various funding alternatives on an ongoing basis. There is no guarantee that additional funding will be available or that, if available, such funding will be adequate or available on terms that we or our stockholders view as favorable.

In October 2010, the FDA issued a CRL regarding our NDA for lorcaserin. Our marketing and supply agreement with Eisai provides that Eisai and we will share equally the cost of certain additional development work required by the FDA prior to approval of lorcaserin. We expect to continue to incur expenses in 2011 for development activities in response to the CRL, and such activities could continue beyond 2011. However, we expect that the costs we incur in connection with such response will be substantially less than the external development expenses we incurred for lorcaserin in 2010.

We expect to submit our response to the lorcaserin CRL around the end of 2011. However, if our submission is after January 13, 2012, we will be required to pay the FDA a filing fee of approximately \$1.8 million.

In January 2008, Arena GmbH acquired from Siegfried certain drug product manufacturing assets under an asset purchase agreement, and, in connection with such purchase, Arena GmbH and Siegfried also entered into a manufacturing services agreement. In October 2011, Arena

GmbH paid Siegfried the final payment of CHF 3.3 million, or \$3.7 million, under the asset purchase agreement, as amended. Under the manufacturing services agreement, as amended, Siegfried agrees (i) to order from Arena GmbH 400 million units of drug product for manufacture by Arena GmbH in 2011, (ii) to use its reasonable commercial effort to order from Arena GmbH 200 million units of drug product for manufacture by Arena GmbH from January 1, 2012 to June 30, 2012, and (iii) to reduce its fees for providing Arena GmbH with certain technical and business services. The prices Siegfried will pay per unit of drug product in 2011 and 2012 will generally be less than cost and the amount it paid in 2010, and we expect the cash we receive in 2011 under the manufacturing services agreement will be lower than in 2010.



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Although our September 30, 2011 condensed consolidated balance sheet reflects a total balance of \$13.8 million for our note payable to Deerfield due to the requirement to separately value the components of the note, warrants and related financial instruments, the principal balance outstanding on this loan was \$22.3 million at September 30, 2011.

We are continuing to fund activities in support of obtaining regulatory approval of lorcaserin, and, at the same time, advancing certain of our earlier-stage research and development programs. We expect that our research and development expenditures will continue to be high in 2011, but substantially less than they were in 2010. We are continuing our cost-containment efforts, including through our 2011 workforce reduction. Even with this workforce reduction and other cost-containment efforts, we may not have sufficient cash to meet all of our objectives beyond the next 12 months which, in addition to our primary focus on seeking regulatory approval for lorcaserin, include maintaining our manufacturing capabilities for lorcaserin and select research and development capabilities. If we do not generate sufficient funding, we may need to further eliminate, postpone or scale back some or all of our research and development programs and further reduce our expenses.

We will continue to monitor and evaluate the level of our research, development and manufacturing expenditures, and may further adjust such expenditures based upon a variety of factors, such as our available cash, our ability to obtain additional cash, the results and progress in our lorcaserin and earlier-stage programs, the time and costs related to clinical trials, nonclinical studies and regulatory decisions, as well as the global economic environment.

### *Long term*

We will need substantial cash to achieve our objectives of discovering, developing and commercializing drugs, which typically take many years and potentially several hundreds of millions of dollars to develop. We do not have adequate internal liquidity to meet these objectives in the long term. To do so, we will need to obtain significant funds under our marketing and supply agreement with Eisai, under new collaborative, licensing or commercial agreements for our drug candidates and programs and patent portfolios, or from other potential sources of liquidity, which may include the public and private financial markets.

With respect to lorcaserin, we expect to continue to incur substantial costs, including manufacturing costs, prior to and after receiving marketing approval for lorcaserin, if ever. If lorcaserin is approved for marketing in the United States, we expect Eisai to commercialize lorcaserin under our marketing and supply agreement. With respect to commercializing lorcaserin outside of the United States, we will need additional funds or a collaborative or other agreement with one or more pharmaceutical companies.

In addition to the public and private financial markets, potential sources of liquidity in the long term include revenues based on Eisai's annual net sales of lorcaserin and milestone and other payments under our marketing and supply agreement, if we receive marketing approval, as well as milestone and royalty payments from future collaborators or licensees and revenues from sales of any drugs we commercialize on our own. The length of time that our current cash and cash equivalents and any available borrowings will sustain our operations will be based on, among other things, our prioritization decisions regarding funding for our programs, progress in our clinical and earlier-stage programs, the time and costs related to current and future clinical trials, nonclinical studies and regulatory decisions, our research, development, manufacturing and commercialization costs (including personnel costs), our progress in any programs under collaborations, costs associated with intellectual property, our capital expenditures, and costs associated with securing any in-licensing opportunities. Any significant shortfall in funding may result in us further reducing our development and/or research activities, which, in turn, would affect our development pipeline and ability to obtain cash in the future. If we determine it is advisable to raise additional funds, we do not know whether adequate funding will be available to us or, if available, that such funding will be available on acceptable terms.

The final principal repayment on the Deerfield loan of \$22.3 million is due in June 2013. At any time we may prepay any or all of the outstanding principal at par.

We evaluate from time to time potential acquisitions and in-licensing and other opportunities. Any such transaction may impact our liquidity as well as affect our expenses if, for example, our operating expenses increase as a result of such license or acquisition or we use our cash to finance the license or acquisition.

### *Sources and Uses of Our Cash*

Net cash used in operating activities increased by \$35.6 million to \$62.5 million in the nine months ended September 30, 2011, compared to \$26.9 million in the nine months ended September 30, 2010. This was primarily due to our receipt of the \$50.0 million non-refundable, upfront payment from Eisai in July 2010 and changes in our operating assets and liabilities.

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Net cash of \$0.3 million was used in investing activities during the nine months ended September 30, 2011, primarily for purchases of equipment and improvements to our facilities. Net cash of \$6.4 million was provided by investing activities during the nine months ended September 30, 2010, and was primarily attributable to net proceeds of \$10.0 million from our short-term investments, which were partially offset by \$3.7 million used for equipment and improvements to our facilities. We expect that our 2011 capital expenditures will be less than the 2010 amount due to our continuing cost-containment efforts.

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Net cash of \$10.2 million was used in financing activities during the nine months ended September 30, 2011, primarily due to principal repayments to Deerfield of \$20.0 million and \$17.7 million in January 2011 and March 2011, respectively, and \$7.3 million paid to Siegfried in 2011 in the nine months ended September 30, 2011. These repayments were partially offset by net proceeds of \$35.3 million from the sale of 12,150,000 shares of common stock and 12,150 shares of formerly outstanding Series C Preferred to Deerfield in March 2011. Net cash of \$89.8 million was provided by financing activities during the nine months ended September 30, 2010, primarily due to net proceeds of \$35.5 million from the sale of 11.0 million shares of common stock and the exchange of warrants to Deerfield, net proceeds of \$30.0 million, after the \$30.0 million principal prepayment, from the sale of approximately 9.0 million shares of common stock to Deerfield and net proceeds of \$24.2 million from the sale of approximately 8.3 million shares of common stock under an equity financing commitment we had with Azimuth Opportunity Ltd.

**CRITICAL ACCOUNTING POLICIES AND MANAGEMENT ESTIMATES**

The SEC defines critical accounting policies as those that are, in management's view, important to the portrayal of our financial condition and results of operations and demanding of management's judgment. Our discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with US generally accepted accounting principles, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosures. We base our estimates on historical experience and on various assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ significantly from those estimates.

Our critical accounting policies include:

**Revenue recognition.** Our revenues to date have been generated primarily through collaborative agreements and a manufacturing services agreement. Our collaborative agreements can include multiple elements including licenses, research services and manufacturing. Consideration we receive under these arrangements may include upfront payments, research funding and milestone payments. For our multiple element transactions, if fair value exists for the undelivered and delivered elements whereby such elements have stand-alone value, we allocate the consideration to the elements based on their relative fair values. In cases where fair value exists for the undelivered elements but does not exist for the delivered elements, we use the residual method to allocate the arrangement consideration. In cases where fair value does not exist for the undelivered elements in an arrangement, we account for the transaction as a single unit of accounting. We typically defer non-refundable upfront payments under our collaborations and recognize them over the period in which we have significant involvement or perform services, using various factors specific to each collaboration. Amounts we receive for research funding for a specified number of full-time researchers are recognized as revenue as the services are performed. Revenue from a milestone payment is recognized when earned, as evidenced by acknowledgment from our collaborator, provided that (i) the milestone event is substantive and its achievability was not reasonably assured at the inception of the agreement, (ii) the milestone represents the culmination of an earnings process, (iii) the milestone payment is non-refundable and (iv) our performance obligations after the milestone achievement will continue to be funded by our collaborator at a level comparable to the level before the milestone achievement. If all of these criteria are not met, the milestone payment is recognized over the remaining minimum period of our performance obligations under the agreement. Any advance payments we receive in excess of amounts earned are classified as deferred revenues until earned.

We manufacture drug products under a manufacturing services agreement for a single customer, Siegfried. Upon Siegfried's acceptance of drug products manufactured by us, we recognize manufacturing services revenues at agreed upon prices for such drug products. We have also contracted with Siegfried for them to provide us with administrative and other services in exchange for a fee paid to Siegfried. We determined that we are receiving an identifiable benefit for these services from Siegfried, and are recording such fees in the operating expense section of our consolidated statement of operations.

**Clinical trial expenses.** We accrue clinical trial expenses based on work performed. In determining the amount to accrue, we rely on estimates of total costs incurred based on the enrollment of subjects, the completion of trials and other events. We follow this method because we believe reasonably dependable estimates of the costs applicable to various stages of a clinical trial can be made. However, the actual costs and timing of clinical trials are highly uncertain, subject to risks and may change depending on a number of factors. Differences between the actual clinical trial costs and the estimated clinical trial costs that we have accrued in any prior period are recorded in the subsequent period in which the actual costs become known. Historically, these differences have not been material; however, material differences could occur in the future.

**Derivative liabilities.** We account for our warrants and other derivative financial instruments as either equity or liabilities based upon the characteristics and provisions of each instrument. Warrants classified as equity are recorded as additional paid-in capital on our consolidated balance sheet and no further adjustments to their valuation are made. Some of our warrants were determined to be ineligible for equity classification because of provisions that may result in an adjustment to their exercise price. Warrants classified as derivative liabilities and other derivative financial instruments that require separate accounting as liabilities are recorded on our consolidated balance sheet at their fair value on

the date of issuance and will be revalued on each subsequent balance sheet date until such instruments are exercised or expire, with any changes in the fair value between reporting periods recorded as other income or expense. We estimate the fair value of these liabilities using option pricing models that are based on the individual characteristics of the warrants or instruments on the valuation date, as well as assumptions for expected volatility, expected life and risk-free interest rate. Changes in the assumptions used could have a material impact on the resulting fair value.

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**Share-based compensation.** We recognize compensation expense for all of our share-based awards based on the grant-date fair value. We determine the grant-date fair value of share-based awards by using the Black-Scholes option pricing model, which is affected by our stock price on the date of grant, as well as assumptions regarding other subjective variables. These assumptions include, but are not limited to, our expected stock price volatility over the term of the awards, the risk-free interest rate and the expected term of awards. Changes in the assumptions used could have a material impact on the compensation expense we recognize.

Stock-based compensation expense recognized is based on awards ultimately expected to vest, and, therefore, is reduced by expected forfeitures. We estimate forfeitures based upon historical forfeiture rates, and will adjust our estimate of forfeitures if actual forfeitures differ, or are expected to differ, from such estimates. Changes in estimated forfeitures will be recognized through a cumulative adjustment in the period of the change and will also impact the amount of stock-based compensation expense in future periods.

**Accounting for lease financing obligations.** We account for our sale and leaseback transactions using the financing method because our options to repurchase these properties in the future are considered continued involvement requiring such method. Under the financing method, the book value of the properties and related accumulated depreciation remain on our balance sheet and no sale is recognized. Instead, the sales price of the properties is recorded as a financing obligation, and a portion of each lease payment is recorded as interest expense. We estimated the borrowing rate that we use to impute interest expense on our lease payments.

*The above listing is not intended to be a comprehensive list of all of our accounting policies. In many cases, the accounting treatment of a particular transaction is specifically dictated by GAAP. See our audited consolidated financial statements and notes thereto included in our 2010 Annual Report, which contain additional accounting policies and other disclosures required by GAAP.*

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

There have been no material changes from the information we included in this section of our annual report on Form 10-K for the year ended December 31, 2010.

### **Item 4. Controls and Procedures.**

Based on an evaluation carried out as of the end of the period covered by this quarterly report, under the supervision and with the participation of our management, including our President and Chief Executive Officer and Vice President, Finance and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures, our President and Chief Executive Officer and Vice President, Finance and Chief Financial Officer have concluded that, as of the end of such period, our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934) were effective at the reasonable assurance level. There was no change in our internal control over financial reporting that occurred during the quarter covered by this quarterly report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## **PART II. OTHER INFORMATION**

### **Item 1. Legal Proceedings.**

Beginning on September 20, 2010, a number of complaints were filed in the US District Court for the Southern District of California against us and certain of our current and former employees and directors on behalf of certain purchasers of our common stock. The complaints have been brought as purported stockholder class actions, and, in general, include allegations that we and certain of our current and former employees and directors violated federal securities laws by making materially false and misleading statements regarding our lorcaserin program, thereby artificially inflating the price of our common stock. The plaintiffs are seeking unspecified monetary damages and other relief. On November 19, 2010, eight prospective lead plaintiffs filed motions to consolidate, appoint a lead plaintiff, and appoint lead counsel. The Court took the motions to consolidate under submission on January 14, 2011. On August 8, 2011, the Court consolidated the actions and appointed a lead plaintiff and lead counsel. On November 1, 2011, the lead plaintiff filed a consolidated amended complaint. Our response to the consolidated amended complaint is due on December 30, 2011. In addition to the class actions, a complaint involving similar legal and factual issues has been brought by at least one individual stockholder and is pending in federal court. Our response to the individual stockholder's complaint is also due on December 30, 2011. We intend to defend against the claims advanced and to seek dismissal of these complaints. Due to the early stage of these proceedings, we are not able to predict or reasonably estimate the ultimate outcome or possible losses relating to these claims.

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On September 24, 2010, a stockholder derivative complaint was filed in the Superior Court of California for the County of San Diego against certain of our current and former employees and directors, and other stockholder derivative complaints were subsequently filed in state court. On October 19, 2010, the Superior Court ordered that the pending state derivative actions be consolidated. The Superior Court also ordered that later filed, related state derivative actions be consolidated as well. We refer to the consolidated state derivative actions as the State Derivative Action. In November 2010, plaintiffs in the State Derivative Action filed a consolidated stockholder

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derivative complaint. We filed a demurrer to the consolidated stockholder derivative complaint on February 15, 2011. On October 6, 2010, a stockholder derivative complaint was filed in the US District Court for the Southern District of California. Thereafter, a number of other stockholder derivative complaints were also filed in federal court. On March 3, 2011, the federal court ordered that the pending federal derivative actions be consolidated. The federal court also ordered that later filed, related federal derivative actions be consolidated as well. We refer to the consolidated federal derivative actions as the Federal Derivative Action. We refer to the State Derivative Action and the Federal Derivative Action collectively as the Derivative Actions. The Derivative Actions allege breaches of fiduciary duties by the defendants and other violations of law. In general, the Derivative Actions allege that certain of our current and former employees and directors caused or allowed for the dissemination of materially false and misleading statements regarding our lorcaserin program, thereby artificially inflating the price of our common stock. On September 9, 2011, we and lead counsel for the plaintiffs in the Derivative Actions entered into a stipulation of settlement that will resolve the Derivative Actions. The current and former employees and directors named as individual defendants in the Derivative Actions have also entered into the stipulation of settlement. On October 19, 2011, the Superior Court of California entered an order preliminarily approving the proposed settlement. The proposed settlement is subject to final approval by the Superior Court of California. Subject to final approval of the settlement by the Superior Court of California, and in exchange for a release of all claims by the plaintiffs, among others, and a dismissal of the Derivative Actions, we have agreed (i) to adopt certain corporate governance measures and (ii) to cause our insurers to pay the plaintiffs' attorneys a total of \$1.1 million.

### **Item 1A. Risk Factors.**

#### **RISK FACTORS**

*Investment in our stock involves a high degree of risk. You should consider carefully the risks described below, together with other information in this quarterly report on Form 10-Q and our other public filings, before making investment decisions regarding our stock. If any of the following events actually occur, our business, operating results, prospects or financial condition could be materially and adversely affected. This could cause the trading price of our common stock to decline and you may lose all or part of your investment. Moreover, the risks described below are not the only ones that we face. Additional risks not presently known to us or that we currently deem immaterial may also affect our business, operating results, prospects or financial condition.*

*The risk factors set forth below with an asterisk (\*) before the title are risk factors containing substantive changes, including any material changes, from the risk factors previously disclosed in Item 1A to Part I of our annual report on Form 10-K for the year ended December 31, 2010, as filed with the Securities and Exchange Commission, or SEC.*

#### ***Risks Relating to Our Business***

**\*We will need additional funds to conduct our planned research, development and commercialization efforts, we may not be able to obtain such funds and we may never become profitable.**

We have accumulated a large deficit since inception that has primarily resulted from the significant research and development expenditures we have made in seeking to identify and validate new drug targets and develop compounds that could become marketed drugs. We expect that our losses and operating expenses will continue to be substantial, even if we are successful in advancing our most advanced drug candidate, lorcaserin, including under our marketing and supply agreement with Eisai Inc., or Eisai, or our other compounds and drug candidates, independently or with another company.

We do not have any commercially available drugs, and may not have adequate funds to develop our compounds into marketed drugs. It takes many years and potentially hundreds of millions of dollars to successfully develop a preclinical or early clinical compound into a marketed drug, and our efforts may not result in any marketed drugs.

Our wholly owned subsidiary, Arena Pharmaceuticals GmbH, or Arena GmbH, has entered into a marketing and supply agreement with Eisai for the commercialization of lorcaserin in the United States and its territories and possessions following approval by the US Food and Drug Administration, or FDA, of our lorcaserin New Drug Application, or NDA. We will need additional funds or a collaborative or other agreement with a pharmaceutical company or companies to commercialize lorcaserin outside of the United States, and we may not be able to secure adequate funding or find a pharmaceutical company to commercialize lorcaserin outside the United States at all or on terms we or others believe are favorable. Even if we receive approval of our lorcaserin NDA and commence commercialization of lorcaserin under our marketing and supply agreement with Eisai, we cannot assure you that any additional payments we receive under such agreement will be sufficient to fund our planned research and development and other activities or to result in profitability. We also believe that it may be difficult for us to obtain additional financing or enter into strategic relationships on terms that we or third parties, including investors, analysts, or potential collaborators,

view as acceptable, if at all. If adequate funding is not available, we may eliminate or postpone or scale back some or all of our research or development programs or delay the advancement of one or more of such programs. Any such reductions may adversely impact our lorcasein development and commercialization timeline or narrow or slow the development of our pipeline, which we believe would reduce our opportunities for success and result in a decline in the market price of our common stock. We will continue to be opportunistic in our efforts to obtain cash, and expect to evaluate various financing alternatives on an ongoing basis. If we do obtain additional funding through equity sales, your ownership may be substantially diluted and it may result in a decline in the market price of our common stock.



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**\*We are focusing a significant portion of our activities and resources on lorcaserin and depend on its marketing approval and commercial success.**

We are focusing a significant portion of our activities and resources on lorcaserin, and we believe a significant portion of the value of our company relates to our ability to obtain marketing approval for, and commercialize, this drug candidate. The marketing approval and successful commercialization of lorcaserin is subject to many risks, including the risks discussed in other risk factors. If the results of clinical trials and preclinical studies of lorcaserin, our and regulatory authorities' actions and decisions related to lorcaserin, the anticipated or actual timing and plan for commercializing lorcaserin, or, ultimately, the market acceptance of lorcaserin do not meet our, your, analysts' or others' expectations, the market price of our common stock could decline significantly. For example, in October 2010, the FDA issued a Complete Response Letter, or CRL, regarding our NDA for lorcaserin. In the CRL, the FDA stated that it completed its review of the NDA and determined that it could not approve the application in its present form.

We are working to submit our response to the lorcaserin CRL, including by conducting additional studies, and we expect to make such submission around the end of 2011. However, such submission may take up to an additional year or more, depending on the timing and results of our ongoing and planned activities, guidance and feedback from the FDA, and the need for any additional studies, trials or other activities. For example, we believe that prolactin studies of both three months and shorter duration will be sufficient to test the hypothesis that lorcaserin causes mammary tumors in rats by increasing prolactin effects on the mammary gland, and we currently do not plan to initiate the 12-month study in female rats the FDA asked us to consider. The FDA has expressed concern that the three-month duration may not be adequate to address issues it identified, which may necessitate longer duration studies.

Our response to the CRL may require other nonclinical studies or clinical trials in addition to the studies and trials we plan to include in our response, may not be submitted in a timely manner or the data and other information provided or learned in connection with such response may not be satisfactory to the FDA, including with regard to demonstrating adequate safety and efficacy for regulatory approval. We will make assumptions, estimations and calculations as part of our analysis of data and our response to the CRL, and the FDA may not accept or agree with our assumptions, estimations, calculations or analysis or may interpret or weigh the importance of data differently, which could result in the FDA reaching different conclusions. In addition, the FDA may request additional information or have additional recommendations prior to approval of our NDA for lorcaserin, and lorcaserin may never receive marketing approval from the FDA or any other regulatory agency. We may ultimately determine not to submit a response to the CRL.

**\*Our ability to generate significant revenues, for at least the short term, depends upon the regulatory approval of lorcaserin, the commercialization of lorcaserin, activities and payments under the marketing and supply agreement with Eisai and our entry into new collaborations.**

We expect that, for at least the short term, our ability to generate significant revenues will depend on the regulatory approval of lorcaserin, the success of Eisai in commercializing lorcaserin, if approved, in the United States, and our ability to enter into new collaborations. Future revenues under our marketing and supply agreement with Eisai will depend on the achievement of milestones under the agreement and Eisai's commercialization of lorcaserin, and, other than possible reimbursement for pre-approval development work, we may receive no additional revenues from Eisai if our NDA for lorcaserin is not approved by the FDA or further development of lorcaserin is unfavorable. In addition, we intend to commercialize lorcaserin outside of the United States with one or more pharmaceutical companies or independently. Lorcaserin may not be approved for sale outside of the United States, and, even if it is approved, we or any collaborator may not be successful in commercializing lorcaserin outside of the United States.

We cannot guarantee that any development, approval or sales milestones in our existing or future collaborations will be achieved in the future, or that we will receive any payments for the achievement of any milestones or product sales. In addition, our marketing and supply agreement with Eisai may be terminated early in certain circumstances, in which case we may not receive milestone or other payments under the agreement.

Moreover, our ability to enter into new collaborations may depend on the outcomes of our preclinical and clinical testing. We do not control these outcomes. In addition, even if our testing is successful, pharmaceutical companies may not enter into agreements with us on terms that we believe are acceptable until we have advanced our drug candidates into the clinic and, possibly, through later-stage clinical trials, approval or successful commercialization, if at all. With respect to lorcaserin, our ability to enter into additional collaborative agreements may also depend on the FDA's approval of our NDA for lorcaserin as well as our interactions with, and decisions by, regulatory agencies outside of the United States.

**\*Our development and commercialization of lorcaserin may be adversely impacted by cardiovascular side effects previously associated with fenfluramine and dexfenfluramine.**

We developed lorcaserin to more selectively stimulate the serotonin 2C receptor than did fenfluramine or dexfenfluramine because we believe this may avoid the cardiovascular side effects associated with fenfluramine and dexfenfluramine (often used in combination with phentermine, the combination of which was commonly referred to as fen-phen ). These two drugs were serotonin-releasing agents and non-selective serotonin receptor agonists, and were withdrawn from the market in 1997 after reported incidences of heart valve disease and pulmonary hypertension associated with their usage. In *in vitro* studies examining affinity, activity and serotonin receptor subtype specificity, lorcaserin demonstrated affinity for, and activity at, serotonin 2A, 2B and 2C receptors, but demonstrated

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greater affinity, activity and selectivity for the serotonin 2C receptor than for the serotonin 2A and 2B receptors. Activation of the latter two receptors has been associated with undesirable effects. Activation of the 2A receptor has been associated with central nervous system, or CNS, effects, including altered perception, mood and abuse potential, and activation of the 2B receptor has been associated with cardiac valvulopathy.

We may not be correct in our belief that more selectively stimulating the serotonin 2C receptor will avoid these undesired side effects, or lorcaserin's selectivity profile may not be adequate to avoid these side effects. Lorcaserin's selectivity profile and the potential relationship between the activity of lorcaserin and the activity of fenfluramine and dexfenfluramine may result in increased FDA regulatory scrutiny of the safety of lorcaserin and may raise potential adverse publicity, which could affect enrollment of any future clinical trials or sales if lorcaserin is approved for commercialization.

Our two large pivotal Phase 3 lorcaserin trials of one and two years' duration, BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management) and BLOSSOM (Behavioral modification and Lorcaserin Second Study for Obesity Management) supported our original NDA submission for lorcaserin. Data from these two trials, including the proportions of patients that developed FDA-defined valvulopathy, were included in the original NDA. There are different ways of analyzing the valvulopathy data from our trials. The pre-specified statistical analysis plan for the NDA provided that the risk difference between lorcaserin and placebo using Baseline and Week 52 echocardiograms would be evaluated using a non-inferiority model that would rule out a greater than 50% increase over the assumed placebo risk of FDA-defined valvulopathy. The assumed placebo risk of FDA-defined valvulopathy was derived from the Data Safety Monitoring Board, or DSMB, interim review of six-month data from the BLOOM trial. Using this analysis, the combined data from the BLOOM and BLOSSOM trials demonstrated that lorcaserin was non-inferior to placebo. Using a relative risk analysis of the Baseline and Week 52 data, which the FDA has used previously and may favor over the above analysis, these trials ruled out an increase of more than 55% in the relative risk for FDA-defined valvulopathy with lorcaserin. We plan to integrate into our response to the CRL the results of our one-year, Phase 3 BLOOM-DM (Behavioral modification and Lorcaserin for Overweight and Obesity Management in Diabetes Mellitus) trial of lorcaserin, which include additional data relating to heart valves and pulmonary artery pressures. Using the analysis of risk difference that we used for our original NDA, the pooled data from the BLOOM, BLOSSOM and BLOOM-DM trials would rule out a greater than 50% increase over the assumed placebo risk of FDA-defined valvulopathy. Using a relative risk analysis, the pooled data from all three trials ruled out an increase of more than 67% in the relative risk of FDA-defined valvulopathy. Statistical methods that consider all echocardiograms rather than restricting the analysis to Baseline and Week 52 produced risk ratio or hazard ratio estimates of 1.08 – 1.09, ruling out a 44% increase in risk. Our Phase 3 trials were not designed to rule out a risk for pulmonary hypertension, which due to the rarity of this event would require a very large database.

We cannot guarantee that the FDA will find the data relating to heart valves and pulmonary artery pressures supportive of approval. In addition, our plans for our response to the CRL for lorcaserin include conducting nonclinical studies, including receptor pharmacology studies. At the FDA's recommendation, we will include in our response to the CRL additional receptor pharmacology studies to more fully characterize lorcaserin's activity at the serotonin 2A, 2B and 2C receptors. The FDA may not find our data favorable, may request additional data or other information or analysis, may decline to approve our NDA for lorcaserin, or may impose post-approval requirements that adversely impact the commercialization of lorcaserin. For example, the FDA could require additional preclinical studies or clinical trials pre- or post-approval to continue to assess risks relating to cardiac or other side effects, or the FDA could require screening or follow-up echocardiograms for patients being prescribed lorcaserin.

**We are dependent on the marketing and supply agreement with Eisai to commercialize lorcaserin in the United States and, if applicable, to further develop lorcaserin, and the failure to maintain such agreement, or poor performance under such agreement, could negatively impact our business.**

Our ability to generate payments under our marketing and supply agreement with Eisai substantially depends on the regulatory approval and market acceptance of lorcaserin in the United States. Eisai has primary responsibility for the marketing and sale of lorcaserin in the United States and responsibility for compliance with certain US regulatory requirements, and we have limited control over the amount and timing of resources that Eisai will dedicate to the commercialization of lorcaserin. In March 2011, Eisai announced plans to realign its operations in the United States, including reducing its workforce by approximately 20% across all US functions by April 1, 2011. Such realignment and workforce reduction may have a negative impact on our marketing and supply agreement with Eisai, including on Eisai's performance of its obligations under the agreement.

We are subject to a number of other risks associated with our dependence on our marketing and supply agreement, including:

Eisai may not comply with applicable regulatory guidelines with respect to commercializing lorcaserin, which could adversely impact sales or any development of lorcaserin;

there could be disagreements regarding the agreement or the development of lorcaserin, including activities in response to the lorcaserin CRL, that delay or terminate the research, development or commercialization of lorcaserin, delay or eliminate potential payments under the agreement or increase our costs under the agreement; or

Eisai may not perform as expected, including with regard to making payments under the agreement, and such agreement may not provide adequate protection or may not be effectively enforced.

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Eisai and we each have the right to terminate the agreement in certain circumstances. Eisai and we could also agree to amend the terms of the agreement, and we or others, including investors and analysts, may not view the amendments as favorable. If the agreement is terminated early, we may not be able to find another company to further develop and commercialize lorcasearin in the United States on acceptable terms, if at all, and even if we elected to pursue further development or commercialization of lorcasearin on our own, we might not have the funds, or otherwise be able, to do so successfully.

We may enter into additional agreements for the commercialization of lorcasearin or other of our drug candidates, and may be similarly dependent on the performance of third parties with similar risk.

### **Negative global economic conditions may pose challenges to our business strategy, which relies on access to capital from the markets or collaborators, and creates other financial risks for us.**

Negative conditions in the global economy, including credit markets and the financial services industry, have generally made equity and debt financing more difficult to obtain, and may negatively impact our ability to complete financing transactions. The duration and severity of these conditions is uncertain, as is the extent to which they may adversely affect our business and the business of current and prospective vendors or our distributors, licensees and collaborators, which we sometimes refer to generally as our collaborators. If negative global economic conditions persist or worsen, we may be unable to secure additional funding to sustain our operations or to find suitable collaborators to advance our internal programs, even if we achieve positive results from our research and development or business development efforts.

From time to time, we may maintain a portfolio of investments in marketable debt securities, which are recorded at fair value. Although we have established investment guidelines relative to diversification and maturity with the objectives of maintaining safety of principal and liquidity, we rely on credit rating agencies to help evaluate the riskiness of investments, and such agencies may not accurately predict such risk. In addition, such agencies may reduce the credit quality of our individual holdings, which could adversely affect their value. Lower credit quality and other market events, such as changes in interest rates and further deterioration in the credit markets, may have an adverse effect on the fair value of our investment holdings and cash position.

### **\*We and certain of our current and former employees and directors have been named as defendants in litigation that could result in substantial costs and divert management's attention.**

Beginning in September 2010, a number of lawsuits were filed against us and certain of our employees and directors on behalf of certain purchasers of our common stock. The lawsuits in general include allegations that we and certain of our employees and directors violated laws by making materially false and misleading statements regarding our lorcasearin trials, thereby artificially inflating the price of our common stock. The plaintiffs are seeking unspecified monetary damages and other relief. Several derivative lawsuits also have been filed.

There is no guarantee that we will be successful in defending these lawsuits. Also, our insurance coverage may be insufficient, our assets may be insufficient to cover any amounts that exceed our insurance coverage, and we may have to pay damage awards or otherwise may enter into settlement arrangements in connection with such claims. Any such payments or settlement arrangements could have material adverse effects on our business, operating results or financial condition. Even if the plaintiffs' claims are not successful, this litigation could result in substantial costs and significantly and adversely impact our reputation and divert management's attention and resources, which could have a material adverse effect on our business, operating results or financial condition. In addition, such lawsuits may make it more difficult to finance our operations, obtain certain types of insurance (including directors and officers liability insurance), and attract and retain qualified executive officers, other employees and directors.

### **\*Our stock price could decline significantly based on the results and timing of clinical trials and preclinical studies of, and decisions affecting, our most advanced drug candidates.**

The results and timing of clinical trials and preclinical studies can affect our stock price. Preclinical studies include experiments performed in test tubes, in animals, or in cells or tissues from humans or animals. These studies, which are sometimes referred to as nonclinical studies, include all drug studies except those conducted in human subjects, and may occur before or after initiation of clinical trials for a particular compound. Results of clinical trials and preclinical studies of lorcasearin or our other drug candidates may not be viewed favorably by us or third parties, including investors, analysts, current or potential collaborators, the academic and medical communities, and regulators. The same may be true of how we design the development programs of our most advanced drug candidates and regulatory decisions (including by us or regulatory authorities) affecting those development programs. Stock prices of companies in our industry have declined significantly when such results and decisions were unfavorable or perceived negatively or when a drug candidate did not otherwise meet expectations.

From time to time we have drug programs in clinical trials. In addition to successfully completing clinical trials, to conduct long-term clinical trials and gain regulatory approval to commercialize drug candidates, regulatory authorities require that all drug candidates complete short- and long-term preclinical toxicity and carcinogenicity studies. These preclinical, animal studies are required to help us and regulatory authorities assess the potential risk that drug candidates may be toxic or cause cancer in humans. The results of clinical trials and preclinical studies are uncertain and subject to different interpretations, and the design of these trials and studies (which may change significantly and be more expensive than anticipated depending on results and regulatory decisions) may also be viewed negatively by us, regulatory authorities or other third parties and adversely impact the development and opportunities for regulatory approval and commercialization of our drug candidates and those under collaborative agreements.

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For example, we conducted long-term carcinogenicity preclinical studies of lorcaserin. In the CRL for lorcaserin, the FDA identified issues related to such studies. We intend to provide in our response to the CRL data and other information to support our view related to such issues, but the FDA may disagree with our view or impose conditions that could significantly delay or preclude approval of our lorcaserin NDA.

We may not be successful in advancing our programs on our projected timetable, if at all. Failure to initiate or delays in the development programs for any of our drug candidates, or unfavorable results or decisions or negative perceptions regarding any of such programs, could cause our stock price to decline significantly. This is particularly the case with respect to lorcaserin.

We may report top-line data from time to time, which is based on a preliminary analysis of then-available efficacy and safety data, and such findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. In addition, we make assumptions, estimations and calculations as part of our analysis of data, and others, including regulatory agencies, may not accept or agree with our assumptions, estimations, calculations or analysis or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability of the particular drug candidate and our company in general.

**\*We have significant indebtedness and debt service obligations as a result of our Deerfield secured loan, which may adversely affect our cash flow, cash position and stock price.**

In July 2009, we received under a facility agreement, or the Facility Agreement, a loan from Deerfield Private Design Fund, L.P., Deerfield Private Design International, L.P., Deerfield Partners, L.P., Deerfield International Limited, Deerfield Special Situations Fund, L.P., and Deerfield Special Situations Fund International Limited, or collectively Deerfield, which substantially increased our total debt and debt service obligations. This loan matures on June 17, 2013, and the outstanding principal, which is \$22.3 million, accrues interest at a rate of 7.75% per annum on the stated principal balance, payable quarterly in arrears. Unless paid earlier, we are required to repay the outstanding principal at maturity.

We may be required to repay the outstanding debt earlier under certain circumstances. For example, we are required to repay the loan upon certain changes of control. The Facility Agreement also places certain restrictions on our business, including our ability to incur additional indebtedness and to undertake certain business transactions.

In the future, if we are unable to generate cash from operations sufficient to meet this debt obligation, we will need to obtain additional funds from other sources, which may include one or more financings. However, we may be unable to obtain sufficient additional funds when we need them on favorable terms or at all. The sale of equity or convertible debt securities in the future may be dilutive to our stockholders, and debt-financing arrangements may require us to enter into covenants that would further restrict certain business activities or our ability to incur additional indebtedness, and may contain other terms that are not favorable to our stockholders or us.

Also, if we are unable to generate cash from operations or obtain additional funds from other sources sufficient to meet this debt obligation, or we need to use existing cash to fund this debt obligation, we may have to delay or curtail some or all of our research, development and commercialization programs or sell or license some or all of our assets. Our indebtedness could have significant additional negative consequences, including, without limitation:

increasing our vulnerability to general adverse economic conditions;

limiting our ability to obtain additional funds; and

placing us at a possible competitive disadvantage to less leveraged competitors and competitors that have better access to capital resources.

If an event of default occurs under our loan documents, including in certain circumstances under the warrants issued in connection with the loan, the lenders may declare the outstanding principal balance and accrued but unpaid interest owed to them immediately due and payable, which would have a material adverse affect on our financial position. We may not have sufficient cash to satisfy this obligation. Also, if a default occurs under our secured loan, and we are unable to repay the lenders, the lenders could seek to enforce their rights under their security interests in our assets. If this were to happen, we may lose or be forced to sell some or all of our assets to satisfy our debt, which could cause our business to fail.

**If we do not commercialize lorcaserin outside of the United States with one or more pharmaceutical companies or raise additional funds, we may have to commercialize lorcaserin outside of the United States on our own and curtail certain of our activities.**

We expect to commercialize lorcaserin outside of the United States, following regulatory approval, with one or more pharmaceutical companies or independently. We may not be able to enter into agreements to commercialize lorcaserin outside of the United States on acceptable terms, if at all. If we are unable to enter into such agreements, and we develop our own capabilities to commercialize lorcaserin outside of the United States, we may require additional capital to develop such capabilities and the marketing and sale of



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lorcaserin outside of the United States may be delayed or limited. Even if we were able to develop our own commercialization capabilities, we have not previously commercialized a drug, and our limited experience may make us less effective at marketing and selling lorcaserin than a pharmaceutical company. Our lack of corporate experience and adequate resources may impede our efforts to successfully commercialize lorcaserin.

We face competition in our search for pharmaceutical companies to commercialize lorcaserin outside of the United States. In addition, if our competitors are able to establish commercialization arrangements with companies who have substantially greater resources than we have (or, with respect to commercializing lorcaserin in the United States, Eisai has), our competitors may be more successful in marketing and selling their drugs, and our ability to successfully commercialize lorcaserin will be limited.

**\*Our drug candidates are subject to extensive regulation, and we may not receive required regulatory approvals, or timely approvals, for any of our drug candidates.**

The preclinical, clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, marketing and distribution, and other possible activities relating to our drug candidates are, and any resulting drugs will be, subject to extensive regulation by the FDA and other regulatory agencies. We are subject to periodic unannounced inspections by the FDA, the Drug Enforcement Administration of the US Department of Justice, or DEA, and other regulatory agencies in the United States, and are also subject to inspections at Arena GmbH by the FDA, Swissmedic and other regulatory agencies. Swissmedic, a public service organization of the Swiss federal government, is the central Swiss agency for the authorization and supervision of therapeutic products. Failure to comply with FDA and other applicable regulatory requirements may, either before or after product approval, if any, subject our company to administrative or judicially imposed sanctions that may delay the advancement or potential approval of our drug candidates or otherwise negatively impact our business. Regulatory agencies have in the past inspected certain aspects of our business in the United States and Switzerland, and we were provided with observations of objectionable conditions or practices with respect to our business in the United States. We believe we satisfactorily addressed such observations, but there is no assurance that regulatory agencies will not provide us with observations in future inspections or that we satisfactorily addressed observations provided to us in past inspections.

Neither collaborators nor we are permitted to market a drug candidate in the United States until the particular drug candidate is approved for marketing by the FDA. Specific preclinical data, chemistry, manufacturing and controls data, a proposed clinical trial protocol and other information must be submitted to the FDA as part of an investigational new drug, or IND, application, and clinical trials may commence only after the IND application becomes effective. None of our drug candidates has received marketing approval. To market a new drug in the United States, we must submit to the FDA and obtain FDA approval of an NDA. An NDA must be supported by extensive clinical and preclinical data, as well as extensive information regarding chemistry, manufacturing and controls to demonstrate the safety and effectiveness of the drug candidate. Following its review of an NDA or a response to a CRL, the FDA may approve the NDA or issue a CRL.

Obtaining approval of an NDA can be a lengthy, expensive and uncertain process. As part of the Prescription Drug User Fee Act, or PDUFA, the FDA has a goal to review and act on a percentage of all submissions in a given time frame. The FDA's review goals are subject to change, and it is unknown whether any particular FDA review will be completed within the FDA's review goals or will be delayed. Moreover, the duration of the FDA's review may depend on the number and types of other submissions with the FDA around the same time period. The review of such other submissions may impact the regulatory review of our submissions related to lorcaserin. Furthermore, any drug that acts on the CNS, such as lorcaserin, has the potential to be scheduled as a controlled substance by the DEA. DEA scheduling is an independent process that can delay drug launch beyond an NDA approval date. DEA scheduling ranges from I to V, with I being the most tightly controlled category. The FDA has expressed concern over the abuse potential of lorcaserin and the data included in our original NDA related to such potential, and has recommended that we, as part of our response to the CRL for lorcaserin, modify and repeat two nonclinical studies to provide additional safety information for labeling and scheduling decisions. If lorcaserin were to be scheduled in a tightly controlled category, such scheduling could negatively impact the ability or willingness to prescribe or dispense lorcaserin, the likelihood that patients will use it and other aspects of our and Eisai's ability to commercialize it.

Regulatory approval of an NDA or NDA supplement is not guaranteed. The number and types of preclinical studies and clinical trials that will be required for FDA approval varies depending on the drug candidate, the disease or condition that the drug candidate is designed to target and the regulations applicable to any particular drug candidate. Despite the time and expense exerted in preclinical and clinical studies, failure can occur at any stage, and we could encounter problems that cause us to abandon clinical trials or to repeat or perform additional preclinical studies and clinical trials. The FDA can delay, limit or deny approval of a drug candidate for many reasons, including:

a drug candidate may not be deemed adequately safe and effective;

FDA officials may not find the data from preclinical studies and clinical trials sufficient;

the FDA's interpretation and our interpretation of data from preclinical studies and clinical trials may differ significantly;

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our or our contractors or collaborators failure to comply with applicable FDA and other regulatory requirements, including those identified in other risk factors;

the FDA may not approve the manufacturing processes or facilities;

the FDA may change its approval policies or adopt new regulations; or

the FDA may not accept an NDA or other submission due to, among other reasons, the content or formatting of the submission. With respect to lorcaserin, the FDA draft guidance document *Developing Products for Weight Management* dated February 2007 provides two alternate benchmarks for the development of drugs for the indication of weight management. The guidance provides that, in general, a product can be considered effective for weight management if after one year of treatment either of the following occurs: (1) the difference in mean weight loss between the active-product and placebo-treated groups is at least 5% and the difference is statistically significant, or (2) the proportion of patients who lose at least 5% of baseline body weight in the active-product group is at least 35%, is approximately double the proportion in the placebo-treated group, and the difference between groups is statistically significant. While we believe the results of our Phase 3 clinical trials of lorcaserin satisfy the latter of the two alternate efficacy benchmarks, the FDA may disagree with our view, not follow its draft guidance or impose other approval conditions that could delay or preclude approval of our lorcaserin NDA. For example, the FDA stated in the CRL for lorcaserin that the weight loss efficacy of lorcaserin in obese and overweight individuals without type 2 diabetes is marginal and recommended that we submit the final study report of our BLOOM-DM trial. The FDA also stated in the CRL that in the event evidence cannot be provided to alleviate the FDA's concern regarding the clinical relevance of certain tumor findings in rats, additional clinical studies may be required to obtain a more robust assessment of lorcaserin's benefit-to-risk profile. In addition, the FDA may revise its guidance document on obesity drugs and any new guidance may include recommendations or requirements that make it cost-prohibitive or otherwise difficult or impossible for us to continue seeking regulatory approval for lorcaserin in the United States.

With the exception of the NDA we submitted for lorcaserin in December 2009, we have not previously submitted an application for marketing approval in the United States or any other jurisdiction. We have also not previously submitted a response to a CRL. This lack of corporate experience may impede our ability to obtain FDA approval in a timely manner, if at all, for lorcaserin or our other drug candidates for which development and commercialization are our responsibility. Even if we believe that data collected from our preclinical studies and clinical trials of our drug candidates are promising and that our information and procedures regarding chemistry, manufacturing and controls are sufficient, our data may not be sufficient to support approval by the FDA or any other US or foreign regulatory authority, or regulatory interpretation of these data and procedures may be unfavorable. In addition, we believe that the regulatory review of NDAs for drug candidates intended for widespread use by a large proportion of the general population is becoming increasingly focused on safety. In this regard, it is possible that some of our drug candidates, including lorcaserin, will be subject to increased scrutiny to show adequate safety than would drug candidates for more acute or life-threatening diseases such as cancer. Even if approved, drug candidates may not be approved for all indications requested and such approval may be subject to limitations on the indicated uses for which the drug may be marketed, restricted distribution methods or other limitations, such as those required by a Risk Evaluation and Mitigation Strategies, or REMS. Our business and reputation may be harmed by any failure or significant delay in receiving regulatory approval for the sale of any drugs resulting from our drug candidates. As a result, we cannot predict when or whether regulatory approval will be obtained for any drug we or our collaborators develop.

To market any drugs outside of the United States, we and current or future collaborators must comply with numerous and varying regulatory requirements of other countries. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks associated with FDA approval as well as additional risks, some of which may be unanticipated.

We plan to submit an application for European Union, or EU, approval of lorcaserin, and the data from our lorcaserin studies and trials may not be sufficient for EU approval, including due to different approval requirements. For example, the European Medicines Agency, or EMA, guidelines provide that clinical trials assessing drug candidates intended for weight control should subject patients to a weight reducing diet run-in period, and our Phase 3 clinical trials did not include a run-in period.

Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. Failure to obtain regulatory approval in a country, any delay or setback in obtaining such approval, or our regulatory strategy or decisions could adversely affect the regulatory approval or commercialization of our drug candidates in other countries, including that our drug candidates may not be approved for all indications requested, that such approval may be

subject to limitations on the indicated uses for which the drug may be marketed, and with regard to the pricing or reimbursement of our approved drugs, if any.

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**\*Even if any of our drug candidates receives regulatory approval, our drug candidates will still be subject to extensive post-marketing regulation.**

If we or collaborators receive regulatory approval for our drug candidates in the United States or other jurisdictions, we and our collaborators will be subject to ongoing obligations and continued regulatory review from the FDA and other applicable regulatory agencies, such as continued adverse event reporting requirements. There may also be additional FDA post-marketing obligations, all of which may result in significant expense and limit the ability to commercialize such drugs in the United States or other jurisdictions.

If any of our drug candidates receive US regulatory approval or approval in other jurisdictions, the FDA or other regulatory agencies may also require that the sponsor of the NDA conduct additional clinical trials to further assess the drug after NDA approval under a post-approval commitment. Such additional studies may be costly and may impact the commercialization of the drug. The FDA or other regulatory agencies may also impose significant restrictions on the indicated uses for which such drug may be marketed.

If the FDA or other regulatory agencies approve any of our drug candidates, the labeling, packaging, adverse event reporting, storage, advertising and promotion for the drug will be subject to extensive regulatory requirements. We and the manufacturers of our products are also required to comply with Current Good Manufacturing Practices, or CGMPs, regulations, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Further, regulatory agencies must approve these manufacturing facilities before they can be used to manufacture our products, and these facilities are subject to ongoing regulatory inspections. In addition, regulatory agencies subject a drug, its manufacturer and the manufacturer's facilities to continual review and inspections. The subsequent discovery of previously unknown problems with a drug, including adverse events of unanticipated severity or frequency, or problems with the facility where the drug is manufactured, may result in restrictions on the marketing of that drug, up to and including withdrawal of the drug from the market. In the United States, the DEA and comparable state-level agencies also heavily regulate the manufacturing, holding, processing, security, recordkeeping and distribution of drugs that are considered controlled substances. If any of our drug candidates are scheduled by the DEA as controlled substances, we will also become subject to the DEA's regulations. The FDA has expressed concern over the abuse potential of lorcaserin and the data included in our original NDA related to such potential, and has recommended that we, as part of our response to the CRL for lorcaserin, modify and repeat two nonclinical studies to provide additional safety information for labeling and scheduling decisions. If lorcaserin were to be scheduled in a tightly controlled category, such scheduling could negatively impact the ability or willingness to prescribe or dispense lorcaserin, the likelihood that patients will use it and other aspects of our and Eisai's ability to commercialize it. The DEA periodically inspects facilities for compliance with its rules and regulations. If our manufacturing facilities or those of our suppliers fail to comply with applicable regulatory requirements, such noncompliance could result in regulatory action and additional costs to us. Failure to comply with applicable FDA and other regulatory requirements may, either before or after product approval, if any, subject our company to administrative or judicially imposed sanctions, including:

issuance of Form 483 notices or Warning Letters by the FDA or other regulatory agencies;

imposition of fines and other civil penalties;

criminal prosecutions;

injunctions, suspensions or revocations of regulatory approvals;

suspension of any ongoing clinical trials;

total or partial suspension of manufacturing;

delays in commercialization;

refusal by the FDA to approve pending applications or supplements to approved applications filed by us or collaborators;

refusals to permit drugs to be imported into or exported from the United States;

restrictions on operations, including costly new manufacturing requirements; and

product recalls or seizures.

The FDA's and other regulatory agencies' policies may change and additional government regulations may be enacted that could prevent or delay regulatory approval of our drug candidates or further restrict or regulate post-approval activities. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to maintain regulatory compliance, we or our collaborators might not be permitted to market our drugs and our business could suffer.

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**\*Even if we receive regulatory approval to commercialize our drug candidates, our ability to generate revenues from any resulting products will be subject to a variety of risks, many of which are out of our control.**

Even if our drug candidates obtain regulatory approval, resulting products may not gain market acceptance among physicians, patients, healthcare payers or the medical community. We believe that the degree of market acceptance and our ability to generate revenues from such products will depend on a number of factors, including:

timing of market introduction of our drugs and competitive drugs;

actual and perceived efficacy and safety of our drug candidates;

incidence and severity of any side effects;

potential or perceived advantages or disadvantages as compared to alternative treatments;

strength of sales, marketing and distribution support;

price of our future products, both in absolute terms and relative to alternative treatments;

the effect of current and future healthcare laws on our drug candidates;

availability of coverage and reimbursement from government and other third-party payers; and

product labeling or product insert requirements of the FDA or other regulatory authorities.

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

In addition, if lorcaserin is approved for marketing, regulatory authorities may determine that lorcaserin will be a scheduled drug if it is found to have abuse potential or for other reasons. If lorcaserin were to be scheduled in a tightly controlled category, such scheduling could negatively impact the ability or willingness to prescribe or dispense lorcaserin, the likelihood that patients will use it, and other aspects of our ability to commercialize it and generate revenue.

**\*The development programs for our drug candidates are expensive, time consuming, uncertain and susceptible to change, interruption, delay or termination.**

Drug development programs are very expensive, time consuming and difficult to design and implement. Our drug candidates are in various stages of research and development and are prone to the risks of failure inherent in drug development. Clinical trials and preclinical studies are needed to demonstrate that drug candidates are safe and effective to the satisfaction of the FDA and similar non-US regulatory authorities. These trials and studies are expensive and uncertain processes that may take years to complete. Failure can occur at any stage of the process, and successful early preclinical studies or clinical trials do not ensure that later studies or trials will be successful. In addition, the commencement or completion of our planned preclinical studies or clinical trials could be substantially delayed or prevented by several factors, including the following:

limited number of, and competition for, suitable patients required for enrollment in our clinical trials or animals to conduct our preclinical studies;

limited number of, and competition for, suitable sites to conduct our clinical trials or preclinical studies;

delay or failure to obtain FDA approval or agreement to commence a clinical trial or FDA approval of a study protocol;

delay or failure to obtain sufficient supplies of our drug candidates or other drugs or materials for the trial or study;

delay or failure to reach agreement on acceptable agreement terms or protocols; and

delay or failure to obtain institutional review board, or IRB, approval to conduct a clinical trial at a prospective site.

Even if the results of our development programs are favorable, the development programs of our most advanced drug candidates, including those being developed by collaborators, may take significantly longer than expected to complete. In addition, the FDA, other regulatory authorities, collaborators, or we may suspend, delay or terminate our development programs at any time for various reasons, including:

lack of effectiveness of any drug candidate during clinical trials;

side effects experienced by study participants or other safety issues;

slower than expected rates of patient recruitment and enrollment or lower than expected patient retention rates;

delays or inability to manufacture or obtain sufficient quantities of materials for use in clinical trials;



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inadequacy of or changes in our manufacturing process or compound formulation;

delays in obtaining regulatory approvals to commence a study, or clinical holds, or delays requiring suspension or termination of a study by a regulatory authority, such as the FDA, after a study is commenced;

changes in applicable regulatory policies and regulations;

delays in identifying and reaching agreement on acceptable terms with prospective clinical trial sites;

uncertainty regarding proper dosing;

unfavorable results from ongoing clinical trials and preclinical studies;

failure of our clinical research organizations to comply with all regulatory and contractual requirements or otherwise perform their services in a timely or acceptable manner;

scheduling conflicts with participating clinicians and clinical institutions;

failure to design appropriate clinical trial protocols;

insufficient data to support regulatory approval;

termination of clinical trials by one or more clinical trial sites;

inability or unwillingness of medical investigators to follow our clinical protocols;

difficulty in maintaining contact with subjects during or after treatment, which may result in incomplete data;

lack of sufficient funding to continue clinical trials and preclinical studies; or

changes in business priorities or perceptions of the value of the program.

There is typically a high rate of attrition from the failure of drug candidates proceeding through clinical trials, and many companies have experienced significant setbacks in advanced development programs even after promising results in earlier studies or trials. We have experienced setbacks in our internal and partnered development programs and may experience additional setbacks in the future. If we or our collaborators abandon or are delayed in our development efforts related to lorcaserin or any other drug candidate, we may not be able to generate sufficient revenues to continue our operations at the current level or become profitable, our reputation in the industry and in the investment community would likely be significantly damaged, additional funding may not be available to us or may not be available on terms we or others believe are favorable, and our stock price would likely decrease significantly.

**The results of preclinical studies and completed clinical trials are not necessarily predictive of future results, and our current drug candidates may not have favorable results in later studies or trials.**

Preclinical studies and Phase 1 and Phase 2 clinical trials are not primarily designed to test the efficacy of a drug candidate, but rather to test safety, to study pharmacokinetics and pharmacodynamics, and to understand the drug candidate's side effects at various doses and schedules. Favorable results in early studies or trials may not be repeated in later studies or trials, including continuing preclinical studies and large-scale clinical trials, and our drug candidates in later-stage trials may fail to show desired safety and efficacy despite having progressed through earlier-stage trials. Unfavorable results from ongoing preclinical studies or clinical trials could result in delays, modifications or abandonment of ongoing or future clinical trials, or abandonment of a clinical program. Preclinical and clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals or commercialization. For example, in the CRL for lorcaserin, the FDA identified issues that indicate that the FDA disagreed with our interpretation of certain of the data from our clinical trials and preclinical studies. Negative or inconclusive results or adverse medical events during a clinical trial could cause a clinical trial to be delayed, repeated or terminated, or a clinical program to be abandoned.

**Many of our research and development programs are in early stages of development, and may not result in the commencement of clinical trials.**

Many of our research and development programs are in the discovery or preclinical stage of development. The process of discovering compounds with therapeutic potential is expensive, time consuming and unpredictable. Similarly, the process of conducting preclinical studies of compounds that we discover requires the commitment of a substantial amount of our technical and financial resources and personnel. We may not discover additional compounds with sufficient therapeutic potential, and any of our preclinical compounds may not result in the commencement of clinical trials. We cannot be certain that results sufficiently favorable to justify commencement of Phase 1 clinical trials will be obtained in these preclinical investigations. Even if such favorable preclinical results are obtained, our financial resources may not allow us to commence Phase 1 clinical trials. If we are unable to identify and develop new drug candidates, we may not be able to maintain a clinical development pipeline or generate revenues.

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### **We may participate in new strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.**

From time to time we consider strategic transactions, such as out-licensing or in-licensing of compounds or technologies, acquisitions of companies and asset purchases. Additional potential transactions we may consider include a variety of different business arrangements, including strategic collaborations, joint ventures, spin-offs, restructurings, divestitures, business combinations and investments. In addition, another entity may pursue us as an acquisition target. Any such transactions may require us to incur non-recurring or other charges, may increase our near- and long-term expenditures and may pose significant integration challenges, require additional expertise or disrupt our management or business, which could harm our operations and financial results.

As part of an effort to enter into significant transactions, we conduct business, legal and financial due diligence with the goal of identifying and evaluating material risks involved in the transaction. Despite our efforts, we ultimately may be unsuccessful in ascertaining or evaluating all such risks and, as a result, might not realize the intended advantages of the transaction. If we fail to realize the expected benefits from any transaction we may consummate, whether as a result of unidentified risks, integration difficulties, regulatory setbacks or other events, our business, results of operations and financial condition could be adversely affected.

### **Drug discovery and development is intensely competitive in the therapeutic areas on which we focus. If our competitors develop treatments that are approved faster, marketed better, less expensive or demonstrated to be more effective or safer than our drug candidates, our commercial opportunities will be reduced or eliminated.**

Many of the drugs we or our collaborators are or may attempt to discover and develop may compete with existing therapies. In addition, many companies are pursuing the development of new drugs that target the same diseases and conditions that we target. Many of our competitors, particularly large pharmaceutical companies, have substantially greater research, development and marketing capabilities and greater financial, scientific and human resources than we do. Companies that complete clinical trials, obtain required regulatory agency approvals and commence commercial sale of their drugs before we do for the same indication may achieve a significant competitive advantage, including certain patent and FDA marketing exclusivity rights. In addition, our competitors may develop drugs with fewer side effects, more desirable characteristics (such as route of administration or frequency of dosing) or better efficacy than our drug candidates or drugs, if any, for the same indication. Our competitors may also market generic or other drugs that compete with our drugs at a lower price than our drugs, which may negatively impact our drug sales, if any. Any results from our research and development efforts, or from our joint efforts with our existing or any future collaborators, may not compete successfully with existing or newly discovered products or therapies.

### **Collaborative relationships may lead to disputes and delays in drug development and commercialization, and we may not realize the full commercial potential of our drug candidates.**

We have had conflicts with collaborators and may in the future have conflicts with our prospective, current or past collaborators, such as conflicts concerning the interpretation of preclinical or clinical data, the achievement of milestone or other payments, the ownership of intellectual property, or research and development or commercialization strategy. Collaborators may stop supporting our drug candidates or drugs if they develop or obtain rights to competing drug candidates or drugs. In addition, collaborators may fail to effectively develop or commercialize our drug candidates, which may result in us not realizing the full commercial potential of our drug candidates. If any conflicts arise with Eisai or any other prospective, current or past collaborator, such collaborator may act in a manner that is adverse to our interests. Any such disagreement could result in one or more of the following, each of which could delay, or lead to termination of, development or commercialization of our drug candidates, and in turn prevent us from generating revenues:

unwillingness on the part of a collaborator to pay us research funding, milestone payments, royalties or other payments that we believe are due to us under a collaboration;

uncertainty regarding ownership of intellectual property rights arising from our collaborative activities, which could prevent us from entering into additional collaborations;

unwillingness on the part of a collaborator to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities;

slowing or cessation of a collaborator's research, development or commercialization efforts with respect to our drug candidates; or

litigation or arbitration.

**Table of Contents****Setbacks, including those relating to drugs and drug candidates intended for weight management, and consolidation in the pharmaceutical and biotechnology industries and inadequate third-party coverage and reimbursement could make entering into agreements with pharmaceutical companies to collaborate or commercialize our drugs more difficult and diminish our revenues.**

Setbacks in the pharmaceutical and biotechnology industries, such as those caused by safety concerns relating to drugs like Meridia, Avandia, Vioxx and Celebrex, or drug candidates, as well as competition from generic drugs, litigation, and industry consolidation, may have an adverse effect on us. For example, the FDA may be more cautious in approving our drug candidates based on safety concerns relating to these or other drugs or drug candidates, or pharmaceutical companies may be less willing to enter into new collaborations or continue existing collaborations if they are integrating a new operation as a result of a merger or acquisition or if their therapeutic areas of focus change following a merger.

Moreover, our and our collaborators' ability to commercialize any of our drugs that may be approved will depend in part on government regulation and the availability of coverage and adequate reimbursement from third-party payers, including private health insurers and government payers, such as the Medicaid and Medicare programs, increases in government-run, single-payer health insurance plans and compulsory licenses of drugs. Government and third-party payers are increasingly attempting to contain healthcare costs by limiting coverage and reimbursement levels for new drugs. In addition, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, PPACA, was passed, which will significantly affect the pharmaceutical industry. In addition to extending coverage to patients otherwise uninsured, PPACA includes, among several other provisions relating to pharmaceuticals, measures that impose a new nondeductible fee on certain branded drugs based on market share in government health care programs, increases in rebates for government programs such as Medicaid, and the creation of a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. Many of the details regarding the implementation of PPACA are yet to be determined, and we cannot predict with certainty whether or to what extent such implementation or adoption of reforms may impair our business. In addition, legal challenges to the PPACA are being made, and the ultimate outcome of such challenges and the impact on our business are unknown. Given the continuing discussion regarding the cost of healthcare, managed care, universal healthcare coverage and other healthcare issues, we also cannot predict with certainty what additional healthcare initiatives, if any, will be implemented or the effect any future legislation or regulation will have on our business. PPACA and any additional legislation or regulations may limit our commercial opportunities by reducing the amount a potential collaborator is willing to pay to license our programs or drug candidates in the future due to a reduction in the potential revenues from drug sales. Moreover, legislation and regulations affecting the pricing of pharmaceuticals may change before regulatory agencies approve our drug candidates for marketing. Adoption of such legislation and regulations could further limit pricing approvals for, and reimbursement of, drugs. A government or third-party payer decision not to approve pricing for, or provide adequate coverage and reimbursements of, our drugs, if any, could limit market acceptance of such drugs.

**We rely on other companies, including third-party manufacturers, and we or such other companies may encounter failures or difficulties that could delay the clinical development or regulatory approval of our drug candidates, or their ultimate commercial production if approved.**

We and third parties manufacture our drug candidates. We do not have manufacturing facilities that can produce sufficient quantities of active pharmaceutical ingredient, or API, and finished drug product for large-scale clinical trials. Accordingly, we must either develop such facilities, which will require substantial additional funds, or rely, at least to some extent, on third-party manufacturers for the production of drug candidates. Furthermore, should we obtain FDA approval for any of our drug candidates, we expect to rely, at least to some extent, on third-party manufacturers for commercial production. Our dependence on others for the manufacture of our drug candidates may adversely affect our ability to develop and deliver such drug candidates on a timely and competitive basis.

Any performance failure on the part of us or a third-party manufacturer could delay clinical development, regulatory approval or, ultimately, sales of our drug candidates. We or third-party manufacturers may encounter difficulties involving production yields, regulatory compliance, lot release, quality control and quality assurance, as well as shortages of qualified personnel. Approval of our drug candidates could be delayed, limited or denied if the FDA does not approve our or a third-party manufacturer's processes or facilities. Moreover, the ability to adequately and timely manufacture and supply drug candidates is dependent on the uninterrupted and efficient operation of the manufacturing facilities, which is impacted by many manufacturing variables including:

availability or contamination of raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier;

capacity of our facilities or those of our contract manufacturers;

facility contamination by microorganisms or viruses or cross contamination;

compliance with regulatory requirements, including Form 483 notices and Warning Letters;

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changes in forecasts of future demand;

timing and actual number of production runs;

production success rates and bulk drug yields; and

timing and outcome of product quality testing.

In addition, we or our third-party manufacturers may encounter delays and problems in manufacturing our drug candidates or drugs for a variety of reasons, including accidents during operation, failure of equipment, delays in receiving materials, natural or other disasters, political or governmental changes, or other factors inherent in operating complex manufacturing facilities. Supply chain management is complex, and involves sourcing from a number of different companies and foreign countries. Commercially available starting materials, reagents and excipients may become scarce or more expensive to procure, and we may not be able to obtain favorable terms in agreements with subcontractors. We or our third-party manufacturers may not be able to operate our respective manufacturing facilities in a cost-effective manner or in a time frame that is consistent with our expected future manufacturing needs. If we or our third-party manufacturers cease or interrupt production or if our third-party manufacturers and other service providers fail to supply materials, products or services to us for any reason, such interruption could delay progress on our programs, or interrupt the commercial supply, with the potential for additional costs and lost revenues. If this were to occur, we may also need to seek alternative means to fulfill our manufacturing needs.

We may not be able to enter into agreements for the manufacture of our drug candidates with manufacturers whose facilities and procedures comply with applicable law. Manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the DEA and corresponding state and foreign authorities to ensure strict compliance with CGMP and other applicable government regulations and corresponding foreign standards. We do not have control over a third-party manufacturer's compliance with these regulations and standards. In addition, Arena GmbH has contracted with Siegfried Ltd, or Siegfried, to provide safety, health and environmental services and assess compliance, train personnel and oversee Arena GmbH's compliance with the applicable safety, health and environmental regulations. We are, therefore, relying at least in part on Siegfried's judgment, experience and expertise. If we or one of our manufacturers fail to maintain compliance, we or they could be subject to civil or criminal penalties, the production of our drug candidates could be interrupted or suspended, or our product could be recalled or withdrawn, resulting in delays, additional costs and potentially lost revenues.

**\*We rely on third parties to conduct our clinical trials and many of our preclinical studies. If those parties do not comply with regulatory and contractual requirements, successfully carry out their contractual duties or meet expected deadlines, our drug candidates may not advance in a timely manner or at all.**

In the course of our discovery, preclinical testing and clinical trials, we rely on third parties, including laboratories, investigators, clinical research organizations and manufacturers, to perform critical services for us. For example, we rely on third parties to conduct our clinical trials and many of our preclinical studies. Clinical research organizations are responsible for many aspects of the trials, including finding and enrolling subjects for testing and administering the trials. Although we rely on these third parties to conduct our clinical trials, we are responsible for ensuring that each of our clinical trials is conducted in accordance with its investigational plan and protocol. Moreover, the FDA and foreign regulatory authorities require us to comply with regulations and standards, commonly referred to as good clinical practices, or GCPs, for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. Our reliance on third parties does not relieve us of these responsibilities and requirements. These third parties may not be available when we need them or, if they are available, may not comply with all regulatory and contractual requirements or may not otherwise perform their services in a timely or acceptable manner, and we may need to enter into new arrangements with alternative third parties and our preclinical studies or clinical trials may be extended, delayed or terminated. These independent third parties may also have relationships with other commercial entities, some of which may compete with us. In addition, if such third parties fail to perform their obligations in compliance with regulatory requirements and our protocols, our preclinical studies or clinical trials may not meet regulatory requirements or may need to be repeated. As a result of our dependence on third parties, we may face delays or failures outside of our direct control. These risks also apply to the development activities of collaborators, and we do not control their research and development, clinical trial or regulatory activities.

**\*Our efforts will be seriously jeopardized if we are unable to retain and attract key and other employees.**

Our success depends on the continued contributions of our principal management, development and scientific personnel, and the ability to hire and retain key and other personnel, particularly in the area of clinical development. We face competition for such personnel, and we believe that

recent developments, including our receipt of the CRL for lorcaserin, the reduction of our US workforce completed around the end of March 2011, subsequent resignations of additional employees, pending and possible future litigation involving us, and our relatively low stock price may impact our ability to hire and retain key and other personnel. The loss of services of any principal member of our management or scientific staff or other personnel, particularly Jack Lief, our Chairman, President and Chief Executive Officer, and Dominic P. Behan, Ph.D., our Senior Vice President and Chief Scientific Officer, or a combination of different key employees, could adversely impact our operations and ability to raise additional capital. To our knowledge, neither Mr. Lief nor Dr. Behan plans to leave, retire or otherwise disassociate with us in the near future.



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**\*If we do not realize the expected benefits from the reduction in workforce we completed around the end of March 2011, our operating results and financial conditions would be negatively impacted.**

Around the end of March 2011, we completed a reduction in our US workforce of approximately 25% designed to focus our resources on selected drug candidates and reduce our future cash expenditures. If we are unable to realize the expected operational efficiencies and financial benefits from this reduction in force, our operating results and financial condition would be adversely affected. We cannot guarantee that we will not have to undertake additional restructuring activities, that we will be able to realize the cost savings and other anticipated benefits from such efforts, or that such efforts will not interfere with our ability to achieve our business objectives.

**\*We may incur substantial liabilities for any product liability claims or otherwise as a drug product manufacturer.**

We develop, test and manufacture drugs that are used by humans. We face an inherent risk of product liability exposure related to the testing of our drug candidates in clinical trials, and will face an even greater risk if we sell our own drugs commercially. In addition, under our marketing and supply agreement with Eisai, Arena GmbH has agreed to indemnify Eisai for certain losses resulting from product liability claims, except to the extent caused by Eisai's negligence, willful misconduct, or violation of law or Eisai's breach of such agreement.

Whether or not we are ultimately successful in any product liability or related litigation, such litigation would consume substantial amounts of our financial and managerial resources, and might result in adverse publicity, all of which would impair our business. In addition, damages awarded in a product liability action could be substantial and could have a negative impact on our financial condition.

An individual may bring a liability claim against us if one of our drug candidates or drugs causes, or merely appears to have caused, an injury. Regardless of merit or eventual outcome, liability claims may result in:

decreased demand for our drug;

injury to our reputation;

withdrawal of clinical trial subjects;

costs of related litigation;

substantial monetary awards to subjects or other claimants;

loss of revenues; and

the inability to commercialize our drug candidates.

We have limited product liability insurance that covers our clinical trials. We intend to expand our insurance coverage to include the sale of drugs if marketing approval is obtained for any of our drug candidates. We may not be able to obtain or maintain insurance coverage at a reasonable cost, and we may not have insurance coverage that will be adequate to satisfy any liability that may arise, which could have an adverse effect on our capital sources and financial condition.

Arena GmbH manufactures drug products for Siegfried and will manufacture lorcaserin for Eisai if lorcaserin is approved. In addition to product liability, Arena GmbH is subject to liability for non-performance, product recalls and breaches of the agreements with Siegfried and Eisai.

**We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse and false claims laws and regulations. Prosecutions under such laws have increased in recent years and we may become subject to such litigation. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.**

If we obtain FDA approval to commercialize any of our drug candidates in the United States, our operations may be directly or indirectly subject to various state and federal fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and federal False Claims Act. These laws may impact, among other things, the sales, marketing and education programs for our drugs.

The federal Anti-Kickback Statute prohibits persons from knowingly and willingly soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. The Anti-Kickback Statute is broad and, despite a series of narrow safe harbors, prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Penalties for violations of the federal Anti-Kickback Statute include criminal penalties and civil sanctions such

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as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

The federal False Claims Act prohibits persons from knowingly filing, or causing to be filed, a false claim to, or the knowing use of false statements to obtain payment from the federal government. Suits filed under the False Claims Act, known as *qui tam* actions, can be brought by any individual on behalf of the government and such individuals, commonly known as whistleblowers, may share in any amounts paid by the entity to the government in fines or settlement. The filing of *qui tam* actions has caused a number of pharmaceutical, medical device and other healthcare companies to have to defend a False Claims Act action. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim. Various states have also enacted laws modeled after the federal False Claims Act.

We are unable to predict whether we could be subject to actions under any of these or other fraud and abuse laws, or the impact of such actions. If we are found to be in violation of any of the laws described above and other applicable state and federal fraud and abuse laws, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from government healthcare reimbursement programs and the curtailment or restructuring of our operations, all of which could have a material adverse effect on our business and results of operations.

**We may not be able to effectively integrate or manage our international operations and such difficulty could adversely affect our stock price, business operations, financial condition and results of operations.**

The headquarters of our operations outside of the United States is in Switzerland. Activities conducted at this location include manufacturing, quality control, quality assurance, development of manufacturing processes, qualifying suppliers and otherwise managing the global supply chain, regulatory compliance, distribution of finished products, and European strategic planning and development. There are significant risks associated with foreign operations, including, but not limited to, compliance with local laws and regulations, the protection of our intellectual property, the ability to integrate our corporate culture with local customs and cultures, the distraction to our management, foreign currency exchange rates and the impact of shifts in the US and local economies on those rates, and integration of our policies and procedures, including disclosure controls and procedures and internal control over financial reporting, with our international operations.

**We use biological materials, hazardous materials, chemicals and radioactive compounds.**

Our research and development and manufacturing activities involve the use of potentially harmful biological materials as well as materials, chemicals and various radioactive compounds that could be hazardous to human health and safety or the environment. These materials and various wastes resulting from their use are stored at our facility pending ultimate use and disposal. We cannot completely eliminate the risk of contamination, which could cause:

interruption of our research and development or manufacturing efforts;

injury to our employees and others;

environmental damage resulting in costly clean up; and

liabilities under domestic or foreign federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products.

In such an event, we may be held liable for any resulting damages, and any such liability could exceed our resources. Although we carry insurance in amounts and type that we consider commercially reasonable, we cannot be certain that the coverage or coverage limits of our insurance policies will be adequate and we do not have insurance coverage for losses relating to an interruption of our research and development efforts caused by contamination.

**Our operations might be interrupted by the occurrence of a natural disaster or other event.**

Our US operations, including laboratories, offices and a chemical development facility, are located in the same business park in San Diego. We also have a drug product facility in Zofingen, Switzerland, and we expect that, at least for the foreseeable future, this facility will be the sole location for the manufacturing of lorcaserin finished drug product. We depend on our facilities and on collaborators, contractors and vendors for the continued operation of our business, some of whom are located in Europe and Asia. Natural disasters or other catastrophic events, including interruptions in the supply of natural resources, political and governmental changes, severe weather conditions, wildfires and other fires, explosions, actions of animal rights activists, terrorist attacks, earthquakes and wars could disrupt our operations or those of our collaborators, contractors and vendors. Even though we believe we carry commercially reasonable business interruption and liability insurance, and our contractors may carry liability insurance that protect us in certain events, we might suffer losses as a result of business interruptions that exceed the coverage available under our and our contractors' insurance policies or for which we or our contractors do not have coverage. For example, we are not insured

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against a terrorist attack. Any natural disaster or catastrophic event could have a significant negative impact on our operations and financial results. Moreover, any such event could delay our research and development programs and adversely affect, which may include stopping, our commercial production.

### **Our executive officers and directors may sell shares of their stock, and these sales could adversely affect our stock price.**

Sales of our stock by our executive officers and directors, or the perception that such sales may occur, could adversely affect the market price of our stock. Our executive officers and directors may sell stock in the future, either as part, or outside, of trading plans under SEC Rule 10b5-1.

### **Currency fluctuations may negatively affect our financial condition.**

We primarily spend and generate cash in US dollars, and present our consolidated financial statements in US dollars. However, a portion of our expected and potential payments and receipts under our agreements are in foreign currencies, including Swiss francs. For example, payments and receipts under our asset purchase agreement, manufacturing services agreement and long-term API manufacturing agreement with Siegfried are required to be paid in Swiss francs. A fluctuation of the exchange rates of foreign currencies versus the US dollar may, thus, adversely affect our financial results, including cash balances, expenses and revenues. We may enter into hedging transactions to try to reduce our foreign currency exposure in the future, but there is no assurance that such transactions will occur or be successful.

### **Laws, rules and regulations relating to public companies may be costly and impact our ability to attract and retain directors and executive officers.**

Laws and regulations affecting public companies, including rules adopted by the SEC and by NASDAQ, as well as the laws and regulations of foreign governments, may result in increased costs to us, particularly as we continue to develop the required capabilities in the United States and abroad to commercialize our products. These laws, rules and regulations could make it more difficult or 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. 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, on our board committees or as executive officers. We cannot estimate accurately the amount or timing of additional costs we may incur to respond to these laws, rules and regulations.

### ***Risks Relating to Our Intellectual Property***

#### **\*Our success is dependent on intellectual property rights held by us and third parties and our interest in these rights is complex and uncertain.**

Our success will depend on our own and on current or future collaborators' abilities to obtain, secure and defend patents. In particular, the patents directed to our most advanced drug candidates and other compounds discovered using our technologies or that are otherwise part of our collaborations are important to commercializing drugs. We have numerous US and foreign patent applications pending for our technologies. There is no assurance that any of our patent applications will issue, or that any of the patents will be enforceable or will cover a drug or other commercially significant technology or method, or that the patents will be held to be valid for their expected terms.

The procedures for obtaining a patent in the United States and in most foreign countries are complex. These procedures require an analysis of the scientific technology related to the invention and many sophisticated legal issues. Obtaining patent rights outside the United States often requires the translation of highly technical documents and an improper translation may lead to the loss of, or otherwise jeopardize, the patent protection of our inventions. Ensuring adequate quality of translators and foreign patent attorneys is often very challenging. Consequently, the process for having our pending patent applications issue as patents will be difficult, complex and time consuming. Our patent position is very uncertain and we do not know when, or if, we will obtain additional patents for our technologies, or if the scope of the patents obtained will be sufficient to protect our drugs, or be considered sufficient by parties reviewing our patent positions pursuant to a potential licensing or financing transaction.

In addition, other entities may challenge the validity or enforceability of our patents and patent applications in litigation or administrative proceedings. Even the issuance of a patent is not conclusive as to its validity or enforceability. We cannot make assurances as to how much protection, if any, will be given to our patents if we attempt to enforce them or they are challenged. It is possible that a competitor or a generic pharmaceutical provider may successfully challenge our patents and those challenges may result in reduction or elimination of our patents coverage.

We also rely on confidentiality agreements and trade secrets to protect our technologies. However, such information is difficult to protect. We require our employees to contractually agree not to improperly use our confidential information or disclose it to others, but we may be unable to

determine if our employees have conformed or will conform to their legal obligations under these agreements. We also enter into confidentiality agreements with prospective collaborators, collaborators, service providers and consultants, but we may not be able to adequately protect our trade secrets or other proprietary information in the event of any

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unauthorized use or disclosure or the lawful development by others of this information. Many of our employees and consultants were, and many of them may currently be, parties to confidentiality agreements with other pharmaceutical and biotechnology companies, and the use of our technologies could violate these agreements. In addition, third parties may independently discover our trade secrets or proprietary information.

Some of our academic institution licensors, research collaborators and scientific advisors have rights to publish data and information to which we have rights. We generally seek to prevent our collaborators from disclosing scientific discoveries before we have the opportunity to file patent applications on such discoveries. In some of our collaborations, we do not control our collaborators' ability to disclose their own discoveries under the collaboration and in some of our academic collaborations we are limited to relatively short periods to review a proposed publication and file a patent application. If we cannot maintain the confidentiality of our technologies and other confidential information in connection with our collaborations, our ability to receive patent protection or protect our proprietary information will be impaired.

We believe that the United States is by far the largest single market for pharmaceuticals in the world. Because of the critical nature of patent rights to our industry, changes in US patent laws could have a profound effect on our future profits, if any. It is unknown which, if any, patent laws will change, how changes to the patent laws will ultimately be enforced by the courts and the impact on our business. For example, in September 2011 the America Invents Act was signed into US law, which changes include, among others, the awarding of a patent to the first inventor to file a patent as opposed to the first inventor to make an invention and the creation of new administrative procedures for challenging US patents. It may be several years before the impact of the America Invents Act has on patent law is understood, and we cannot predict with certainty whether or to what extent the changes may impair our business.

**A dispute regarding the infringement or misappropriation of our proprietary rights or the proprietary rights of others could be costly and result in delays or termination of our future research, development, manufacturing and sales activities.**

Our commercial success also depends upon our ability to develop and manufacture our drug candidates and market and sell drugs, if any, and conduct our research and development activities without infringing or misappropriating the proprietary rights of others. There are many patents and patent applications filed, and that may be filed, by others relating to drug discovery and development programs that could be determined to be similar, identical or superior to ours or our licensors or collaborators. We may be exposed to future litigation by others based on claims that our drug candidates, technologies or activities infringe the intellectual property rights of others. Numerous US and foreign issued patents and pending patent applications owned by others exist in the area of G protein-coupled receptors, or GPCRs, including some which purport to allow the patent holder to control the use of all drugs that modulate a particular drug target or GPCR, regardless of whether the infringing drug bears any structural resemblance to a chemical compound known to the patent holder at the time of patent filing. Numerous US and foreign issued patents and pending patent applications owned by others also exist in the therapeutic areas in, and for the therapeutic targets for, which we are developing drugs. There are also numerous issued patents and patent applications to chemical compounds or synthetic processes that may be necessary or useful to use in our research, development, manufacturing or commercialization activities. These could materially affect our ability to develop our drug candidates or manufacture, import or sell drugs, and our activities, or those of our licensors or collaborators, could be determined to infringe these patents. Because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our drug candidates or technologies may infringe. There also may be existing patents, of which we are not aware, that our drug candidates or technologies may infringe. Further, there may be issued patents or pending patent applications in fields relevant to our business, of which we are or may become aware, that we believe (i) are invalid or we do not infringe; (ii) relate to immaterial portions of our overall drug discovery, development, manufacturing and commercialization efforts; or (iii) in the case of pending patent applications, the resulting patent would not be granted or, if granted, would not likely be enforced in a manner that would materially impact such efforts. We cannot assure you that others holding any of these patents or patent applications will not assert infringement claims against us for damages or seek to enjoin our activities. We also cannot assure you that, in the event of litigation, we will be able to successfully assert any belief we may have as to non-infringement, invalidity or immateriality, or that any infringement claims will be resolved in our favor.

In addition, others may infringe or misappropriate our proprietary rights, and we may have to institute costly legal action to protect our intellectual property rights. We may not be able to afford the costs of enforcing or defending our intellectual property rights against others.

Other organizations, companies and individuals are seeking proprietary positions on genomics information that overlap with the government-sponsored project to sequence the human genome. Our activities, or those of our licensors or collaborators, could be affected by conflicting positions that may exist between any overlapping genomics information made available publicly as a result of the government-sponsored project and genomics information that other organizations, companies or individuals consider to be proprietary. There could also be significant litigation and other administrative proceedings in our industry that affect us regarding patent and other intellectual property rights. Any legal action or administrative action against us, or our collaborators, claiming damages or seeking to enjoin commercial activities relating to our drug discovery, development, manufacturing and commercialization activities could:

require us, or our collaborators, to obtain a license to continue to use, manufacture or market the affected drugs, methods or processes, which may not be available on commercially reasonable terms, if at all;



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prevent us from importing, making, using, selling or offering to sell the subject matter claimed in patents held by others and subject us to potential liability for damages;

consume a substantial portion of our managerial, scientific and financial resources; or

be costly, regardless of the outcome.

Furthermore, because of the substantial amount of pre-trial document and witness discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the trading price of our common stock.

We have been contacted from time to time by third parties regarding their intellectual property rights, sometimes asserting that we may need a license to use their technologies. If we fail to obtain any required licenses or make any necessary changes to our technologies, we may be unable to develop or commercialize some or all of our drug candidates.

**We cannot protect our intellectual property rights throughout the world.**

Filing, prosecuting, defending and enforcing patents on all of our drug discovery technologies and all of our potential drug candidates throughout the world would be prohibitively expensive. Competitors may use our technologies to develop their own drugs in jurisdictions where we have not obtained patent protection. These drugs may compete with our drugs, if any, and may not be covered by any of our patent claims or other intellectual property rights. The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. Many countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties (for example, the patent owner has failed to work the invention in that country or the third party has patented improvements). In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the patent. Compulsory licensing of life-saving drugs is also becoming increasingly popular in developing countries either through direct legislation or international initiatives. Such compulsory licenses could be extended to include some of our drug candidates, which could limit our potential revenue opportunities. Moreover, the legal systems of certain countries, particularly certain developing countries, do not favor the aggressive enforcement of patents and other intellectual property protection, particularly those relating to biotechnology and/or pharmaceuticals, which makes it difficult for us to stop the infringement of our patents. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

***Risks Relating to Our Securities***

**\*Our stock price will likely be volatile, and your investment in our stock could decline in value.**

Our stock price has fluctuated historically. From January 1, 2009 to October 28, 2011, the market price of our stock was as low as \$1.21 per share and as high as \$8.00 per share.

Very few drug candidates being tested will ultimately receive FDA approval, and companies in our industry sometimes experience a significant drop in stock price. Our stock price may fluctuate significantly depending on a variety of factors, including:

regulatory actions affecting lorcaserin, including those relating to our response to the CRL for lorcaserin, or other drug candidates or drugs;

discussions or recommendations affecting lorcaserin or other drug candidates or drugs by FDA advisory committees or other reviewers of preclinical or clinical data or other information related to lorcaserin or other drug candidates or drugs;

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the success or failure of our clinical-stage development programs or other results or decisions affecting the development of our drug candidates, including the results of any studies, trials or analyses related to our response to the CRL for lorcaserin;

the timing of the discovery of drug leads and the development of our drug candidates;

the modification or termination of an existing collaboration or the entrance into, or failure to enter into, a new collaboration;

the timing and receipt by us of milestone or other payments or failing to achieve and receive the same;

changes in our research and development budget or the research and development budgets of our existing or potential collaborators;

the introduction, development or withdrawal of drug candidates or drugs by others that target the same diseases and conditions that we or our collaborators target or the introduction of new drug discovery techniques;

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the success, failure or setbacks of our or a perceived competitor's drug candidate or drug;

expenses related to, and the results of, litigation, other disputes and other proceedings;

financing strategy or decisions;

developments in intellectual property rights or related announcements;

capital market conditions; and

accounting changes.

We are not able to control many of these factors. If our financial or scientific results in a particular period do not meet stockholders' or analysts' expectations, our stock price may decline and such decline could be significant.

**\*There are a substantial number of shares of our common stock eligible for future sale in the public market, and the sale of these shares could cause the market price of our common stock to fall.**

There were 146,024,830 shares of our common stock outstanding as of October 28, 2011. We also had outstanding as of October 28, 2011, a seven-year warrant issued in June 2006 to purchase 1,227,743 shares of our common stock at an exercise price of \$10.47 per share and a seven-year warrant issued in August 2008 to purchase 1,640,368 shares of our common stock at an exercise price of \$5.20 per share. Such warrants were adjusted as a result of certain equity sales following their issuance to decrease the exercise price and increase the number of shares issuable upon exercise of the warrants. Certain future equity issuances below the pre-defined warrant adjustment price may result in additional adjustments to any such warrants then outstanding.

As of October 28, 2011, we had outstanding warrants we issued to Deerfield to purchase an aggregate of 28,000,000 shares of our common stock with a weighted-average exercise price of \$3.37 per share and expiration dates of June 17, 2013 and June 17, 2015.

Along with our outstanding warrants, as of October 28, 2011, there were (i) options to purchase 10,530,109 shares of our common stock outstanding under our equity incentive plans at a weighted-average exercise price of \$5.68 per share, (ii) 1,180,850 performance-based restricted stock unit awards outstanding under our 2006 Long-Term Incentive Plan, as amended, (iii) 3,911,391 additional shares of common stock remaining issuable under our 2009 Long-Term Incentive Plan, (iv) 622,622 shares of common stock remaining issuable under our 2009 Employee Stock Purchase Plan, and (v) 79,169 shares of common stock remaining issuable under our Deferred Compensation Plan.

The shares described above, when issued, will be available for immediate resale in the public market. The market price of our common stock could decline as a result of such resales due to the increased number of shares available for sale in the market.

**Any future equity or debt issuances by us may have dilutive or adverse effects on our existing stockholders.**

We have primarily financed our operations, and we expect to continue to finance our operations, by issuing and selling our common stock or securities convertible into or exercisable for shares of our common stock. In light of our need for additional funding, we may issue additional shares of common stock or convertible securities that could dilute your ownership in our company and may include terms that give new investors rights that are superior to yours. Moreover, any issuances by us of equity securities may be at or below the prevailing market price of our common stock and in any event may have a dilutive impact on your ownership interest, which could cause the market price of our common stock to decline. In addition, we may also raise additional funds through the incurrence of debt, and the holders of any debt we may issue would have rights superior to your rights in the event we are not successful and are forced to seek the protection of bankruptcy laws. For example, in July 2009 we issued debt to Deerfield that is secured by our assets, and Deerfield's right to repayment would be senior to your rights to receive any proceeds from a liquidation in bankruptcy or otherwise.

**The holders of our common stock and other securities may take actions that are contrary to your interests, including selling their stock.**

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A small number of our stockholders hold or have rights to acquire a significant amount of our outstanding stock. These stockholders may support competing transactions and have interests that are different from yours. In addition, sales of a large number of shares of our stock by these large stockholders or other stockholders within a short period of time could adversely affect our stock price.

We may also be involved with disagreements with the holders of our stock, warrants or other securities in the future. Such disagreements may lead to litigation which may be expensive and consume management's time, or involve settlements, the terms of which may not be favorable to us.

**Our rights agreement and certain provisions in our charter documents and Delaware law could delay or prevent a change in management or a takeover attempt that you may consider to be in your best interest.**

We have adopted certain anti-takeover provisions, including a stockholders' rights agreement, dated as of October 30, 2002, between us and Computershare Trust Company, Inc., as Rights Agent, as amended. The rights agreement will cause substantial dilution to any person who attempts to acquire us in a manner or on terms not approved by our board of directors.

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The rights agreement, as well as other provisions in our certificate of incorporation and bylaws and under Delaware law, could delay or prevent the removal of directors and other management and could make more difficult a merger, tender offer or proxy contest involving us that you may consider to be in your best interest. For example, these provisions:

allow our board of directors to issue preferred stock without stockholder approval;

limit who can call a special meeting of stockholders;

eliminate stockholder action by written consent; and

establish advance notice requirements for nomination for election to the board of directors or for proposing matters to be acted upon at stockholders meetings.

**Item 6. Exhibits.**

EXHIBIT NO.	DESCRIPTION
3.1	Fifth Amended and Restated Certificate of Incorporation of Arena (incorporated by reference to Exhibit 3.1 to Arena's quarterly report on Form 10-Q for the quarter ended June 30, 2002, filed with the Securities and Exchange Commission on August 14, 2002, Commission File No. 000-31161)
3.2	Certificate of Amendment of the Fifth Amended and Restated Certificate of Incorporation of Arena (incorporated by reference to Exhibit 4.2 to Arena's registration statement on Form S-8 filed with the Securities and Exchange Commission on June 28, 2006, Commission File No. 333-135398)
3.3	Certificate of Amendment No. 2 of the Fifth Amended and Restated Certificate of Incorporation of Arena, as amended (incorporated by reference to Exhibit 4.3 to Arena's registration statement on Form S-8 filed with the Securities and Exchange Commission on June 30, 2009, Commission File No. 333-160329)
3.4	Amended and Restated Bylaws of Arena (incorporated by reference to Exhibit 3.1 to Arena's current report on Form 8-K filed with the Securities and Exchange Commission on October 4, 2007, Commission File No. 000-31161)
3.5	Certificate of Designations of Series A Junior Participating Preferred Stock of Arena, dated November 4, 2002 (incorporated by reference to Exhibit 3.3 to Arena's quarterly report on Form 10-Q for the quarter ended September 30, 2002, filed with the Securities and Exchange Commission on November 14, 2002, Commission File No. 000-31161)
4.1	Rights Agreement, dated October 30, 2002, between Arena and Computershare Trust Company, Inc. (incorporated by reference to Exhibit 4.1 to Arena's current report on Form 8-K filed with the Securities and Exchange Commission on November 1, 2002, Commission File No. 000-31161)
4.2	Amendment No. 1, dated December 24, 2003, to Rights Agreement, dated October 30, 2002, between Arena and Computershare Trust Company, Inc. (incorporated by reference to Exhibit 4.1 to Arena's current report on Form 8-K filed with the Securities and Exchange Commission on December 30, 2003, Commission File No. 000-31161)
4.3	Amendment No. 2, dated November 16, 2006, to Rights Agreement, dated October 30, 2002, between Arena and Computershare Trust Company, Inc. (incorporated by reference to Exhibit 4.3 to Amendment No. 2 to Arena's registration statement on Form 8-A filed with the Securities and Exchange Commission on November 16, 2006, Commission File No. 000-31161)
4.4	Form of common stock certificate (incorporated by reference to Exhibit 4.2 to Arena's registration statement on Form S-1, as amended, filed with the Securities and Exchange Commission on July 19, 2000, Commission File No. 333-35944)

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10.1*	Employment offer letter with Robert E. Hoffman, dated August 1, 2011
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(A) promulgated under the Securities Exchange Act of 1934
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(A) promulgated under the Securities Exchange Act of 1934
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350 and Rule 13a-14(B) promulgated under the Securities Exchange Act of 1934
101.INS**	XBRL Instance Document
101.SCH**	XBRL Taxonomy Extension Schema Document

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<b>EXHIBIT NO.</b>	<b>DESCRIPTION</b>
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF**	XBRL Taxonomy Extension Definition Document
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document

\* Management contract or compensatory plan or arrangement.

\*\* Furnished herewith.

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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.

Date: November 9, 2011

ARENA PHARMACEUTICALS, INC.

By: /s/ Jack Lief  
Jack Lief  
President and Chief Executive Officer (principal executive officer authorized to sign on behalf of the registrant)

By: /s/ Robert E. Hoffman  
Robert E. Hoffman  
Vice President, Finance and Chief Financial Officer (principal financial officer authorized to sign on behalf of the registrant)



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