

ARENA PHARMACEUTICALS INC

Form 10-K

March 15, 2011

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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-K**

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

For the fiscal year ended December 31, 2010

or

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

For the transition period from to

COMMISSION FILE NUMBER 000-31161

**ARENA PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction of  
incorporation or organization)  
**6166 Nancy Ridge Drive, San Diego, CA**  
(Address of principal executive offices)

**23-2908305**  
(I.R.S. Employer  
Identification No.)  
**92121**  
(Zip Code)

**858.453.7200**  
(Registrant's telephone number, including area code)

**Securities registered pursuant to 12(b) of the Act:**

<b>Title of each class</b>	<b>Name of each exchange on which registered</b>
Common Stock, \$0.0001 par value	NASDAQ Global Select Market
Preferred Stock Purchase Rights	NASDAQ Global Select Market

**Securities registered pursuant to 12(g) of the Act: None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer  Accelerated filer   
Non-accelerated filer  (Do not check if a smaller reporting company) Smaller reporting company   
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was approximately \$341.0 million as of June 30, 2010, based on the last sale price of the registrant's common stock as reported on the NASDAQ Global Market on such

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date. For purposes of this calculation, shares of the registrant's common stock held by directors and executive officers have been excluded. This number is provided only for purposes of this Annual Report on Form 10-K and does not represent an admission that any particular person or entity is an affiliate of the registrant.

As of March 8, 2011, there were 121,515,805 shares of the registrant's common stock outstanding.

### **DOCUMENTS INCORPORATED BY REFERENCE**

Certain information required by Part III of this Annual Report on Form 10-K is incorporated by reference from the registrant's definitive proxy statement for the annual meeting of stockholders to be held in June 2011, which will be filed with the Securities and Exchange Commission within 120 days after the close of the registrant's fiscal year ended December 31, 2010.

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**INFORMATION RELATING TO FORWARD-LOOKING STATEMENTS**

This Annual Report on Form 10-K includes forward-looking statements, which involve a number of risks and uncertainties. These forward-looking statements can generally be identified as such because the context of the statement will include words such as "may," "will," "intend," "plan," "believe," "anticipate," "expect," "estimate," "predict," "potential," "continue," "likely," or "opportunity," the negative of these words or other similar words. Similarly, statements that describe our future plans, strategies, intentions, expectations, objectives, goals or prospects and other statements that are not historical facts are also forward-looking statements. Discussions containing these forward-looking statements may be found, among other places, in "Business" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this Annual Report on Form 10-K. For such statements, we claim the protection of the Private Securities Litigation Reform Act of 1995. Readers of this Annual Report on Form 10-K are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the time this Annual Report on Form 10-K was filed with the Securities and Exchange Commission, or SEC. These forward-looking statements are based largely on our expectations and projections about future events and future trends affecting our business, and are subject to risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. These risks and uncertainties include, without limitation, those discussed in "Risk Factors" and in "Management's Discussion and Analysis of Financial Condition and Results of Operations" of this Annual Report on Form 10-K. In addition, past financial or operating performance is not necessarily a reliable indicator of future performance, and you should not use our historical performance to anticipate results or future period trends. We can give no assurances that any of the events anticipated by the forward-looking statements will occur or, if any of them do, what impact they will have on our results of operations and financial condition. Except as required by law, we undertake no obligation to update publicly or revise our forward-looking statements to reflect events or circumstances that arise after the filing of this Annual Report on Form 10-K or documents incorporated by reference herein that include forward-looking statements.

Arena Pharmaceuticals®, Arena® and our corporate logo are registered service marks of Arena. CART is an unregistered service mark of Arena. All other brand names or trademarks appearing in this Annual Report on Form 10-K are the property of their respective holders.

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In this Annual Report on Form 10-K, Arena Pharmaceuticals, Arena, we, us and our refer to Arena Pharmaceuticals, Inc., and our wholly owned subsidiaries on a consolidated basis, unless the context otherwise provides. APD is an abbreviation for Arena Pharmaceuticals Development.

### **PART I**

#### **Item 1. Business. Overview**

We are a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing oral drugs that target G protein-coupled receptors, or GPCRs, an important class of validated drug targets, in four major therapeutic areas: cardiovascular, central nervous system, inflammatory and metabolic diseases. Our most advanced drug candidate is lorcaserin hydrochloride, or lorcaserin, which is intended for weight management.

After completing two pivotal Phase 3 clinical trials for lorcaserin, we submitted in December 2009 a New Drug Application, or NDA, to the US Food and Drug Administration, or FDA, for regulatory approval of lorcaserin. In October 2010, the FDA issued a Complete Response Letter, or CRL, with respect to the lorcaserin NDA. 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. Our primary focus is working to address the FDA's concerns identified in the CRL and subsequent communications, and we believe that we may be in position to resubmit the lorcaserin NDA by the end of 2011. It may, however, take up to an additional year or more to resubmit the NDA, depending on the results of our ongoing and planned activities, any new guidance and feedback we receive from the FDA, and the need for any additional activities. Our wholly owned subsidiary, Arena Pharmaceuticals GmbH, or Arena GmbH, has granted Eisai Inc., or Eisai, exclusive rights to commercialize lorcaserin in the United States and its territories and possessions subject to FDA approval of the lorcaserin NDA, and we are working closely with Eisai in planning and conducting studies and other activities in support of the lorcaserin NDA resubmission.

As a result of receiving the CRL for lorcaserin, we recently revised our corporate strategy and reduced our expenditures, including through a recent workforce reduction of approximately 25% of our US workforce, or 66 employees, which we plan to complete around March 28, 2011. We intend to focus our resources on working with Eisai to obtain regulatory approval of lorcaserin in the United States, seeking approval of lorcaserin outside of the United States, and advancing certain of our earlier-stage research and development programs. We are also actively seeking collaborators or other licensing opportunities for our programs.

In 2011, in addition to our lorcaserin-related activities, we plan to complete an ongoing Phase 1a clinical trial for APD811 (an internally discovered, orally available agonist of the prostacyclin receptor intended for the treatment of pulmonary arterial hypertension), advance APD334 (an internally discovered, orally available agonist of the SIP1 receptor intended for the treatment of a number of conditions related to autoimmune diseases, including multiple sclerosis) toward clinical development, and continue development of our research programs on cannabinoid receptor 2, or CB2, agonists (intended for the treatment of osteoarthritis and pain) and GPR119 agonists (intended for the treatment of type 2 diabetes).

Our research and development programs also include APD597, APD916, APD791 and APD125. All of these candidates are oral drug candidates that we internally discovered. APD597, which targets the GPR119 receptor, is intended for the treatment of type 2 diabetes, and has completed a Phase 1 clinical trial program under our former collaboration with Ortho-McNeil-Janssen Pharmaceuticals, Inc., or Ortho-McNeil-Janssen, which terminated in December 2010. APD916 is a histamine H3 inverse agonist intended for the treatment of narcolepsy with cataplexy, and has completed a Phase 1 clinical trial. APD791 is an inverse agonist of the serotonin 2A receptor intended for the treatment of arterial thrombosis and other related conditions, and has completed Phase 1a and Phase 1b clinical trials. APD125 is a serotonin 2A receptor inverse agonist that we previously studied for insomnia, and has completed Phase 2a and Phase 2b clinical trials.

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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.

We have retained commercial rights for all of our programs and drug candidates, with the exception of Eisai's right to commercialize lorcaserin in the United States. We have not received regulatory approval to market or sell any drugs or generated commercial revenues from selling any drugs, other than in connection with manufacturing drugs for Siegfried Ltd, or Siegfried, in our Swiss drug product manufacturing facility. We were incorporated in 1997.

**Our Research and Development Programs**

We are currently focusing our resources and activities on the following programs:

<b>Program (Indication)</b>	<b>Development Status</b>	<b>Commercial Rights</b>
Lorcaserin (weight management)	FDA issued CRL October 2010	Arena Ex-US; Eisai US
APD811 (pulmonary arterial hypertension)	Phase 1	Arena
APD334 (autoimmune diseases, including multiple sclerosis)	Preclinical	Arena
CB2 (osteoarthritis and pain)	Research	Arena
GPR119 receptor (type 2 diabetes)	Research	Arena

We also have the below research and development programs, although we are not planning to conduct significant development activities, including any additional clinical trials, for any of these programs at this time. We may consider resuming development of such drug candidates in the future depending on the cost of further development, our financial condition and our assessment of their potential.

<b>Program (Indication)</b>	<b>Development Status</b>	<b>Commercial Rights</b>
APD597 (type 2 diabetes)	Phase 1	Arena
APD916 (narcolepsy with cataplexy)	Phase 1	Arena
APD791 (arterial thrombosis)	Phase 1	Arena
APD125 (formerly for insomnia)	Phase 2	Arena

*Note: The above tables do not include all of our research programs.*

**Currently Active Programs**

*Lorcaserin Program and Eisai Collaboration*

Our most advanced drug candidate, lorcaserin, is intended for weight management, including weight loss and maintenance of weight loss. According to the Centers for Disease Control and Prevention, approximately one-third of US adults were obese in 2007-2008. Studies have shown that a weight loss of 5% to 10% of body weight from baseline can result in meaningful improvements in cardiovascular risk factors (e.g., lipids, blood pressure and blood glucose) and a significant reduction in the incidence of type 2 diabetes. There are currently limited pharmaceutical treatment options to help patients lose weight.

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Lorcaserin is a new chemical entity that we believe acts as a selective serotonin 2C receptor agonist. The serotonin 2C receptor is expressed in the brain, including the hypothalamus, an area believed to be involved in the control of appetite and metabolism. In *in vitro* studies examining affinity, activity and serotonin receptor subtype specificity, lorcaserin demonstrated 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. As described in the next section, we are conducting additional nonclinical studies to further characterize lorcaserin's activity on the serotonin 2A and 2B receptors. These results may help us and the FDA (and other regulatory authorities) assess the risk of causing undesirable CNS effects or valvulopathy.

We have evaluated the safety, pharmacokinetics and pharmacodynamics of lorcaserin in 18 clinical trials as follows: six Phase 1 trials, two Phase 2 trials, a bioavailability study, a mass balance study, a ECG/QT trial, two drug interaction trials, three Phase 3 trials, an abuse potential trial and an energy expenditure trial.

### *Regulatory and Post-CRL Activities and Developments.*

After completing two Phase 3 clinical trials for lorcaserin, we submitted an NDA for lorcaserin to the FDA in December 2009. In October 2010, the FDA issued a CRL regarding the lorcaserin NDA. 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. The FDA outlined reasons for its decision and provided recommendations for addressing the issues it identified in the CRL.

In November 2010, we reported top-line results from our third Phase 3 clinical trial for lorcaserin, the BLOOM-DM (Behavioral modification and Lorcaserin for Overweight and Obesity Management in Diabetes Mellitus) trial, which demonstrated that lorcaserin met all three primary efficacy endpoints. In December 2010, we completed our end-of-review, or EOR, meeting with the FDA, which included a discussion of the FDA's position on issues identified in the CRL and our plan to respond to the CRL. We have had additional communications, and expect to have ongoing communications, with the FDA relating to the lorcaserin NDA, the requirements for resubmission of the NDA and related activities.

We are currently engaged in activities to address the issues raised by the FDA in the CRL and subsequent discussions and communications. These issues and activities can be grouped as follows:

Diagnostic uncertainty in the classification of mammary masses in female rats. We have conducted two-year carcinogenicity studies in rats and mice. Increases in tumors were found in rats, but not in mice, that were given lorcaserin, including tumors of the breast, brain, thyroid gland, liver, skin and nerve sheath. Lorcaserin was found to not be genotoxic in a standard battery of tests. As part of addressing the FDA's concern that there was diagnostic uncertainty in the classification of mammary masses in female rats in the two-year rat study, we convened five independent veterinary pathologists to re-adjudicate the female rat mammary tumor diagnoses in the rat carcinogenicity study, and the pathologists will also interpret the data. This work is ongoing.

Unresolved exposure-response relationship for lorcaserin-emergent mammary adenocarcinoma. The FDA has requested that we demonstrate a mechanism for mammary adenocarcinoma in female rats that is reasonably irrelevant to human risk. Our working hypothesis is that lorcaserin causes mammary tumors in rats by increasing prolactin effects on the mammary gland, and we are conducting experiments to further support this theory. The FDA has suggested several experimental approaches that may be useful to test the prolactin hypothesis, and it has recommended a dosing duration of no less than three months with interim measures to establish a causal relationship between lorcaserin, prolactin and mammary tumor development in rats. Among these suggestions, the FDA asked that we consider performing a 12-month study in female rats that would test whether transient prolactin elevation caused by short-term exposure to lorcaserin can result in mammary tumors in rats.

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We believe it may be possible to demonstrate this relationship between lorcaserin, prolactin and mammary tumors in rats in different ways. This could include demonstrating that lorcaserin administration causes robust and persistent elevation of circulating prolactin or demonstrating that prolactin hyperstimulation at the mammary gland occurs in response to lorcaserin. The latter findings would be further strengthened by demonstrating that such hyperstimulation was prevented by a prolactin blocker. The FDA has not provided numerical thresholds for the results of these studies.

We plan to conduct several experiments to test the overarching hypothesis that lorcaserin causes mammary tumors in female rats by increasing prolactin effects on the mammary gland. We will evaluate data as they become available from preliminary experiments, the re-adjudication of the female rat carcinogenicity study and other studies. We believe that if the experiments of three months and shorter duration provide convincing evidence of prolactin elevation and/or prolactin hyperstimulation, that we could have sufficient evidence to support our prolactin hypothesis. If the results of these studies are inconclusive, additional experiments may be required to better characterize the role of prolactin in rat mammary tumor pathogenesis or to identify an alternative mechanism that is reasonably irrelevant to human risk. We have submitted protocols for the prolactin studies of three months and shorter duration, and we are awaiting the FDA's feedback. To mitigate against the possibility that the data from the studies of three months and shorter duration may be insufficient, we and Eisai are considering a 12-month study. We intend to finalize our plans after we receive the FDA's feedback on the protocols for the studies of three months and shorter duration.

Unidentified mode of action and unclear safety margin for lorcaserin-emergent brain astrocytoma in male rats. Because the causation of astrocytomas in rats is unknown, we intend to focus on providing additional information designed to demonstrate that a dose range exists, above expected human dosing levels, within which these adverse effects are not observed. Our plans include nonclinical experiments that include receptor pharmacology studies, and a clinical study that will enroll a small number of volunteers to measure lorcaserin concentrations in human cerebrospinal fluid to provide additional data that may be informative for predicting human brain levels at therapeutic doses of lorcaserin.

Further assessment of receptor pharmacology to refine estimated margins and more fully characterize lorcaserin's functional activity. We plan to more fully characterize lorcaserin's activity to further assess the relative *in vitro* potencies of lorcaserin at serotonin subtype 2 receptors (2C, 2A, 2B) in order to refine the estimated margins for 2A and 2B activation in humans at therapeutic doses.

Further assessment of abuse potential for labeling and scheduling decisions. The FDA expressed concern over the abuse potential of lorcaserin, and questioned whether our available data related to abuse potential were adequate. The FDA's concerns appeared, in part, to relate to incidents of euphoria and other CNS adverse events experienced in connection with certain of our Phase 1 clinical trials. Prior to filing the lorcaserin NDA, we completed two short-term, nonclinical studies in rats, which were a study of serotonin 2A receptor behaviors and a drug discrimination study. To provide additional safety information for labeling and scheduling decisions, the FDA has recommended that we modify and repeat these studies.

In addition, the FDA stated in the CRL that the clinical weight loss efficacy of lorcaserin in overweight and obese individuals without type 2 diabetes was marginal in the BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management) and BLOSSOM (Behavioral modification and Lorcaserin Second Study for Obesity Management) trials, and we will submit the final study report from the BLOOM-DM trial to allow further evaluation of lorcaserin's benefit-risk profile.

We are working to address the FDA's concerns and we believe that we may be in position to resubmit the lorcaserin NDA by the end of 2011. It may, however, take up to an additional year or more to resubmit the NDA, depending on the results of our ongoing and planned activities, any new guidance and feedback we receive from the FDA, and the need for any additional activities, which may include the 12-month study in rats discussed above. In connection with our planned resubmission, we expect the FDA to conduct another benefit-risk assessment based upon the totality of the new and previously provided data to determine the approvability of lorcaserin.



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*Phase 3 Clinical Development.*

The Phase 3 clinical trials included in the initial NDA for lorcaserin were the BLOOM and BLOSSOM trials, which evaluated 7,190 patients for up to two years. In addition to the BLOOM and BLOSSOM trials, we evaluated the safety and efficacy of lorcaserin for weight management in 604 obese and overweight patients with type 2 diabetes in our Phase 3 BLOOM-DM trial. We will file the results of BLOOM-DM with the FDA as part of our resubmission of the NDA.

We initiated BLOOM in September 2006, and completed enrollment in February 2007 with 3,182 patients in about 100 centers in the United States. BLOOM was a randomized, double-blind and placebo-controlled trial evaluating 10 mg of lorcaserin dosed twice daily versus placebo over a two-year treatment period in obese patients (Body Mass Index, or BMI, of 30 to 45) with or without co-morbid conditions and overweight patients (BMI of 27 to less than 30) with at least one co-morbid condition. All patients underwent echocardiography at screening, Months 6, 12 and 18, and at the end of the trial to assess heart valve function and other parameters over time.

In December 2007, we initiated BLOSSOM and BLOOM-DM, the second and third Phase 3 clinical trials evaluating lorcaserin's efficacy and safety. These trials were one-year, randomized, double-blind and placebo-controlled clinical trials. BLOSSOM completed enrollment in June 2008 with 4,008 patients and BLOOM-DM completed enrollment in June 2009 with 604 patients.

The BLOSSOM trial evaluated 10 mg of lorcaserin dosed once or twice daily versus placebo over a one-year treatment period in obese patients with or without co-morbid conditions and overweight patients with at least one co-morbid condition at about 100 centers in the United States. The BLOOM-DM trial evaluated 10 mg of lorcaserin dosed once or twice daily versus placebo over a one-year treatment period in obese and overweight patients with type 2 diabetes being treated with other oral agents at about 60 centers in the United States.

The three hierarchically ordered primary efficacy endpoints in each Phase 3 clinical trial were the proportion of patients achieving 5% or greater weight loss from baseline at Week 52, mean weight change from baseline at Week 52 and the proportion of patients achieving 10% or greater weight loss from baseline at Week 52. Secondary endpoints included changes in physical measures, serum lipids, blood pressure, HbA1c levels and other indicators of glycemic control, body compositions (in BLOSSOM and BLOOM-DM), high-sensitivity C-Reactive Protein, or hs-CRP, (in BLOOM and BLOOM-DM) and quality of life. A standardized program of diet and exercise advice was included in the Phase 3 trials in accordance with current FDA guidelines.

Under the protocols for BLOSSOM and BLOOM-DM, patients underwent echocardiography at baseline, at Month 6 and at the end of the trial to assess heart valve function and other parameters over time. Consistent with our proposal, the FDA allowed us to eliminate the requirement to perform echocardiographic testing prior to enrolling patients in BLOSSOM and BLOOM-DM. As a result, patients with preexisting FDA-defined valvulopathy and other echocardiographic variants and abnormalities were enrolled in these trials. This is different from the design of BLOOM, the initial Phase 3 trial, in which echocardiography was used to screen for patients with FDA-defined valvulopathy and certain other echocardiographic abnormalities and exclude those patients from enrolling in the trial. Instead, in BLOSSOM and BLOOM-DM, there were no such echocardiographically defined exclusion criteria, although serial echocardiograms were obtained to extend the lorcaserin safety database.

Valvular regurgitation, a measure of backflow or leakage of blood through heart valves due to imperfect valve closing, was scored on a five-point scale (absent, trace, mild, moderate or severe) for the mitral and aortic valves. The FDA has defined significant regurgitant valvulopathy as mild or greater aortic valve regurgitation and/or moderate or greater mitral valve regurgitation. Echocardiographic findings meeting this criterion are sometimes called FDA-defined valvulopathy.

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### *Phase 3 Results: BLOOM*

#### Efficacy

Analyses of efficacy using a modified intent-to-treat population with last observation carried forward imputation for missing values, or ITT-LOCF, showed that lorcaserin met all primary endpoints. Patients treated with lorcaserin dosed twice daily achieved highly statistically significant categorical and average weight loss after one year:

47.5% of lorcaserin patients lost at least 5% of their body weight, compared to 20.3% for placebo. This result satisfies one of two alternate efficacy benchmarks in the most recent FDA draft guidance, which provides that a weight-management product can be considered effective if after one year of treatment 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.

Lorcaserin patients achieved an average weight loss of 5.8% of their body weight, or 12.7 pounds, compared to 2.2%, or 4.7 pounds, for placebo.

22.6% of lorcaserin patients lost at least 10% of their body weight, compared to 7.7% for placebo.

An analysis of the population of patients who completed one year of treatment according to the trial's protocol, which does not impute missing data, also demonstrated the benefits of long-term treatment with lorcaserin:

66.4% of lorcaserin patients lost at least 5% of their body weight, compared to 32.1% for placebo, and the average weight loss among the lorcaserin-treated patients who lost at least 5% of baseline body weight was 26 pounds.

Lorcaserin patients achieved an average weight loss of 8.2% of their body weight, or 17.9 pounds, compared to 3.4%, or 7.3 pounds, for placebo.

36.2% of lorcaserin patients lost at least 10% of their body weight, compared to 13.6% for placebo.

#### Safety and Tolerability Profile

Treatment with lorcaserin was well tolerated, resulting in few adverse events with greater frequency than the placebo group. The most frequent adverse events reported in Year 1 and their incidences for lorcaserin and placebo patients, respectively, were as follows: headache (18.0% vs. 11.0%), upper respiratory tract infection (14.8% vs. 11.9%), nasopharyngitis (13.4% vs. 12.0%), sinusitis (7.2% vs. 8.2%) and nausea (7.5% vs. 5.4%). Adverse events of depression, anxiety and suicidal ideation were infrequent and were reported by a similar proportion of each treatment group.

Echocardiograms were evaluated to assess whether there was an association between lorcaserin and valvular insufficiency. Incidences of new FDA-defined valvulopathy in BLOOM were as follows: lorcaserin 10 mg twice daily (2.7%) and placebo (2.3%) at Week 52 and lorcaserin 10 mg twice daily (2.6%) and placebo (2.7%) at Week 104.

#### Secondary Endpoints

Treatment with lorcaserin over one year was associated with statistically significant improvements compared to placebo in multiple secondary endpoints, including:

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Blood Pressure: systolic blood pressure, diastolic blood pressure and heart rate.

Lipids: total cholesterol, LDL cholesterol and triglycerides.

Glycemic Parameters: fasting glucose, fasting insulin and insulin resistance.

Inflammatory Markers of Cardiovascular Risk: hs-CRP and fibrinogen.

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### Patient Demographics and Disposition

BLOOM evaluated 3,182 patients with an average BMI of 36.2 and baseline weight of 220 pounds. The average age was 44 and 84% were women. Most patients were Caucasian (67%), African-American (19%) or Hispanic (12%). The Week 52 completion rate was higher for patients on lorcaserin (54.9%) compared to patients on placebo (45.1%). Discontinuation rates for adverse events were similar in the lorcaserin and placebo groups for Year 1 (7.1% vs. 6.7%) and 3.0% for both groups in Year 2.

### *Phase 3 Results: BLOSSOM*

#### Efficacy

Analyses of efficacy using ITT-LOCF showed that lorcaserin met all primary endpoints. Patients treated with 10 mg of lorcaserin dosed twice daily achieved highly statistically significant categorical and average weight loss after one year, as compared to placebo:

47.2% of lorcaserin patients lost at least 5% of their body weight, compared to 25.0% for placebo. As with BLOOM, this result satisfies one of two alternate efficacy benchmarks in the most recent FDA draft guidance for weight-management products described above in Phase 3 Results: BLOOM Efficacy.

Lorcaserin patients achieved an average weight loss of 5.9%, or 12.7 pounds, compared to 2.8%, or 6.3 pounds, for placebo.

22.6% of lorcaserin patients lost at least 10% of their body weight, compared to 9.7% for placebo.

In addition to the ITT-LOCF analyses, an analysis of patients treated with 10 mg of lorcaserin dosed twice daily who completed the one-year trial according to the trial's protocol demonstrated the benefits of long-term treatment with lorcaserin:

63.2% of lorcaserin patients lost at least 5% of their body weight, compared to 34.9% for placebo.

Lorcaserin patients achieved an average weight loss of 7.9% of their body weight, or 17.0 pounds, compared to 3.9%, or 8.7 pounds, for placebo.

35.1% of lorcaserin patients lost at least 10% of their body weight, compared to 16.1% for placebo.

The quartile of lorcaserin patients with the greatest weight loss lost an average of 35.1 pounds, or 16.3%, of their body weight. These patients lost 36% more body weight than the top quartile of placebo patients.

#### Safety and Tolerability Profile

Lorcaserin was well tolerated. The most frequent adverse events and their incidences for lorcaserin twice daily and placebo patients, respectively, were as follows: headache (15.6% vs. 9.2%), upper respiratory tract infection (12.7% vs. 12.6%), nasopharyngitis (12.5% vs. 12.0%), nausea (9.1% vs. 5.3%) and dizziness (8.7% vs. 3.9%). Adverse events of depression, anxiety and suicidal ideation were infrequent and were reported by a similar proportion of each treatment group.

Echocardiograms were evaluated to assess whether there was an association between lorcaserin and the development of heart valve insufficiency. The proportions of patients who developed new FDA-defined valvulopathy in BLOSSOM at Week 52 were as follows: lorcaserin 10 mg twice daily (2.0%), 10 mg once daily (1.4%) and placebo (2.0%).

Secondary Endpoints

Treatment with lorcaserin over one year was associated with statistically significant improvements or favorable trends compared to placebo in multiple secondary endpoints, including blood pressure and lipids.

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### Patient Demographics and Disposition

BLOSSOM evaluated 4,008 patients with an average BMI of 35.9 and baseline weight of 220 pounds. The average age was 44 and 80% were women. Most patients were Caucasian (67%), African-American (20%) or Hispanic (11%). The Week 52 completion rate was higher for patients on lorcaserin 10 mg twice daily (57.2%) and 10 mg once daily (59.0%) compared to patients on placebo (52.0%). Discontinuation rates for adverse events were low and as follows: lorcaserin 10 mg twice daily (7.2%), 10 mg once daily (6.2%) and placebo (4.6%).

### *BLOOM and BLOSSOM: Pooled Echocardiographic Data*

In the pooled dataset of BLOOM and BLOSSOM, the Week 52 incidence of FDA-defined valvulopathy was 2.33% in the lorcaserin 10 mg twice daily group and 2.18% in the placebo group. In combination, these trials were adequately powered to rule out an increase of 55% or more in the relative risk for FDA-defined valvulopathy with lorcaserin 10 mg twice daily.

### *Phase 3 Results: BLOOM-DM*

#### Efficacy

In BLOOM-DM, patients with type 2 diabetes who were treated with lorcaserin dosed twice daily achieved statistically significant categorical and absolute weight loss and improvements in HbA1c and fasting glucose at one year using an ITT-LOCF analysis:

37.5% of lorcaserin patients lost at least 5% of their body weight, compared to 16.1% for placebo. As with BLOOM and BLOSSOM, this result satisfies one of two alternate efficacy benchmarks in the most recent FDA draft guidance for weight-management products described above in Phase 3 Results: BLOOM Efficacy.

Lorcaserin patients achieved an average weight loss of 4.5%, or 10.3 pounds, compared to 1.5%, or 3.5 pounds, for placebo.

16.3% of lorcaserin patients lost at least 10% of their body weight, compared to 4.4% for placebo.

Lorcaserin patients achieved a 0.9% reduction in HbA1c, compared to a 0.4% reduction for placebo.

Lorcaserin patients achieved a 27.4 mg/dL reduction in fasting glucose, compared to a 11.9 mg/dL reduction for placebo.

#### Safety and Tolerability Profile

Lorcaserin was well tolerated. The most frequent adverse events and their incidences for lorcaserin twice daily and placebo patients, respectively, were as follows: headache (14.5% vs. 7.1%), upper respiratory tract infection (13.7% vs. 14.7%), back pain (11.7% vs. 7.9%), nasopharyngitis (11.3% vs. 9.9%) and symptomatic hypoglycemia (7.4% vs. 6.3%).

Echocardiograms were used to evaluate the association between lorcaserin and valvular insufficiency. The proportions of patients who developed new FDA-defined valvulopathy in BLOOM-DM were as follows: lorcaserin 10 mg twice daily (2.5%) and placebo (1.9%) at Week 24 and lorcaserin 10 mg twice daily (2.9%) and placebo (0.5%) at Week 52. By design, BLOOM-DM enrolled too few patients to be adequately powered to detect meaningful differences in the incidence of valvulopathy. We expect the FDA will consider the BLOOM-DM safety and efficacy data in combination with BLOOM, BLOSSOM and other data and information in our lorcaserin NDA resubmission.

### Patient Demographics and Disposition, Enrollment and Randomization

BLOOM-DM evaluated 604 obese and overweight patients with type 2 diabetes and an average BMI of 36 and baseline weight of 228 pounds. The average age was 53 and 54% were women. Most patients were



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Caucasian (61%), African-American (21%) or Hispanic (14%). Patients were randomized to lorcaserin 10 mg twice daily (N=256), lorcaserin 10 mg dosed once daily (N=95) or placebo (N=253). To expedite enrollment, randomization to the lorcaserin 10 mg once daily dose was discontinued after approximately 300 patients were enrolled in the trial. Patients in the low dose group were continued in the trial to maintain the blind, but this group was recruited over a different time period and from a different spectrum of study sites, and, as a result, we believe there are limitations on comparing the results of the low dose group to the other two groups. The Week 52 completion rate was higher for patients on lorcaserin 10 mg twice daily (66.0%) compared to patients on placebo (62.1%). Discontinuation rates for adverse events were low and as follows: lorcaserin 10 mg twice daily (8.6%) and placebo (4.3%).

*Prior Clinical Development of Lorcaserin.*

Prior to initiating our Phase 3 clinical trial program, we completed multiple Phase 1 and Phase 2 clinical trials of lorcaserin.

Our Phase 2a clinical trial included 352 obese patients dosed for 28 days, and our Phase 2b clinical trial included 469 obese patients dosed for 12 weeks. Highly statistically significant weight loss was observed in both Phase 2 clinical trials. Lorcaserin was also well tolerated in both Phase 2 clinical trials. The most common adverse events occurring in the Phase 2a and b clinical trials included headache, nausea and dizziness.

The randomized, double-blind, multiple-dose, 28-day Phase 2a clinical trial of lorcaserin in obese patients compared doses of 1 mg, 5 mg and 15 mg of lorcaserin to placebo. Patients did not receive any diet or exercise advice, other than to abstain from consuming alcohol during the trial. Over the 28-day treatment period there was a highly statistically significant mean weight loss of 2.9 pounds in patients taking the 15 mg dose of lorcaserin versus 0.7 pounds for the placebo group. Lorcaserin was well tolerated at all doses investigated in the trial. An assessment of follow-up echocardiograms taken at the end of dosing and approximately 90 days after patients received their first doses of lorcaserin supported further development of lorcaserin.

The randomized, double-blind, multiple-dose, 12-week Phase 2b clinical trial of lorcaserin in obese patients compared doses of 10 mg and 15 mg once daily and 10 mg twice daily of lorcaserin to placebo. Patients did not receive any diet or exercise advice, other than to abstain from consuming alcohol during the trial. Patients completing the 12-week treatment period with lorcaserin achieved a highly statistically significant mean weight loss of 4.0, 5.7 and 7.9 pounds at doses of 10 mg and 15 mg once daily and 10 mg twice daily, respectively, compared to 0.7 pounds for the placebo group. The weight loss in the lorcaserin groups was significantly greater than that in the placebo group. Using an ITT-LOCF analysis, treatment with lorcaserin was also associated with a highly statistically significant mean weight loss of 3.7, 4.8 and 6.8 pounds at daily doses of 10 mg and 15 mg once daily and 10 mg twice daily, respectively, in patients taking lorcaserin compared to 0.4 pounds for the placebo group. The proportions of patients completing the 12-week treatment period with lorcaserin who achieved a 5% or greater weight loss from baseline were 13%, 20% and 31% at doses of 10 mg and 15 mg once daily and 10 mg twice daily, respectively, compared to 2% in the placebo group. Lorcaserin was well tolerated at all doses investigated in the trial. Average weight loss increased progressively at each time point measured throughout the trial for all lorcaserin dose groups and was dose-dependent. An assessment of echocardiograms at baseline and Day 85 in the Phase 2b trial supported further development of lorcaserin.

Our Phase 1 clinical trials included a three-part Phase 1a clinical trial of lorcaserin that established a maximum tolerated dose for the drug candidate and a multiple-dose Phase 1b clinical trial of lorcaserin in obese volunteers. There were no severe or serious adverse events reported and no withdrawals due to an adverse event. The most common adverse events reported in the Phase 1 clinical trials were related to the central nervous system and the gastrointestinal system. Dose escalation was terminated at the 40 mg dose in the Phase 1a trial, a dose that resulted in euphoria and other CNS adverse effects. In each of the Phase 1a and b trials, serial echocardiograms supported further development of lorcaserin.



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*Lorcaserin Intellectual Property.*

As of February 15, 2011, we owned issued patents that cover compositions of matter for lorcaserin and related compounds and methods of treatment utilizing lorcaserin and related compounds in 66 jurisdictions, including the United States, Japan, Germany, France, China, the United Kingdom, Italy, Spain and Canada, and had applications pending in five other jurisdictions, of which those with the largest pharmaceutical markets were Brazil and Poland. Based on sales statistics provided by IMS Health, the jurisdictions where lorcaserin patents have been issued accounted for more than 93% of global pharmaceutical sales in 2009, while jurisdictions where lorcaserin patents remain pending accounted for more than 2% of global pharmaceutical sales in that same year. The patents on lorcaserin issued by the US Patent and Trademark Office have serial numbers US 6,953,787 and US 7,514,422, while the corresponding patent granted by the European Patent Office has serial number EP 1 411 881 B1. Other of our lorcaserin patent applications, including those directed to the lorcaserin HCl salt, the hemihydrate of the lorcaserin HCl salt as well as its crystalline forms, synthetic routes and intermediates useful in the manufacturing of lorcaserin and pharmaceutical combinations of lorcaserin and phentermine, have all been filed in a lesser number of commercially important jurisdictions. The earliest priority date for the patents on lorcaserin is 2002. The terms of these patents are capable of continuing into 2023 in most jurisdictions without taking into account any patent term adjustment or extension regimes of any country or any additional term of exclusivity we might obtain by virtue of the later filed patent applications.

*Eisai Collaboration*

In July 2010, our wholly owned subsidiary, Arena GmbH, entered into a marketing and supply agreement with Eisai. Under this agreement, Arena GmbH granted Eisai exclusive rights to commercialize lorcaserin in the United States and its territories and possessions subject to FDA approval of the lorcaserin NDA. As part of the agreement, Arena GmbH is obligated to manufacture lorcaserin at our facility in Switzerland, and Eisai is obligated to purchase all of its requirements of lorcaserin from Arena GmbH.

We received a non-refundable, upfront payment of \$50.0 million from Eisai, and, following regulatory approval of lorcaserin and upon the delivery of product supply for launch, may receive up to an additional \$60.0 million depending on the label. We are obligated to sell lorcaserin to Eisai for a purchase price starting at 31.5% of Eisai's annual net product sales, and the purchase price will increase on a tiered basis to 36.5% on the portion of annual net product sales exceeding \$750.0 million, subject to reduction in the event of generic competition and certain other circumstances. We are also eligible to receive up to an aggregate of \$1.19 billion in purchase price adjustment payments based on Eisai's annual net sales of lorcaserin, with the first and last amounts payable with annual net sales of \$250.0 million and \$2.5 billion, respectively. Of these purchase price adjustment payments, Eisai is obligated to pay us a total of \$330.0 million for annual net sales of up to \$1.0 billion. We are also eligible to receive up to an additional \$70.0 million in regulatory and development milestone payments.

Eisai and we will share equally the development expenses for the additional development work required by the FDA prior to approval of our NDA for lorcaserin. If the FDA requires development work following approval of lorcaserin, Eisai will bear 90% and we will bear 10% of such expenses, except that Eisai and we will share equally the costs of certain pediatric or adolescent studies.

Eisai and we have agreed to not commercialize outside of our marketing and supply agreement any product that competes with lorcaserin in the United States. Our marketing and supply agreement includes a stand-still provision limiting Eisai's ability to acquire our securities and assets.

Unless terminated earlier, our marketing and supply agreement will continue in effect until terminated by Eisai following the later of the expiration of all issued lorcaserin patents for the United States and 12 years after the first commercial sale of lorcaserin in the United States. Either party has the right to terminate this agreement early in certain circumstances, including (i) if the other party is in material breach, (ii) for certain commercialization concerns and (iii) for certain intellectual property infringement. Eisai also has the right to terminate this agreement

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early in certain circumstances, including (a) if sales of generic equivalents of lorcaserin in the United States exceed sales of lorcaserin in the United States (based on volume) and (b) if Eisai is acquired by a company that has a product that competes with lorcaserin.

### *APD811 Program*

APD811, an orally available agonist of the prostacyclin receptor, is intended for the treatment of pulmonary arterial hypertension, or PAH. In December 2010, we initiated a Phase 1 clinical trial to evaluate the safety, tolerability and pharmacokinetics of single-ascending doses of APD811.

PAH is a progressive, life-threatening disorder characterized by increased pressure in the arteries that carry blood from the heart to the lungs. The increased pressure strains the heart, which can lead to limited physical activity and a reduced life expectancy. Over time, the heart muscle weakens and can no longer pump blood efficiently. If PAH is not treated, the heart will eventually fail. Data from the National Institutes of Health Registry indicate that without treatment, patients in the United States with PAH have a median survival time of approximately three years from diagnosis.

Prostacyclin receptor agonists, through regulation of vascular smooth muscle tone, slow disease progression and improve exercise tolerance in PAH patients, and they are among the treatments administered as standard of care for advanced PAH. Currently available prostacyclin receptor agonists belong to the prostanoid class of molecules and these products need to be administered frequently or continuously through intravenous, subcutaneous or inhaled delivery methods. We believe that APD811, as a non-prostanoid prostacyclin agonist, has the potential to improve the standard of care for PAH by providing an oral form of administration with clinical benefits similar to currently available prostacyclin receptor agonists.

APD811 demonstrated efficacy in a chronic model of PAH in rats. In this model, APD811 attenuated the development of several indexes of PAH, including pulmonary artery remodeling, increased pulmonary arterial pressure, right ventricular hypertrophy and mortality. As prostacyclin receptors are expressed in both systemic and pulmonary arteries, a reduction in systemic blood pressure following APD811 administration has also been measured in preclinical studies. There was a small safety margin from the no observed adverse effect level to significant adverse events in preclinical studies of APD811, and appropriate dosing in humans may require balancing the systemic hypotensive and other potential adverse effects with therapeutic benefits. Pharmacokinetics across species suggest the plasma half life in humans may support once-daily dosing.

### *APD334 Program*

We are researching and developing S1P1 receptor agonists, including APD334, as potential treatments for a number of conditions related to autoimmune diseases, including multiple sclerosis and rheumatoid arthritis. S1P1 receptors have been demonstrated to be involved in the modulation of several biological responses, including lymphocyte trafficking. We have optimized potent small molecule S1P1 receptor agonists that reduce the severity of disease in preclinical autoimmune disease models of multiple sclerosis, such as the experimental autoimmune encephalomyelitis, or EAE, model, and the collagen-induced arthritis, or CIA, animal disease model. We intend to advance APD334 toward clinical development in 2011.

### *CB2 Program*

We are researching and developing cannabinoid, or CB, receptor agonists for the potential treatment of pain. The analgesic effects of CB receptor agonists are well established in the scientific literature. However, they have been limited in utility by the psychotropic effects associated with activation of the CB1, but not CB2, receptor subtype. We have identified several novel, potent, CB2-selective, orally available lead compounds that are intended to retain the analgesic activity of CB receptor agonists while avoiding the limiting psychotropic side effects. Preclinical efficacy with these CB2 receptor agonists has been established in animal models of pain. Our current lead candidate is in exploratory preclinical development.

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### *GPR119 Receptor Program and APD597*

We believe GPR119 represents a novel pharmaceutical target for discovering orally available small molecule agonists for the treatment of type 2 diabetes. GPR119 is expressed in beta cells, which are located in the pancreas and responsible for secreting insulin in response to increases in blood glucose. Stimulation of GPR119 has been shown to promote insulin release by beta cells in response to elevated blood glucose levels. In addition, GPR119 is expressed in cells other than pancreatic beta cells, such as endocrine cells in the gastrointestinal tract. In preclinical studies and clinical trials, GPR119 agonists have stimulated the release of GLP-1, GIP and PYY, incretins that play important roles in insulin regulation and other metabolic pathways.

We own a broad array of internally discovered, orally available GPR119 agonists, including APD597 and next generation compounds that we discovered after the research portion of our collaboration with Ortho-McNeil-Janssen ended, and a portfolio of patents and patent applications directed to a range of materials and methods that are related to the discovery and development of GPR119 receptor agonists. The technologies covered by our patents and patent applications include materials and methods that may be used to identify and determine the activity of molecules that modulate the GPR119 receptor, methods that measure the incretin response to GPR119 agonists and pharmaceutical compositions containing both GPR119 agonists and DPP-4 inhibitors.

According to the Centers for Disease Control and Prevention, diabetes affects approximately 26 million of the people in the United States, and type 2 diabetes accounts for 90-95% of the diabetes prevalence. Type 2 diabetes is characterized by dysregulation of insulin sensitivity, insulin secretion and hepatic glucose production. Therapies for type 2 diabetes act by improving insulin release, enhancing insulin sensitivity, increasing insulin levels, modifying glucose absorption from the gut, or modifying hepatic glucose production. Current oral medications for type 2 diabetes may have side effects that include hypoglycemia, weight gain, edema or possible increases in cardiovascular mortality, prompting continuing efforts to develop therapeutics to improve the treatment of diabetes.

### *Development and Collaboration Status*

In December 2004, we entered into a collaboration and license agreement with Ortho-McNeil-Janssen to further develop GPR119 agonists for the potential treatment of type 2 diabetes and other disorders.

Under the collaboration, Ortho-McNeil-Janssen initiated a Phase 1 clinical trial of APD668, a novel, oral drug candidate we discovered that is intended to stimulate GPR119. The initial clinical trials of APD668 by Ortho-McNeil-Janssen were randomized, double-blind, placebo-controlled, ascending dose trials involving healthy volunteers and patients with type 2 diabetes, and evaluated the safety, tolerability, pharmacokinetics and pharmacodynamics of single and multiple doses of APD668.

In January 2008, we announced that initial clinical trial results for APD668 suggest that GPR119 agonists may improve glucose control in patients with type 2 diabetes. Based on such data, Ortho-McNeil-Janssen placed APD668 on hold and advanced APD597, a potentially more potent Arena-discovered GPR119 agonist, into preclinical development. In December 2008, we announced that Ortho-McNeil-Janssen initiated a first-in-human Phase 1 clinical trial of APD597 under the collaboration. Ortho-McNeil-Janssen's Phase 1 program evaluated the safety, tolerability, pharmacokinetics and pharmacodynamics of APD597 in single and multiple ascending dose studies in healthy volunteers and patients with type 2 diabetes. APD597 showed dose-proportional pharmacokinetics with a half-life of six to seven hours in solution and approximately 13 hours in suspension in healthy volunteers. The clinical data also provided evidence for increased incretin (GLP-1, GIP and PYY) release and reductions in glucose rise following a test meal or oral glucose load with APD597 treatment in both overweight and obese non-diabetic volunteers and in subjects with type 2 diabetes. In general, reductions in post-meal glucose increases were greater with APD597 in combination with sitagliptin, a DPP-4 inhibitor, compared to sitagliptin alone. We believe APD597 may have utility alone and in combination with a DPP-4 inhibitor for the treatment of type 2 diabetes.

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Following completion of the Phase 1 program, Ortho-McNeil-Janssen decided not to advance APD597 and terminated the collaboration, effective December 28, 2010. APD597, along with other GPR119 compounds, and related intellectual property and other information (including the investigational new drug, or IND, application relating to APD597), reverted to us upon termination of the collaboration. As a result of such termination, Ortho-McNeil-Janssen no longer reimburses us for the cost of prosecuting our GPR119 patent portfolio.

From the inception of this collaboration through December 31, 2010, we received \$27.5 million from Ortho-McNeil-Janssen in upfront and milestone payments and \$20.1 million for patent activities and additional sponsored research. In addition, prior to the end of the research portion of the collaboration, we received research funding from Ortho-McNeil-Janssen totaling \$7.2 million.

### **Other of Our Advanced Research and Development Programs**

Below is a summary of other of our programs, for which we are not currently planning to conduct significant development activities, including any additional clinical trials.

#### *APD916 Program*

APD916, a histamine H3 inverse agonist intended for the treatment of narcolepsy with cataplexy, has completed a Phase 1 clinical trial.

The histamine H3 receptor is predominantly expressed in the brain, and inverse agonists of the H3 receptor increase the synthesis and release of histamine through inhibition of presynaptic autoreceptors. Enhanced histamine release plays an important role in arousal, and the histaminergic system is at least partly under the control of orexin/hypocretin neurons. Narcolepsy, with and without cataplexy, has been associated with orexin/hypocretin deficiency and low levels of histamine in cerebrospinal fluid. Therefore, an H3 inverse agonist, by increasing central histaminic activity, may potentially be effective in the treatment of these conditions.

Narcolepsy is a chronic neurological disorder caused by the brain's inability to regulate sleep-wake cycles normally. At various times throughout the day, people with narcolepsy experience fleeting urges to sleep. If the urge becomes overwhelming, individuals will fall asleep for periods lasting from a few seconds to several minutes. Cataplexy, or the sudden loss of muscle tone often triggered by emotional factors, is a symptom of narcolepsy and can cause a range of physical changes, from slurred speech to complete weakness of most muscles.

According to the National Institutes of Health, narcolepsy is estimated to affect about one in every 2,000 Americans. Treatments are limited and consist of stimulant drugs to suppress daytime sleepiness and antidepressants for cataplexy. The only approved treatment for cataplexy in the United States is Xyrem (sodium oxybate), a drug scheduled as Schedule III by the Drug Enforcement Administration of the US Department of Justice, or DEA, and available only through specialty pharmacies.

#### *Development*

In March 2010, we initiated a randomized, double-blind, placebo-controlled Phase 1 trial evaluating the safety, tolerability and pharmacokinetics of 1 mg, 3 mg and 5 mg single doses of APD916. The trial evaluated 24 healthy volunteers in three cohorts of eight participants each, six randomized to APD916 and two to placebo. APD916 demonstrated dose-proportional pharmacokinetic exposure over the tested dose range. The terminal half-life was approximately 50 hours.

Dose-limiting CNS adverse events occurred at the 5 mg dose, including insomnia, abnormal dreams and a nightmare. Adverse events of insomnia, nausea, headache, parosmia, alterations in perception of body temperature, abnormal dreams and visual and tactile hallucinations were commonly reported at the 3 mg and 5 mg

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doses, and adverse events of insomnia were commonly reported at the 1 mg dose. All adverse events in the trial were mild or moderate in nature. No serious adverse events were reported nor were there any significant safety issues with respect to vital signs, ECGs or laboratory testing.

APD916 was efficacious in multiple preclinical models, including the demonstration of dose-dependent improvements in wakefulness, cognitive function and cataplexy. These data suggest APD916 to be a potent and selective inhibitor of the histamine H3 receptor across species with potential utility in the treatment of narcolepsy and cataplexy.

### *APD791 Program*

APD791, an inverse agonist of the serotonin 2A receptor intended for the treatment of arterial thrombosis and other related conditions, has completed Phase 1a and Phase 1b clinical trials. APD791 is intended to lower the risk of arterial thrombosis and related conditions by reducing the amplification of platelet aggregation, arterial constriction and intimal hyperplasia, or thickening of the vessel wall, mediated by serotonin. Thrombosis is the formation of a clot, or thrombus, inside a blood vessel that restricts the flow of blood. The formation of a thrombus is often caused by an injury to the wall of the blood vessel, such as the rupture of an atherosclerotic plaque. The injury to the blood vessel activates platelets, which then aggregate and adhere to one another as they start to release certain factors, including serotonin, that facilitate thrombosis. Thrombi that form in diseased atherosclerotic arteries of the heart may cause acute coronary syndrome or myocardial infarction, and thrombi that form in the vessels of the brain may cause stroke. The American Heart Association estimates that in the United States 14.9 million people alive in 2006 had survived either a myocardial infarction or a stroke. To reduce the risk of future events, many patients receive daily anti-thrombotic therapy.

Serotonin activation of the serotonin 2A receptor on platelets and vascular smooth muscle is thought to play an important role in the events leading to thrombosis, and elevated serotonin levels have been associated with increased cardiovascular risk. Normally, when a platelet is activated by one of a number of factors such as thrombin or collagen, the platelet releases serotonin, which promotes platelet aggregation, vasoconstriction and intimal hyperplasia in preclinical models. By blocking activation of the serotonin 2A receptor on platelets and in other cardiovascular tissues, APD791 may curb platelet aggregation, vasoconstriction and intimal hyperplasia in the clinical setting, thereby reducing or preventing thrombosis.

### *Development*

In July 2007, we initiated a single-ascending dose Phase 1a clinical trial evaluating APD791 in healthy volunteers. This Phase 1a trial was a randomized, double-blind, placebo-controlled, single-ascending dose trial in 90 healthy male and female volunteers. Doses originally intended for study ranged from 1 mg to 160 mg, but due to favorable tolerability the maximum dose was increased to 320 mg. In the Phase 1a trial, doses were well tolerated, without any dose related adverse events, such that a maximum tolerated dose could not be defined despite achieving high concentrations in blood. APD791 was rapidly absorbed, and exposures were generally related to dose. Terminal half-life ( $t_{1/2}$ ) of parent plus active metabolites was also related to dose, reaching approximately 11 hours at the higher doses. Dose-dependent inhibition of serotonin-mediated amplification of platelet aggregation was demonstrated, supporting the preclinical data generated around APD791 and establishing initial clinical validation for APD791's novel mechanism of action.

The Phase 1b trial, initiated in January 2008, was a randomized, double-blind, placebo-controlled, multiple-ascending dose trial in 50 healthy male and female volunteers. This trial evaluated safety, tolerability, pharmacokinetics and pharmacodynamics of multiple-ascending doses of APD791 over a period of one week. Total daily doses ranged from 15 mg to 80 mg and were generally well tolerated. APD791 was rapidly absorbed and exposures were related to dose. The most frequently reported adverse event was headache, which was more common in the placebo group than in any APD791 dose group. None of the adverse events occurred in a dose-related fashion with the exception of epistaxis (nose bleed), which occurred in two of the volunteers who

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received the 80 mg dose, a dose above the anticipated therapeutic range. Dose-dependent inhibition of serotonin-mediated amplification of platelet aggregation was demonstrated starting at the 15 mg dose and may permit the identification of exposure ranges that produce minimal, moderate and near-complete inhibition of serotonin-amplified platelet aggregation.

APD791 demonstrated improved coronary artery flow in the Folts model, an established animal model of acute coronary syndrome. In other preclinical studies, blocking activation of the serotonin 2A receptor on platelets was associated with an improved separation, relative to existing therapies, of the dose needed for inhibition of thrombosis versus the dose that increased bleeding. These data suggest that APD791 has the potential for improved safety relative to existing therapies. We believe these results are consistent with blocking the role of serotonin in the thrombotic process.

### *APD125 Program*

In December 2008, we announced preliminary data from a Phase 2b clinical trial of APD125, an internally discovered drug candidate that was being evaluated for the treatment of insomnia. The trial measured subjective endpoints in patients with primary insomnia. Treatment with APD125 was well tolerated, and there were no reports of serious adverse events and no emerging safety findings as compared to placebo. However, APD125 did not meet the trial's primary or secondary endpoints, and we are not currently planning any further clinical development of APD125. In the future, we may consider clinical development for other indications, but do not have definitive plans to do so at this time.

### **Other Earlier-Stage Development and Research Programs**

We are continuing our efforts to discover and develop additional oral drugs that target GPCRs in four major therapeutic areas: cardiovascular, central nervous system, inflammatory and metabolic diseases. The extent of our earlier-stage research and developments efforts will depend on our available resources and prioritization decisions.

### **Our GPCR Focus, Technologies and Programs**

Our drug candidates have resulted from our GPCR-focused drug discovery and development approach, specialized expertise and technologies, including Constitutively Activated Receptor Technology, or CART, and our Melanophore technology. GPCRs are categorized as *known* when their naturally occurring, or native, ligands have been identified. Scientists have used molecular cloning in combination with the sequencing of the human genome to identify both additional receptor subtypes of known GPCRs as well as hundreds of novel GPCRs. GPCRs are categorized as *orphan* GPCRs when their native ligands have not been identified. We believe both orphan and known GPCRs offer significant promise for the development of novel GPCR-based therapeutics.

Our drug discovery approach, specialized expertise and technologies allow us to identify drug leads that act as receptor activators, or agonists, which increase the detected biological response, or act as receptor inhibitors, which decrease the detected response. We can also identify inverse agonists, which inhibit ligand-independent, as well as ligand-dependent, receptor activity.

We believe that our drug discovery approach, specialized expertise and technologies offer several advantages for drug discovery, including:

eliminating the need to identify the native ligand for an orphan receptor;

enhancing the detection of, and allowing us to simultaneously identify, both receptor inhibitor and receptor activator drug leads;

allowing for the identification of drug leads that inhibit both ligand-independent and ligand-dependent activity; and

providing the ability to discover novel and improved therapeutics directed at known receptors.

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### **Our Strategy**

The key elements of our general strategy are as follows:

***Focus on lorcaserin approval and commercialization.*** We intend to focus our efforts on seeking approval for lorcaserin in the United States and in select markets outside of the United States. Pending regulatory approvals, we intend to commercialize lorcaserin in the United States under our marketing and supply agreement with Eisai and in other markets independently or with a pharmaceutical company or companies.

***Selectively advance our other lead candidates.*** We intend to selectively advance our pipeline of drug candidates independently or through licensing, collaborations or other opportunities.

***Maintain research and development capabilities to advance our pipeline.*** Our technologies, our drug discovery infrastructure and the integrated approach to research used by our scientists have allowed us to identify and develop a number of GPCR targets and novel compounds. We expect that these capabilities will play an important role in the research intended to generate data for our planned resubmission of the lorcaserin NDA. We intend to maintain our research and development capabilities to selectively advance our programs and to discover additional drug candidates.

### **Intellectual Property**

Our success depends in large part on our ability to protect our proprietary technologies, compounds and information, and to operate without infringing the proprietary rights of third parties. We rely on a combination of patent, trade secret, copyright, and trademark laws, as well as confidentiality, licensing and other agreements, to establish and protect our proprietary rights. We seek patent protection for our key inventions, including drug candidates we identify, routes for chemical synthesis, pharmaceutical formulations and drug screening technologies.

As of February 15, 2011, we owned, in part or in whole, or had exclusively licensed the following patents: 49 in the United States, 9 in Japan, 28 in Germany, 28 in France, 28 in the United Kingdom, 24 in Italy, 24 in Spain, 8 in Canada, 10 in China, and approximately 942 in other jurisdictions. In addition, as of February 15, 2011, we had approximately 894 patent applications before the US Patent and Trademark Office, foreign patent offices and international patent authorities. These patents and patent applications are divided into 109 distinct families of related patents that are directed to chemical compositions of matter, methods of treatment using chemical compositions, research on GPCR genes, CART, Melanophore technology, other novel screening methods or pharmaceutical manufacturing processes. One of our patent families was exclusively in-licensed and contains a single issued patent. One hundred and four of our patent families, which include a total of about 1,051 patents and 864 patent applications, were invented solely by our employees. The remaining 4 of our patent families, which include a total of about 98 patents and 30 patent applications, were the subject of joint inventions by our employees and the employees of other entities. 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 product or method. As part of our efforts to conserve our financial resources, we are reviewing our patent portfolio to identify patents and patent applications that we deem to have relatively low value to our ongoing business operations. To the extent we identify such patents and patent applications and abandon them, the number of patents and patent applications reported above will be reduced in the future. There is also no assurance that we will correctly identify which of our patents and patent applications should be maintained and which should be abandoned. Except for the US patents relating to our Melanophore technology, the term of most of our other current patents commenced, and most of our future patents, if any, will commence, on the date of issuance and terminate 20 years from the earliest effective filing date of the patent application. Since our US Melanophore patents were issued under now superseded rules that provided a patent term of 17 years from the date of issuance, the term of these patents is scheduled to end in 2012. Because the time from filing a patent application relating to our business to the issuance, if ever, of the patent is often more than three years and because any marketing and

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regulatory approval for a drug often occurs several years after the related patent application is filed, the resulting market exclusivity afforded by any patent on our drug candidates and technologies will likely be substantially less than 20 years. In the United States, the European Union and some other jurisdictions, patent term extensions are available for certain delays in either patent office proceedings or marketing and regulatory approval processes. However, due to the specific requirements for obtaining these extensions, there is no assurance that our patents will be afforded extensions even if we encounter significant delays in patent office proceedings or marketing and regulatory approval.

In addition to patent protection, we rely on trade secrets, proprietary know-how, and continuing technological advances to develop and maintain our competitive position. To maintain the confidentiality of our trade secrets and proprietary information, all of our employees are required to enter into and adhere to an employee confidentiality and invention assignment agreement, laboratory notebook policy, and invention disclosure procedures as a condition of employment. Additionally, our employee confidentiality and invention assignment agreements require that our employees not bring to us, or use without proper authorization, any third-party proprietary technology. We also require our consultants and collaborators that have access to proprietary property and information to execute confidentiality and invention rights agreements in our favor before beginning their relationship with us. While such arrangements are intended to enable us to better control the use and disclosure of our proprietary property and provide for our ownership of proprietary technology developed on our behalf, they may not provide us with meaningful protection for such property and technology in the event of unauthorized use or disclosure.

## **Competition**

The biotechnology and pharmaceutical industries are highly competitive and are subject to rapid and significant change. We face significant competition from organizations that are pursuing the same or similar technologies. We also face significant competition from organizations that are pursuing drugs that would compete with the drug candidates we are developing. We may not be able to compete successfully against these organizations, which include many large, well-financed and experienced pharmaceutical and biotechnology companies, as well as academic and research institutions and government agencies.

The focus of our scientific and business strategy is on GPCRs. We believe that many pharmaceutical and biotechnology companies and other organizations also have internal drug discovery programs focused on GPCRs. In addition, other companies have attempted to overcome the problems associated with traditional drug screening by embarking on a variety of alternative strategies. Developments by others may render our drug candidates or technologies obsolete or noncompetitive.

Our present competitors with respect to lorcaserin include Hoffmann-La Roche Inc., the US prescription drug unit of the Roche Group, which markets orlistat under the brand name Xenical, and GlaxoSmithKline Consumer Healthcare which markets an over-the-counter low-dose version of orlistat in the United States under the brand name alli. Another competitor is phentermine, which is a generic drug sold by a number of companies.

In addition to currently marketed obesity drugs, there are potentially competing obesity drug candidates that are in development at various pharmaceutical and biotechnology companies, including drug candidates in similar stages of development as lorcaserin. Some programs in discovery, preclinical or other stages of development may include serotonin 2C programs. In October 2010, the FDA issued a CRL with respect to VIVUS Inc.'s NDA for a drug candidate for the treatment of obesity that is a combination of phentermine and topiramate. In January 2011, the FDA issued a CRL with respect to Orexigen Therapeutics, Inc.'s NDA for a drug candidate for the treatment of obesity that is a combination of bupropion and naltrexone.

Many of our existing and potential competitors have substantially greater drug development capabilities and financial, scientific and marketing resources than we do. Additional consolidation in the pharmaceutical industry may result in even more resources being concentrated with our competitors. As a result, our competitors may be able to devote greater resources than we can to the research, development, marketing and promotion of drug



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discovery techniques or therapeutic products, or to adapt more readily to technological advances than we can. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA approval or commercializing drugs before we do.

We expect to encounter significant competition in the therapeutic areas targeted by our principal drug candidates. Companies that complete clinical trials, obtain regulatory approvals and commence commercial sales of their drug candidates before us may achieve a significant competitive advantage. Furthermore, we may be competing against companies with substantially greater manufacturing, marketing, distribution and selling capabilities, and any drug candidate that we successfully develop may compete with existing therapies that have long histories of safe and effective use.

We may rely on collaborators for support of development programs and for the manufacturing and marketing of drug candidates. Such collaborators may be conducting multiple drug development efforts within the same disease areas that are the subject of their agreements with us, which may negatively impact the development of drugs that are subject to our agreements. In addition, we face and will continue to face intense competition from other companies for such collaborative arrangements, and technological and other developments by others may make it more difficult for us to establish such relationships.

## **Government Regulation**

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, pre-market approval, manufacture, marketing and distribution of pharmaceutical products. These agencies and other regulatory agencies regulate research and development activities and the testing, approval, manufacture, quality control, safety, effectiveness, labeling, storage, recordkeeping, advertising and promotion of drug candidates. Failure to comply with applicable FDA or other requirements may result in notices on Form 483, Warning Letters, civil or criminal penalties, suspension or delays in clinical development, recall or seizure of products, partial or total suspension of production or withdrawal of a product from the market.

In the United States, the FDA regulates drug products under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations. The process required by the FDA before drug candidates may be marketed in the United States generally involves the following:

completion of extensive preclinical laboratory tests and preclinical animal studies, many of which are required to be performed in accordance with the FDA's Good Laboratory Practice, or GLP, regulations;

submission to the FDA of an IND, which must become effective before human clinical trials may begin and be updated annually;

performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug candidate for each proposed indication;

submission to the FDA of an NDA after completion of all pivotal clinical trials;

a determination by the FDA within 60 days of its receipt of the NDA to file the NDA for review;

satisfactory completion of an FDA pre-approval inspection, or PAI, of the manufacturing facilities at which the active pharmaceutical ingredient, or API, and finished drug product, or FDP, are produced and tested to assess compliance with Current Good Manufacturing Practices, or CGMPs, regulations; and

FDA review and approval of the NDA prior to any commercial marketing or sale of the drug in the United States. Prior to commercialization, centrally acting drugs are generally subject to review and potential scheduling by the DEA.

## Edgar Filing: ARENA PHARMACEUTICALS INC - Form 10-K

The development and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our drug candidates will be granted on a timely basis, if at all.

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The results of preclinical tests (which include laboratory evaluation as well as GLP studies to evaluate toxicity in animals) for a particular drug candidate, together with related manufacturing information and analytical data, are submitted as part of an investigational new drug, or IND, application to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. IND submissions may not result in FDA authorization to commence a clinical trial. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development. Further, an independent institutional review board, or IRB, for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center and it must monitor the study until completed. The FDA, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive Good Clinical Practice, or GCP, regulations and regulations for informed consent and privacy of individually identifiable information.

*Clinical Trials.* For purposes of NDA submission and approval, clinical trials are typically conducted in the following sequential phases, which may overlap:

*Phase 1 Clinical Trials.* Studies are initially conducted in a limited population to test the drug candidate for safety, dose tolerance, absorption, metabolism, distribution and excretion, typically in healthy humans, but in some cases in patients.

*Phase 2 Clinical Trials.* Studies are generally conducted in a limited patient population to identify possible adverse effects and safety risks, explore the initial efficacy of the product for specific targeted indications and to determine dose range or pharmacodynamics. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

*Phase 3 Clinical Trials.* These are commonly referred to as pivotal studies. When Phase 2 evaluations demonstrate that a dose range of the product is effective and has an acceptable safety profile, Phase 3 clinical trials are undertaken in large patient populations to further evaluate dosage, provide substantial evidence of clinical efficacy and further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial centers.

*Phase 4 Clinical Trials.* The FDA may approve an NDA for a drug candidate, but require that the sponsor conduct additional clinical trials to further assess the drug after NDA approval under a post-approval commitment. In addition, a sponsor may decide to conduct additional clinical trials after the FDA has approved an NDA. Post-approval trials are typically referred to as Phase 4 clinical trials.

*New Drug Applications.* The results of drug development, preclinical studies and clinical trials are submitted to the FDA as part of an NDA. NDAs also must contain extensive manufacturing and control information. An NDA must be accompanied by a significant user fee, which is waived for the first NDA submitted by a qualifying small business. Once the submission has been accepted for filing, the FDA's goal is to review applications within 10 months of submission or, if the application relates to an unmet medical need in a serious or life-threatening indication, 6 months from submission. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee. The FDA may deny approval of an NDA by issuing a CRL if the applicable regulatory criteria are not satisfied. A CRL may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. Data are not always conclusive and the FDA may interpret data differently than we or our collaborators interpret data. Approval may occur with Risk Evaluation and Mitigation Strategies, or REMS, that limit the labeling, distribution or promotion of a drug

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product. Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety problems occur after the product reaches the market. In addition, the FDA may require testing, including Phase 4 clinical trials, and surveillance programs to monitor the safety effects of approved products which have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs or other information.

*Other Regulatory Requirements.* Products manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including recordkeeping, annual product quality review and reporting requirements. Adverse event experience with the product must be reported to the FDA in a timely fashion and pharmacovigilance programs to proactively look for these adverse events are mandated by the FDA. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including CGMPs, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Following such inspections, the FDA may issue notices on Form 483 and Warning Letters that could cause us to modify certain activities. A Form 483 notice, if issued at the conclusion of an FDA inspection, can list conditions the FDA investigators believe may have violated CGMP or other FDA regulations or guidelines. FDA guidelines specify that a Warning Letter be issued only for violations of regulatory significance, also known as Official Action Indicated, or OAI. Failure to adequately and promptly correct the observation(s) can result in regulatory action. In addition to Form 483 notices and Warning Letters, failure to comply with the statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as suspension of manufacturing, seizure of product, injunctive action or possible civil penalties. We cannot be certain that we or our present or future third-party manufacturers or suppliers will be able to comply with the CGMP regulations and other ongoing FDA regulatory requirements. If we or our present or future third-party manufacturers or suppliers are not able to comply with these requirements, the FDA may halt our clinical trials, require us to recall a drug from distribution or withdraw approval of the NDA for that drug.

The FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, dissemination of off-label information, industry-sponsored scientific and educational activities and promotional activities involving the Internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label. Further, if there are any modifications to the drug, including changes in indications, labeling, or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new or supplemental NDA, which may require us to develop additional data or conduct additional preclinical studies and clinical trials. Failure to comply with these requirements can result in adverse publicity, Warning Letters, corrective advertising and potential civil and criminal penalties.

Physicians may prescribe legally available drugs for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, impose stringent restrictions on manufacturers' communications regarding off-label use.

In Zofingen, Switzerland, our Swiss subsidiary, Arena GmbH operates a drug product manufacturing facility. Swissmedic, a public service organization of the Swiss federal government, is the central Swiss agency for the authorization and supervision of therapeutic products. Our Swiss manufacturing facility has been inspected by the competent regional authorities (Regionales Heilmittelinstitut der Nordostschweiz, Basel, Switzerland), acting on behalf of Swissmedic, which issued GMP and production licenses to Arena GmbH for the production of drugs. The production license is valid until July 2012. The FDA conducted a PAI of this facility in July 2010, which resulted in No Actions Indicated, and classified this facility as acceptable. However, this facility may be re-inspected by the FDA prior to approval of our lorcaserin NDA.

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*DEA Regulation.* The DEA regulates drugs that are controlled substances. Controlled substances are those drugs that appear on one of the five schedules promulgated and administered by the DEA under the Controlled Substances Act, or CSA. The CSA governs, among other things, the inventory, distribution, recordkeeping, handling, security and disposal of controlled substances. Any drug that acts on the central nervous system has the potential to become a controlled substance, and scheduling by the DEA is an independent process that may delay the commercial launch of a drug even after FDA approval of the NDA. If our drug candidates are scheduled by the DEA as controlled substances, we will be subject to periodic and ongoing inspections by the DEA and similar state drug enforcement authorities to assess our ongoing compliance with the DEA's regulations. Any failure to comply with these regulations could lead to a variety of sanctions, including the revocation, or a denial of renewal of any DEA registration, injunctions, or civil or criminal penalties.

### **Manufacturing and Sources and Availability of Raw Materials, Intermediates and Clinical Supplies**

In January 2008, we acquired from Siegfried certain drug product facility assets, including manufacturing facility production licenses, fixtures, equipment, other personal property and real estate assets in Zofingen, Switzerland, under an Asset Purchase Agreement between Siegfried and Arena GmbH. This facility is generating revenue from the manufacture of certain drug products for Siegfried. We have also used this facility to produce and package lorcaserin tablets for registration and validation. If lorcaserin is approved, we plan to use this facility for the commercial production and packaging of lorcaserin. We also plan to use this facility for producing and packaging tablets and capsules for other programs.

All of our manufacturing services revenues are attributable to Siegfried, which is our only customer for such services. Our revenues of \$16.6 million for the year ended December 31, 2010 included \$7.1 million, or 42.5% of our total revenues, from Siegfried. Our revenues of \$10.4 million for the year ended December 31, 2009 included \$6.6 million, or 63.3% of our total revenues, from Siegfried. Prior to entering into the manufacturing services agreement with Siegfried in January 2008, we recorded no manufacturing services revenues.

We purchase raw materials and intermediates when necessary from commercial sources. To decrease the risk of an interruption to our supply, when reasonably possible for us to do so, we source these materials from multiple suppliers so that, in general, the loss of any one source of supply would not have a material adverse effect on project timelines or inventory of clinical supplies for use in human trials. However, currently we have a primary source of supply for some key intermediates, API excipients, components and drug products for our lead development projects. The loss of a primary source of supply would potentially delay our lead development projects and commercialization efforts, including for lorcaserin, and potentially those of current or future collaborators. As a result of our receipt of the CRL for lorcaserin, commercial production has been delayed and the modification to the supply chain could result in scheduling conflicts at multiple suppliers, which may result in product delay.

### **Compliance with Environmental Regulations**

Our research and development programs involve the controlled use of hazardous materials, chemicals, biological materials and various radioactive compounds. In the United States, we are subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act, the Controlled Substances Act and other federal, state or local regulations.

With regard to Arena GmbH's drug product manufacturing facility, Arena GmbH has contracted with 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. Arena GmbH is subject to regulation under the Environmental Protection Act (Umweltschutzgesetz, USG), the Chemicals Act (Chemikaliengesetz, ChemG), and the Federal Act on the Protection of Waters (Gewässerschutzgesetz, GSchG), which refer to several ordinances such as the Ordinance on Air Pollution Control (Luftreinhalteverordnung),

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LRV), the Ordinance on Incentive Taxes on Volatile Organic Compounds (Verordnung über die Lenkungsabgabe auf flüchtigen organischen Verbindungen, VOCV), the Water Protection Ordinance (Gewässerschutzverordnung, GSchV), the Ordinance of the Handling of Wastes (Verordnung über den Verkehr mit Abfällen, VeVA), the Chemicals Ordinance (Chemikalienverordnung, ChemV), the Ordinance on Chemical Risk Reduction (Chemikalien-Risikoreduktions-Verordnung, ChemRRV) and the Ordinance on Protection against Major Accidents (Störfallverordnung, StfV). The competent authorities in Switzerland for the implementation of environmental regulations are BAFU (Bundesamt für Umwelt / Federal Office for the Environment), which is the Swiss federal agency for the environment, and the respective authorities of the Canton of Aargau (Abteilung für Umwelt, AfU). Furthermore, the BAFU and the BAG (Bundesamt für Gesundheit / Federal Office of Public Health) share authorities with regard to the implementation and, together with the respective authority of the Canton of Aargau (Amt für Verbraucherschutz), the supervision of compliance with the laws and regulations related to chemicals. Occupational health and safety is regulated, in particular, by the EKAS (Eidgenössische Koordinationskommission für Arbeitssicherheit) guideline No. 6508 (ASA), governing the evaluation of worker safety and the reporting to the relevant authorities. The competent authority for the implementation of occupational health and safety regulations is the Canton of Aargau (Amt für Wirtschaft und Arbeit), whereby exposure limits are set by SUVA (Schweizerische Unfallversicherungsanstalt), which is the Swiss Accident Insurance Fund.

The Registration, Evaluation, Authorization and Restriction of Chemicals Regulation (EC) No 1907/2006, commonly referred to as REACH, is Europe's broad chemicals legislation, which is directly applicable in all EU Member States. REACH creates a new system for gathering information, assessing risks to human health and the environment, and authorizing or restricting the marketing and use of chemicals produced or supplied in the EU. It applies to EU producers, importers and distributors/retailers of products, and users of chemicals in the course of industrial or professional activities. In compliance with REACH, we have registered relevant materials that could be imported into the EU by us or our third-party manufactures for the production of lorcaseerin and select components of other of our more advanced drug candidates.

We may be subject to further such regulations in the future. Although we believe that our operations comply in all material respects with the applicable environmental laws and regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. In the event of such an accident, we could be held liable for any damages that result, and the extent of that liability could exceed our resources. Our compliance with these laws and regulations has not had, and is not expected to have, a material effect upon our capital expenditures, results of operations or competitive position.

### **Research and Development Expenses**

Research and development activities are the primary source of our expenses. Our research and development expenses include personnel costs, research supplies, facility and equipment costs, clinical and preclinical study fees and manufacturing costs. Such expenses totaled \$75.5 million for the year ended December 31, 2010, \$110.2 million for the year ended December 31, 2009, and \$204.4 million for the year ended December 31, 2008. We include research and development sponsored by collaborators in our total research and development expenses.

### **Employees**

As of February 28, 2011, we had a total of 351 employees, including 294 in research, development and manufacturing and 57 in administration, which includes finance, legal, facilities, information technology and other general support areas.

On January 27, 2011, we committed to a reduction of our US workforce of approximately 25%, or 66 employees, which we plan to complete around March 28, 2011. Of these 66 employees, 60 are in research, development and manufacturing and 6 are in administration.

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### **Available Information**

Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, or the Exchange Act, are available free of charge on our website ([www.arenapharm.com](http://www.arenapharm.com)) as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC.

### **Item 1A. 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 Annual Report on Form 10-K and 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.*

#### ***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 lorcaserin 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 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 address the FDA's concerns, including by conducting nonclinical studies and a clinical trial with a small number of volunteers, and believe that we may be able to resubmit the lorcaserin NDA by the end of 2011. It may, however, take up to an additional year or more to resubmit the NDA, depending on the results of our ongoing and planned activities, any new guidance and feedback we receive from the FDA, and the need for any additional activities, which may include a 12-month study in rats. We may ultimately determine not to resubmit the NDA.

Our response to the CRL may require other nonclinical studies or clinical trials in addition to the studies and trials that are ongoing or planned, 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. 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.

**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 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.



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**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 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. Moreover, 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 in the marketplace, which could affect clinical enrollment or sales if lorcaserin is approved for commercialization.

We have completed 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). These trials ruled out an increase of more than 55% in the relative risk for FDA-defined valvular heart disease with lorcaserin. We plan to submit to the FDA 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. 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 expand the receptor pharmacology studies to more fully characterize lorcaserin's activity at the serotonin 2A and 2B receptors. The FDA may not find our data favorable, or may request additional data or other information or analysis, or decline to approve our NDA for 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;

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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.

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 lorcaserin in the United States on acceptable terms, if at all, and even if we elected to pursue further development or commercialization of lorcaserin 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 lorcaserin 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 complaints were filed in the US District Court for the Southern District of California against us and certain of our 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 employees and directors violated federal securities laws by making materially false and misleading statements regarding our lorcaserin 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 in federal and state courts.

We intend to vigorously defend these lawsuits. There is, however, no guarantee that we will be successful. 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

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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.

### **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 lorcaserin 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.

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.

### **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

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obligations. This loan matures on June 17, 2013, and the outstanding principal 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 currently-outstanding principal of \$40.0 million at maturity, which was \$60.0 million at December 31, 2010.

We may be required to make the \$40.0 million repayment earlier in connection with certain equity issuances. For example, we were required to repay \$10.0 million, which was initially required to be repaid in July 2010, in connection with the closing of our July 2009 public offering. In addition, we are required to repay the loan upon certain changes of control and in the event we issue equity securities (other than certain exempted issuances) at a price of less than \$2.00 per share. The Facility Agreement also places certain restrictions on our business, including our ability to incur additional indebtedness and to undertake certain business transactions.

On or before June 17, 2011, Deerfield may elect to provide us with an additional loan in a principal amount of up to \$20.0 million under similar terms as the July 2009 loan, with the additional loan also maturing on June 17, 2013.

In the future, if we are unable to generate cash from operations sufficient to meet these debt obligations, 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 these debt obligations, or we need to use existing cash to fund these debt obligations, 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 lorcaserin outside of

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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 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 objectional 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, 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 Drug Enforcement Administration of the US Department of Justice, or 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 available data 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

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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;

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 NDAs to the FDA. 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



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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 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 other countries or any delay or setback in obtaining such approval could have the same adverse effects associated with regulatory approval in the United States, including the risk that our drug candidates may not be approved for all indications requested and that such approval may be subject to limitations on the indicated uses for which the drug may be marketed.

### **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



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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 available data 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.

**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.**

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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;

prevalence and severity of any side effects;

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potential or perceived advantages or disadvantages over 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;

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

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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;

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

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

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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.

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### **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.

### **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.

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**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.

**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 Affordability 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



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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;

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.

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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

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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 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 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 our clinical trial protocols or GCPs, our 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

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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 initiated in January 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.

**If we do not realize the expected benefits from the reduction in force that we announced in January 2011, our operating results and financial conditions would be negatively impacted.**

We announced in January 2011 a reduction in our US workforce of approximately 25%, which is 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. However, insurance coverage is increasingly expensive. 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.

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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 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

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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 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 Securities and Exchange Commission, or 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





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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

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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 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. Several of the patent law changes that are being considered could significantly weaken patent protections in the United States in general. They may also have a disproportionately large negative impact on our industry in particular, as well as tilt the balance of market control and distribution of profits between the manufacturers of patented pharmaceutical products and the manufacturers of generic pharmaceutical products towards the generics manufacturers. At present there is considerable uncertainty as to which patent laws will be changed and exactly how changes to the patent laws will ultimately be enforced by the courts.

**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 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,

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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;

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

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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 February 28, 2011, the market price of our stock was as low as \$1.26 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;

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;

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.

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**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 121,515,805 shares of our common stock outstanding as of February 28, 2011. We also had outstanding as of February 28, 2011 a seven-year warrant issued in June 2006 to purchase 1,046,781 shares of our common stock at an exercise price of \$12.28 per share and a seven-year warrant issued in August 2008 to purchase 1,398,346 shares of our common stock at an exercise price of \$6.10 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.

We also had outstanding as of February 28, 2011, warrants we issued to Deerfield to purchase 16,200,000 and 11,800,000 shares of our common stock at per share exercise prices of \$3.45 and \$5.42, respectively. In certain circumstances we may be obligated to issue Deerfield additional warrants to purchase up to 5,600,000 shares of common stock at an exercise price of \$5.42 per share. All of these warrants are or will be exercisable until June 17, 2013.

In addition to our outstanding warrants, as of February 28, 2011, there were (i) options to purchase 8,214,732 shares of our common stock outstanding under our equity incentive plans at a weighted-average exercise price of \$7.55 per share, (ii) 1,652,400 performance-based restricted stock unit awards outstanding under our 2006 Long-Term Incentive Plan, as amended, (iii) 5,613,753 additional shares of common stock remaining issuable under our 2009 Long-Term Incentive Plan, (iv) 826,647 shares of common stock remaining issuable under our 2009 Employee Stock Purchase Plan, and (v) 84,169 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.**

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.

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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.

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 1B. Unresolved Staff Comments.**

None.

**Table of Contents****Item 2. Properties.**

As set forth in the below table, the principal facilities that we occupy include approximately 345,000 square feet of research, development, warehouse and office space located at various addresses in the same business park in San Diego, California and approximately 81,000 square feet of laboratory, manufacturing, warehouse and office space located in the same business park in Zofingen, Switzerland.

<b>Location</b>	<b>Own/ Lease</b>	<b>Description</b>
6114 Nancy Ridge Drive	Lease with option to purchase	This chemical development facility consists of approximately 40,000 square feet (which includes approximately 18,000 of internal square feet and approximately 22,000 square feet of integrated external space), of which approximately 5,000 square feet is office space. The remaining approximately 35,000 square feet of space is dedicated to process research and scale-up chemistry, the production of intermediates and other compounds for research and development purposes, and the production of active pharmaceutical ingredients to support our clinical trials. We are using this facility for the production of scale-up lots for our internal research programs, safety studies and clinical trials. We commenced CGMP operations in this facility in 2004. In May 2007, we completed a sale and leaseback of this facility, and have an option to purchase it back.
6118 Nancy Ridge Drive	Lease with option to purchase	This facility of approximately 30,000 square feet consists of approximately 50% laboratory space and 50% office space. In May 2007, we completed a sale and leaseback of this facility, and have an option to purchase it back.
6122-6124-6126 Nancy Ridge Drive	Lease with option to purchase	The portion of this facility we lease consists of approximately 40,000 square feet, of which approximately 24,000 square feet is laboratory space and 16,000 square feet is office space. We have assigned our option to purchase the entire facility, which includes approximately 68,000 square feet, and have an option to purchase the facility back.
6138-6150 Nancy Ridge Drive	Lease with option to purchase	This facility of approximately 55,000 square feet consists of approximately 33,000 square feet of laboratory space and 22,000 square feet of office space. In December 2003, we completed a sale and leaseback of this facility, and have an option to purchase it back.
6154 Nancy Ridge Drive	Lease with option to purchase	This facility of approximately 143,000 square feet consists of approximately 131,000 square feet of office space and 12,000 square feet of warehouse space, including approximately 75,000 square feet of office space that was added in December 2008. In May 2007, we completed a sale and leaseback of the original 68,000 square foot facility. We have an option to purchase the entire 143,000 square feet facility back.
6162 Nancy Ridge Drive	Own	This facility includes approximately 20,000 square feet of warehouse and office space, all of which is presently unoccupied except for approximately 1,000 square feet that we have leased to a third party.
6166 Nancy Ridge Drive	Lease	This facility of approximately 37,000 square feet consists of approximately 23,000 square feet of laboratory space and 14,000 square feet of office space.



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<b>Location</b>	<b>Own/ Lease</b>	<b>Description</b>
Zofingen, Switzerland	Own	The portion of this facility we own consists of approximately 67,000 square feet, including approximately 39,000 square feet of manufacturing space, 21,000 square feet of warehouse space and 7,000 square feet of office space.
Zofingen, Switzerland	Lease	We lease from Siegfried a total of approximately 14,000 square feet, consisting of approximately 6,000 square feet of warehouse space, 5,000 square feet of office space and 3,000 square feet of laboratory space, in various facilities.

We expect these facilities to be sufficient for our needs for at least the near term.

**Item 3. Legal Proceedings.**

Beginning 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 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 employees and directors violated federal securities laws by making materially false and misleading statements regarding our lorcaserin trials, 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, to appoint a lead plaintiff, and to appoint lead counsel. The Court took the motions to consolidate under submission on January 14, 2011. We expect the Court to consolidate the actions, to appoint a lead plaintiff and lead counsel, and to order the lead plaintiff to file a consolidated complaint. In addition to the class actions, a complaint involving similar legal and factual issues has been brought by at least one individual stockholder. We intend to vigorously defend against the claims advanced, and intend to seek dismissal of these complaints.

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 employees and directors, and other stockholder derivative complaints were subsequently filed in state court. On October 19, 2010, the Superior Court ordered the pending state derivative complaints be consolidated; we refer to such complaints as the State Derivative Action. The Superior Court also ordered that later filed, related derivative complaints be consolidated as well. In November 2010, plaintiffs in the State Derivative Action filed a consolidated stockholder derivative complaint. We filed a demurrer to the consolidated stockholder derivative complaint on February 15, 2011. A hearing on the demurrer has been scheduled for April 1, 2011. On October 6, 2010, a stockholder derivative suit was filed in the US District Court for the Southern District of California. Thereafter, a number of other stockholder derivative actions were filed in federal court, which we refer to as the Federal Derivative Action. The court consolidated the Federal Derivative Action and appointed lead counsel, and we expect a consolidated derivative complaint will be filed. We refer to the State Derivative Action and the Federal Derivative Action collectively as the Derivative Actions. The complaints in the Derivative Actions allege breaches of fiduciary duties by the defendants and other violations of law. In general, the complaints 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 trials, thereby artificially inflating the price of our common stock. The plaintiffs are seeking unspecified monetary damages and other relief, including reforms and improvements to our corporate governance and internal procedures. We intend to vigorously defend against the claims advanced and to seek dismissal of the Derivative Actions.

**Table of Contents****PART II****Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.**  
**Market information**

Our common stock is listed on the NASDAQ Global Select Market under the symbol ARNA. The following table sets forth, for the periods indicated, the high and low sale prices for our common stock as reported by the NASDAQ Global Select Market.

	<b>High</b>	<b>Low</b>
<b>Year ended December 31, 2009</b>		
First Quarter	\$ 7.42	\$ 2.85
Second Quarter	\$ 5.64	\$ 2.26
Third Quarter	\$ 5.93	\$ 3.82
Fourth Quarter	\$ 4.83	\$ 3.26
	<b>High</b>	<b>Low</b>
<b>Year ended December 31, 2010</b>		
First Quarter	\$ 3.85	\$ 2.89
Second Quarter	\$ 3.48	\$ 2.70
Third Quarter	\$ 8.00	\$ 1.51
Fourth Quarter	\$ 2.38	\$ 1.26

**Holdings**

As of February 28, 2011, there were approximately 137 stockholders of record of our common stock, one of which is Cede & Co., a nominee for Depository Trust Company, or DTC. Shares of common stock that are held by financial institutions as nominees for beneficial owners are deposited into participant accounts at DTC, and are considered to be held of record by Cede & Co. as one stockholder.

**Dividends**

We have never paid cash dividends on our capital stock, and we are prohibited from doing so under the Facility Agreement, dated June 17, 2009, between us and 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. We anticipate that we will retain earnings, if any, to support operations and finance the growth and development of our business and, therefore, do not expect to pay cash dividends in the foreseeable future.

**Table of Contents****Item 6. Selected Financial Data.**

The following Selected Financial Data should be read in conjunction with Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations and Item 8. Financial Statements and Supplementary Data included below in this Annual Report on Form 10-K.

	Years ended December 31,				
	2010	2009	2008	2007	2006
(In thousands, except share and per share data)					
<b>Revenues</b>					
Manufacturing services	\$ 7,057	\$ 6,579	\$ 7,434	\$ 0	\$ 0
Collaborative agreements	9,556	3,808	2,375	19,332	30,569
Total revenues	16,613	10,387	9,809	19,332	30,569
<b>Operating Expenses</b>					
Cost of manufacturing services	7,414	6,536	8,515	0	0
Research and development	75,459	110,159	204,374	149,524	103,388
General and administrative	27,936	25,247	30,535	26,571	18,466
Restructuring charges	0	3,324	0	0	0
Amortization of acquired technology and other intangibles	2,159	3,508	2,314	1,537	1,537
Total operating expenses	112,968	148,774	245,738	177,632	123,391
Interest and other income (expense), net	(28,179)	(14,817)	(1,644)	15,134	6,574
Net loss	(124,534)	(153,204)	(237,573)	(143,166)	(86,248)
Dividends on redeemable convertible preferred stock	0	0	(1,912)	(2,114)	(2,031)
Net loss allocable to common stockholders	\$ (124,534)	\$ (153,204)	\$ (239,485)	\$ (145,280)	\$ (88,279)
Net loss per share allocable to common stockholders, basic and diluted	\$ (1.14)	\$ (1.82)	\$ (3.24)	\$ (2.31)	\$ (1.89)
Shares used in calculating net loss per share allocable to common stockholders, basic and diluted	109,573,177	84,341,362	73,840,716	62,782,850	46,750,596

	As of December 31,				
	2010	2009	2008	2007	2006
(In thousands)					
<b>Balance Sheet Data:</b>					
Cash and cash equivalents	\$ 150,669	\$ 94,733	\$ 73,329	\$ 386,989	\$ 373,044
Short-term investments, available-for-sale	0	20,716	36,800	11,196	15,781
Total assets	266,362	236,278	241,331	487,506	468,465
Total deferred revenues	48,077	4,086	4,049	4,049	13,054
Total lease financing obligations	76,769	77,486	63,067	62,307	13,678
Total derivative liabilities	2,271	6,642	0	0	0
Total notes payable	48,138	57,049	8,567	0	0
Redeemable convertible preferred stock	0	0	0	53,922	51,808
Accumulated deficit	(989,121)	(864,587)	(718,936)	(479,451)	(334,171)
Total stockholders' equity	80,015	74,567	117,632	336,377	366,115

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**Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.**

You should read the following discussion and analysis in conjunction with Item 8. Financial Statements and Supplementary Data included below in this Annual Report on Form 10-K, or Annual Report. Operating results are not necessarily indicative of results that may occur in future periods.

This discussion and analysis contains forward-looking statements that involve a number of risks, uncertainties and assumptions. Actual events or results may differ materially from our expectations. Important factors that could cause actual results to differ materially from those stated or implied by our forward-looking statements include, but are not limited to, those set forth in Item 1A. Risk Factors in this Annual Report. All forward-looking statements included in this Annual Report are based on information available to us as of the time we file this Annual Report and, except as required by law, we undertake no obligation to update publicly or revise any forward-looking statements.

**OVERVIEW AND RECENT DEVELOPMENTS**

We have incurred net losses of \$1.0 billion from our inception in April 1997 through December 31, 2010, and expect to incur significant net losses in the future as we work to obtain regulatory approval of our most advanced drug candidate, lorcaserin hydrochloride, or lorcaserin, and advance certain earlier-stage research and development programs. Arena Pharmaceuticals GmbH, or Arena GmbH, our wholly owned subsidiary, has granted Eisai Inc., or Eisai, exclusive rights to market and distribute lorcaserin in the United States and its territories and possessions subject to US Food and Drug Administration, or FDA, approval of our New Drug Application, or NDA, for lorcaserin. In October 2010, the FDA issued us 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. The FDA also described nonclinical and clinical reasons for its decision and provided recommendations relating to addressing such issues. Following our receipt of the CRL, we had an end-of-review meeting and additional communications with the FDA regarding the CRL and our response, and expect to have ongoing discussions with the FDA. Our plan to address the issues raised by the FDA in the CRL and in subsequent discussions and communications includes various activities, including nonclinical studies and a clinical study in a small number of volunteers.

We have obtained cash and funded our operations to date primarily through the sale of common and preferred stock, the issuance of debt and related financial instruments, payments from collaborators and sale leaseback transactions. From our inception through December 31, 2010, we have generated \$1.4 billion in cash from these sources, of which \$1.0 billion was through sales of equity, \$219.3 million was through payments from collaborators, \$96.9 million was through the issuance to certain Deerfield entities of debt and related financial instruments and \$77.1 million was from sale leaseback transactions. At December 31, 2010, we had \$150.7 million in cash and cash equivalents. We will continue to be opportunistic in our efforts to obtain cash, and expect to evaluate various financing alternatives on an ongoing basis.

Our recent and 2010 developments include:

**Lorcaserin**

In October 2010, received a CRL from the FDA regarding the lorcaserin NDA and, in December 2010, completed an end-of-review meeting with the FDA and reported our plans related to resubmitting the NDA.

In November 2010, announced top-line results from our Phase 3 BLOOM-DM (Behavioral modification and Lorcaserin for Overweight and Obesity Management in Diabetes Mellitus) trial, which evaluated lorcaserin for weight management in obese and overweight patients with type 2 diabetes. Lorcaserin met the three primary efficacy endpoints, and we believe the results favorably support the benefit-risk profile of lorcaserin.

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In October 2010, presented at Obesity 2010, the 28th Annual Scientific Meeting of The Obesity Society, results from a lorcaserin mechanism of action study conducted at the Pennington Biomedical Research Center. The data showed that lorcaserin reduces energy intake and appetite, and causes weight loss without stimulating energy expenditure.

In July 2010, the FDA completed the Pre-Approval Inspection, or PAI, of our drug product manufacturing facility in Switzerland and classified the inspection as No Action Indicated.

In July 2010, results from our two-year, Phase 3 BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management) trial were published in the July 15, 2010, issue of the *New England Journal of Medicine*.

In July 2010, Arena GmbH entered into a marketing and supply agreement with Eisai for the commercialization of lorcaserin in the United States subject to FDA approval of our NDA for lorcaserin. Under the terms of the agreement, we received a non-refundable, upfront payment of \$50.0 million from Eisai.

In June 2010, presented pooled Week 52 data from our BLOOM and BLOSSOM (Behavioral modification and Lorcaserin Second Study for Obesity Management) trials at the American Diabetes Association's 70th Scientific Sessions.

## **Other**

In March 2011, announced the issuance of US Reissue Patent No. RE42,190 with claims to methods of identifying compounds that modulate the activity of the GPR119 receptor, a target for identifying small molecules for the treatment of diabetes.

In February 2011, announced the resignation of Robert E. Hoffman, Vice President, Finance and Chief Financial Officer, which is effective upon the filing of this Annual Report.

In January 2011, committed to a reduction in our US workforce of approximately 25%, or 66 employees, which is expected to be completed around March 28, 2011. As a result of this workforce reduction, we expect to incur charges, primarily in the first quarter of 2011, of approximately \$3.8 million in connection with one-time employee termination costs.

In December 2010, initiated dosing in a Phase 1 clinical trial of APD811, an oral drug candidate we discovered that targets the prostacyclin receptor for the potential treatment of pulmonary arterial hypertension. This randomized, double-blind, placebo-controlled trial is evaluating the safety, tolerability and pharmacokinetics of single-ascending doses of APD811.

In October 2010, announced that following the completion of a Phase 1 clinical trial program for APD597, Ortho-McNeil-Janssen Pharmaceuticals, Inc., or Ortho-McNeil-Janssen, decided not to advance APD597 and terminated our collaboration effective December 28, 2010. APD597 targets the GPR119 receptor for the potential treatment of type 2 diabetes, which, along with other compounds and intellectual property, reverted to us under the terms of the collaboration. We believe APD597 may have utility alone and in combination with a DPP-4 inhibitor for the treatment of type 2 diabetes.

In October 2010, announced results from a Phase 1 clinical trial of APD916, a novel drug candidate we discovered that targets the histamine H3 receptor for the potential treatment of narcolepsy with cataplexy. In this randomized, double-blind, placebo-controlled trial in 24 healthy volunteers, APD916 demonstrated dose-proportional pharmacokinetic exposure over the tested dose range.

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In August 2010, received gross proceeds of approximately \$60.0 million from the sale of approximately 9.0 million shares of our common stock to certain Deerfield entities. As part of the transaction, we amended our June 2009 Facility Agreement with Deerfield pursuant to which \$30.0 million of the proceeds from this transaction was used to prepay the portion of the principal amount that we otherwise would have been required to repay in July 2012.

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In June 2010, received net proceeds of \$35.5 million from the sale of 11.0 million shares of common stock to Deerfield. As part of the transaction, the exercise price of outstanding warrants to purchase 16.2 million shares of common stock that we previously issued to Deerfield were reduced from \$5.42 to \$3.45 per share.

In March 2010, received aggregate net proceeds of \$24.2 million from the sale of approximately 8.3 million shares of common stock under an equity financing commitment with Azimuth Opportunity Ltd, which agreement terminated in connection with this financing.

We refer you to our previously filed Current Reports on Form 8-K for a more complete discussion of these developments.

The drug development and approval process is long, uncertain and expensive, and our ability to achieve our goals depends on numerous factors, many of which are out of our control. We will continue to seek to balance the high costs of research, development and manufacturing to advance lorcaserin and certain of our other drug candidates against the need to sustain our operations long enough to commercialize the results of our efforts. To date, we have not generated any revenues from the sale of any of our drug candidates. We do not expect any of our drug candidates to be commercially available until at least the second half of 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. 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 our expected lower clinical trial expenses, cost savings from our recently announced workforce reduction 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 earlier-stage research and development programs and continue to incur general and administrative expenses.

**SUMMARY OF REVENUES AND EXPENSES**

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	Years ended December 31,			% change from 2009 to 2010	% change from 2008 to 2009
	2010	2009	2008		
Manufacturing services agreement	\$ 7.1	\$ 6.6	\$ 7.4	7.3%	(11.5)%
Collaborative agreements	9.5	3.8	2.4	151.0%	60.3%
Total revenues	\$ 16.6	\$ 10.4	\$ 9.8	60.0%	5.9%

**Table of Contents****Research and development expenses**

Type of expense	Years ended December 31,			% change from 2009 to 2010	% change from 2008 to 2009
	2010	2009	2008		
Salary and other personnel costs (excluding non-cash share-based compensation)	\$ 33.5	\$ 35.5	\$ 42.4	(5.4)%	(16.5)%
External clinical and preclinical study fees and expenses, including manufacturing costs	16.0	45.7	123.5	(65.1)%	(63.0)%
Facility and equipment costs	14.2	15.4	16.0	(7.5)%	(3.7)%
Research supplies	3.9	4.6	10.8	(15.1)%	(57.1)%
Non-cash share-based compensation	3.4	4.1	5.0	(16.6)%	(17.9)%
Other	4.5	4.9	6.7	(9.6)%	(27.4)%
<b>Total research and development expenses</b>	<b>\$ 75.5</b>	<b>\$ 110.2</b>	<b>\$ 204.4</b>	<b>(31.5)%</b>	<b>(46.1)%</b>

**General and administrative expenses**

Type of expense	Years ended December 31,			% change from 2009 to 2010	% change from 2008 to 2009
	2010	2009	2008		
Salary and other personnel costs (excluding non-cash share-based compensation)	\$ 9.9	\$ 9.1	\$ 10.6	9.0%	(14.1)%
Legal, accounting and other professional fees	9.7	7.9	9.8	21.7%	(19.0)%
Facility and equipment costs	3.8	3.5	3.6	6.5%	(1.4)%
Non-cash share-based compensation	2.1	2.8	3.5	(24.0)%	(21.8)%
Other	2.4	1.9	3.0	30.6%	(37.0)%
<b>Total general and administrative expenses</b>	<b>\$ 27.9</b>	<b>\$ 25.2</b>	<b>\$ 30.5</b>	<b>10.7%</b>	<b>(17.3)%</b>

**YEAR ENDED DECEMBER 31, 2010 COMPARED TO YEAR ENDED DECEMBER 31, 2009**

**Revenues.** We recognized revenues of \$16.6 million during the year ended December 31, 2010, compared to \$10.4 million during the year ended December 31, 2009. Our revenues recognized during the year ended December 31, 2010 included (i) \$7.1 million in manufacturing services revenue under our manufacturing services agreement with Siegfried Ltd, or Siegfried, (ii) \$4.0 million of deferred non-cash revenues recognized from our license agreement with TaiGen Biotechnology Co., Ltd., or TaiGen, (iii) \$3.2 million for patent activities, primarily related to our collaboration with Ortho-McNeil-Janssen that was terminated effective December 28, 2010, (iv) \$1.9 million from amortization of the \$50.0 million non-refundable, upfront payment we received in July 2010 under our marketing and supply agreement with Eisai and (v) \$0.4 million related to a license agreement with GlaxoSmithKline LLC and GlaxoSmithKline Research & Development Limited for their use of our Melanophore screening technology. Our revenues recognized during the year ended December 31, 2009 included \$6.6 million in manufacturing services revenue under our manufacturing services agreement with Siegfried and \$3.8 million for patent activities and additional sponsored research from our former collaborations with Ortho-McNeil-Janssen and Merck & Co., Inc., or Merck.

When collaborators pay us before revenues are earned, we record such payments as deferred revenues until earned. As of December 31, 2010, we had a total of \$48.1 million in deferred revenues, all of which was attributable to our marketing and supply agreement with Eisai and will be recognized as revenue ratably over 13 years, which represents the period in which we expect to have significant involvement. 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, as well as research funding and reimbursement from Eisai for 50% of the cost of additional external 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 our manufacturing services agreement will be lower than in 2010. We do not expect to recognize any revenues in 2011 from our license agreement with TaiGen.





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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.

**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 \$7.4 million and \$6.5 million for the years ended December 31, 2010 and 2009, respectively.

**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. Other than external expenses for our clinical and preclinical programs, we generally do not track our earlier-stage research and development expenses by project; rather, we track such expenses by the type of cost incurred.

Research and development expenses decreased by \$34.7 million to \$75.5 million for the year ended December 31, 2010, from \$110.2 million for the year ended December 31, 2009. This difference was primarily due to decreases of (i) \$29.7 million in external clinical and preclinical study fees and expenses, primarily due to completing our lorcaserin Phase 3 clinical trials, (ii) \$2.0 million in salary and other personnel costs as a result of our June 2009 workforce reduction and (iii) \$1.2 million in facility and equipment costs. 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 recently announced workforce reduction. We expect to incur manufacturing costs for lorcaserin as we prepare for the launch of lorcaserin following FDA approval 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 \$16.0 million total external clinical and preclinical study fees and expenses noted in the table above for the year ended December 31, 2010 was \$12.9 million related to our lorcaserin program, \$1.4 million related to our APD811 program for the potential treatment of pulmonary arterial hypertension, \$1.1 million related to our APD334 program for the potential treatment of autoimmune diseases, including multiple sclerosis, and \$0.5 million related to our APD916 program for the potential treatment of narcolepsy with cataplexy. Included in the \$45.7 million total external clinical and preclinical study fees and expenses noted in the table above for the year ended December 31, 2009 was \$43.3 million related to our lorcaserin program, \$1.3 million related to our APD811 program and \$0.5 million related to our APD125 program, which we previously studied for insomnia.

Cumulatively through December 31, 2010, we have recognized \$269.1 million, \$43.7 million, \$7.3 million, \$2.8 million, \$2.7 million and \$1.1 million in external clinical and preclinical study fees and other related expenses for lorcaserin, APD125, APD791, APD916, APD811 and APD334, respectively. APD791 is intended for the treatment of arterial thrombosis and other related conditions. While expenditures on current and future clinical development programs are expected to be substantial, they are subject to many uncertainties, including whether we have adequate funds and develop our drug candidates independently or with a collaborator. As a

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result of such uncertainties, we cannot predict with any significant degree of certainty the duration and completion costs of our research and development projects or whether, when and to what extent we will generate revenues from the commercialization and sale of any of our drug candidates. The duration and cost of clinical trials may vary significantly over the life of a project as a result of unanticipated events arising during clinical development and a variety of factors, including:

the nature and number of trials and studies in a clinical program;

the number of patients who participate in the trials;

the number of sites included in the trials;

the rates of patient recruitment and enrollment;

the duration of patient treatment and follow-up;

the costs of manufacturing our drug candidates; and

the costs, requirements, timing of, and the ability to secure regulatory approvals.

**General and administrative expenses.** General and administrative expenses increased by \$2.7 million to \$27.9 million for the year ended December 31, 2010, from \$25.2 million for the year ended December 31, 2009. This was primarily due to increases of (i) \$1.7 million in legal fees, including litigation and patent legal fees, (ii) \$0.8 million in salary and other personnel costs and (iii) \$0.7 million in non-cash share-based compensation. We expect that our 2011 general and administrative expenses will be lower than in 2010, primarily as a result of our cost-containment efforts, including our recently announced workforce reduction and lower legal fees, primarily patent legal fees.

**Restructuring charges.** We recognized no restructuring charge in the year ended December 31, 2010 compared to a charge of \$3.3 million in the year ended December 31, 2009 in connection with a June 2009 reduction of our US workforce of approximately 31%, or a total of 130 employees. On January 27, 2011, we committed to a reduction in our US workforce of approximately 25%, or 66 employees, which we plan to complete around March 28, 2011. As a result of this workforce reduction, we expect to incur charges, primarily in the first quarter of 2011, of approximately \$3.8 million in connection with one-time employee termination costs, including severance and other benefits. We expect this workforce reduction will result in annual operating cost savings of approximately \$13.5 million.

**Amortization of acquired technology and other intangibles.** We recognized \$2.2 million for amortization of acquired technology and other intangibles for the year ended December 31, 2010, compared to \$3.5 million for the year ended December 31, 2009. This decrease is primarily due to the workforce we acquired from Siegfried in January 2008, which was amortized over its estimated benefit of two years through the end of 2009. The amortization expense recognized in 2010 relates to the manufacturing facility production licenses we acquired in January 2008, which are being amortized over their estimated useful life of 20 years, and the Melanophore screening technology, our primary screening technology, which is being amortized over its estimated useful life of 10 years. Using the exchange rate in effect on December 31, 2010, we expect to record amortization expense of \$0.7 million per year through 2027 for the manufacturing facility production licenses. We also expect to record \$0.3 million for the remaining amortization expense related to our Melanophore screening technology in the first quarter of 2011.

**Interest and other expense, net.** Interest and other expense, net, increased by \$13.4 million to \$28.2 million for the year ended December 31, 2010, from \$14.8 million for the year ended December 31, 2009. This increase was primarily due to increases of (i) \$9.9 million in non-cash loss on extinguishment of debt and (ii) \$3.0 million in interest expense related to the loan we received from Deerfield in July 2009. This increase was partially offset by (i) a \$1.0 million decrease in the non-cash gain from revaluation of our derivative liabilities and (ii) a \$0.9 million gain on investments. The interest expense recognized in 2010 includes \$6.1 million we paid to Deerfield in cash and the non-cash correction of prior period errors described in the notes to our consolidated financial statements herein, which resulted in a \$3.0 million decrease to interest expense

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second quarter of 2010. On January 28, 2011, we prepaid \$20.0 million of principal that was due on the Deerfield loan in July 2011 and expect to recognize a non-cash loss on extinguishment of debt of \$2.5 million in the first quarter of 2011. We expect that our interest expense will continue to be substantial as a result of the Deerfield loan and, to a lesser degree, payments on our lease financing obligations.

**YEAR ENDED DECEMBER 31, 2009 COMPARED TO YEAR ENDED DECEMBER 31, 2008**

**Revenues.** We recognized revenues of \$10.4 million during the year ended December 31, 2009, compared to \$9.8 million during the year ended December 31, 2008. Our revenues recognized during the year ended December 31, 2009 included \$6.6 million in manufacturing services revenue under our manufacturing services agreement with Siegfried and \$3.8 million for patent activities and additional sponsored research from our former collaborations with Ortho-McNeil-Janssen and Merck. Our revenues recognized during the year ended December 31, 2008 included \$7.4 million in manufacturing services revenue under our manufacturing services agreement with Siegfried and \$2.4 million for patent activities from our former collaborations with Ortho-McNeil-Janssen and Merck.

**Cost of manufacturing services.** Cost of manufacturing services was \$6.5 million and \$8.5 million for the years ended December 31, 2009 and 2008, respectively.

**Research and development expenses.** Research and development expenses decreased by \$94.2 million to \$110.2 million for the year ended December 31, 2009, from \$204.4 million for the year ended December 31, 2008. This difference was primarily due to decreases of (i) \$77.7 million in external clinical and preclinical study fees and expenses primarily due to completing our lorcaserin pivotal Phase 3 clinical trials in 2009 and prioritizing our spending towards activities that supported the lorcaserin NDA filing, (ii) \$7.0 million in salary and other personnel costs as a result of our June 2009 workforce reduction and (iii) \$6.2 million in research supplies due to less research personnel and our cost-containment efforts. Included in the \$45.7 million total external clinical and preclinical study fees and expenses noted in the table above for the year ended December 31, 2009 was \$43.3 million related to our lorcaserin program, \$1.3 million related to our APD811 program and \$0.5 million related to our APD125 program. Included in the \$123.5 million total external clinical and preclinical study fees and expenses for the year ended December 31, 2008 was \$106.0 million related to our lorcaserin program, \$13.5 million related to our APD125 program, \$1.4 million related to our APD916 program and \$1.1 million related to our APD791 program.

**General and administrative expenses.** General and administrative expenses decreased by \$5.3 million to \$25.2 million for the year ended December 31, 2009, from \$30.5 million for the year ended December 31, 2008. This difference was primarily due to decreases of (i) \$1.9 million in legal and other professional fees, primarily patent fees, (ii) \$1.5 million in salary and other personnel costs as a result of our 2009 workforce reduction and (iii) \$0.7 million in market research expenses.

**Restructuring charges.** We recognized a charge of \$3.3 million in the year ended December 31, 2009 in connection with our June 2009 workforce reduction, and no such charge in the year ended December 31, 2008.

**Amortization of acquired technology and other intangibles.** We recognized \$3.5 million for amortization of acquired technology and other intangibles for the year ended December 31, 2009, compared to \$2.3 million for the year ended December 31, 2008. The increased amortization related to the manufacturing facility production licenses we acquired in January 2008.

**Interest and other expense, net.** Interest and other expense, net, increased by \$13.2 million to \$14.8 million for the year ended December 31, 2009, from \$1.6 million for the year ended December 31, 2008. This increase in expense was primarily due to (i) an \$11.2 million increase in interest expense related to our Deerfield loan, (ii) a \$6.7 million decrease in interest income attributable to lower interest rates and, for much of the year, cash balances and (iii) a \$2.5 million non-cash loss on extinguishment of debt resulting from our \$10.0 million repayment on the

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Deerfield loan. This increase was partially offset by (i) a \$5.4 million non-cash gain from the revaluation of our derivative liabilities and (ii) a \$2.2 million non-cash warrant settlement that we recognized in 2008.

**Dividends on redeemable convertible preferred stock.** Because we redeemed all of the outstanding shares of our Series B Convertible Preferred Stock, or Series B Preferred, in November 2008, we recognized no dividend expense related to such stock in the year ended December 31, 2009.

**LIQUIDITY AND CAPITAL RESOURCES**

*Short term*

Our sources of liquidity include our cash balances and short-term investments. As of December 31, 2010, we had \$150.7 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. In addition, on or before June 17, 2011, Deerfield can make a one-time election to loan us up to an additional \$20.0 million under similar terms as the initial \$100.0 million loan.

To date, we have obtained cash and funded our operations primarily through the sale of common and preferred stock, 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 financing 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 addition, as a result of our outstanding loan from Deerfield, our ability to engage in financing transactions is subject to certain limitations. Certain financing transactions, if consummated, would accelerate our repayment obligations to Deerfield. For example, we are required to prepay the Deerfield loan in full in connection with certain issuances of common stock at a price of less than \$2 per share.

In October 2010, the FDA issued us a CRL regarding our NDA for lorcaserin. Our marketing and supply agreement with Eisai provides that Eisai and we will share equally the development expenses for any additional development work required by the FDA prior to approval of lorcaserin, including development expenses in connection with responding to the CRL. We expect to incur expenses in 2011 for development activities in response to the CRL and that such activities may 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.

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. Pursuant to the asset purchase agreement, Arena GmbH paid Siegfried CHF 21.8 million, or \$19.6 million, of the cash purchase price in January 2008 and CHF 3.3 million, or \$3.4 million, in January 2011. The asset purchase agreement required Arena GmbH to pay Siegfried the remaining CHF 6.7 million of the cash purchase price in two equal installments, with the first due in January 2012 and the second due in January 2013. On March 11, 2011, Arena GmbH amended its agreements with Siegfried, effective January 1, 2011, whereby, among other changes, Arena GmbH agreed to pay to Siegfried these remaining two installments in June 2011 and October 2011, respectively, and Siegfried agreed (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 be less than it paid in 2010, and we expect that revenues we recognize in 2011 under the manufacturing services agreement will be lower than in 2010.

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Although our December 31, 2010 consolidated balance sheet reflects a total balance of \$37.8 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 \$60.0 million at December 31, 2010. In January 2011, we prepaid the \$20.0 million principal repayment that was due to Deerfield in July 2011, which is expected to save us \$0.7 million in interest payments.

We are continuing to fund activities in support of obtaining regulatory approval of lorcaserin, and, at the same time, advancing certain earlier-stage research and development programs, including the ongoing Phase 1a clinical trial for APD811 and advancing APD334 toward clinical development. We also plan to continue development of our research programs on cannabinoid receptor 2, or CB2, agonists (intended for the treatment of osteoarthritis and pain) and GPR119 agonists (intended for the treatment of type 2 diabetes). 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 recently announced workforce reduction of 66 employees. We expect this workforce reduction will result in annual operating cost savings of approximately \$13.5 million, and charges, primarily in the first quarter of 2011, of approximately \$3.8 million in connection with one-time employee termination costs, including severance and other benefits. Even with this workforce reduction, deferring of expenses 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 of 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 or 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, continue to seek collaborators for our drug candidates and programs and look to other external 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

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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 \$40.0 million, after we prepaid \$20.0 million in January 2011, is due in June 2013. At any time we may prepay any or all of the outstanding principal of the Deerfield loan at par, and we may be required to make the remaining repayment earlier in connection with certain equity issuances. In addition, we are required to make mandatory prepayments of the loan under certain circumstances.

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 decreased by \$103.6 million in 2010 to \$52.3 million. This decrease resulted from our lower net loss in 2010, primarily due to completing our BLOOM and BLOSSOM lorcaserin Phase 3 trials in 2009, as well as changes in our operating assets and liabilities, primarily receipt of a \$50.0 million non-refundable, upfront payment from Eisai. Net cash used in operating activities decreased by \$35.5 million in 2009 to \$155.9 million. This decrease resulted from our lower net loss in 2009, primarily due to completing BLOOM and BLOSSOM in 2009, offset by changes in our operating assets and liabilities. Net cash used in operating activities during 2008 increased by \$63.3 million to \$191.4 million. This resulted from the increase in our net loss from 2007 to 2008, primarily due to expenses for our lorcaserin trials, offset by changes in our operating assets and liabilities.

Net cash of \$16.3 million was provided by investing activities in 2010, and was primarily attributable to net proceeds of \$20.4 million from our short-term investments, which were partially offset by \$4.2 million used for equipment and improvements to our facilities, primarily for our manufacturing facility in Switzerland. Net cash of \$11.4 million was provided by investing activities in 2009, and was primarily attributable to net proceeds of \$16.3 million from our short-term investments, which were partially offset by \$5.3 million used for equipment and improvements to our facilities. Net cash of \$68.5 million was used in investing activities in 2008, and was primarily the result of net purchases of short-term investments of \$25.9 million, \$23.2 million used for equipment and improvements to our facilities and \$19.6 million used for the purchase of our drug product facility in Switzerland. We expect that our 2011 capital expenditures will be less than the 2010 amount due to our continuing cost-containment efforts.

Net cash of \$89.7 million was provided by financing activities in 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 in June, 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 in August, and net proceeds of \$24.2 million from the sale of approximately 8.3 million shares of common stock in March under an equity financing commitment we had with Azimuth Opportunity Ltd, or Azimuth. Net cash of \$166.7 million was provided by financing activities in 2009, and was primarily attributable to net financing proceeds of \$96.9 million from the issuance of a note, warrants and related financial instruments to Deerfield, net proceeds of \$49.7 million from the sale of 12.5 million shares of common stock, \$15.0 million in reimbursements for improvements made to one of our leased facilities and net proceeds of \$14.7 million from the sale of approximately 5.7 million shares of common stock under the equity financing commitment with Azimuth. Such proceeds were partially offset by the \$10.0 million of principal we repaid to Deerfield in 2009. Net cash of \$53.3 million was used in financing activities in 2008, primarily due to the payment of \$55.8 million for the redemption of all of the outstanding shares of our Series B Preferred in



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November 2008. This was partially offset by net proceeds of \$1.7 million received from option exercises and purchases under our employee stock purchase plan and additional proceeds of \$1.0 million received as reimbursement for certain improvements made to one of our facilities.

**CONTRACTUAL OBLIGATIONS**

The following table summarizes our contractual obligations as of December 31, 2010, in thousands:

Contractual Obligations	Total	Payments due by period			
		Less than			More than
		1	1-3	3-5	5
		year	years	years	years
Financing obligations	\$ 145,224	\$ 7,512	\$ 16,992	\$ 17,852	\$ 102,868
Note payable to Deerfield	68,595	24,068	44,527	0	0
Note payable to Siegfried	10,686	3,562	7,124	0	0
Purchase obligations	5,465	5,443	22	0	0
Operating leases	2,497	1,351	1,146	0	0
Total	\$ 232,467	\$ 41,936	\$ 69,811	\$ 17,852	\$ 102,868

In December 2003, we completed the sale and leaseback of one of our properties for total consideration of \$13.0 million, and, in May 2007, we completed the sale and leaseback of three of our properties and assigned an option to purchase a fourth property for total consideration of \$50.1 million. Our option to repurchase these properties in the future is considered continued involvement under the applicable accounting rules and, therefore, we have applied the financing method which requires that the book value of the properties and related accumulated depreciation remain on our balance sheet with no sale 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. As of December 31, 2010, we expect interest expense over the term of these leases to total \$78.4 million. We have included our lease obligations related to these properties in the above table as financing obligations. The aggregate residual value of the facilities at the end of the lease terms is \$10.0 million.

In January 2008, Arena GmbH acquired from Siegfried certain drug product manufacturing assets under an asset purchase agreement. Pursuant to the asset purchase agreement, Arena GmbH paid Siegfried CHF 21.8 million, or \$19.6 million, of the cash purchase price in January 2008 and CHF 3.3 million, or \$3.4 million, in January 2011. The asset purchase agreement required Arena GmbH to pay Siegfried the remaining CHF 6.7 million of the cash purchase price in two equal installments, with the first due in January 2012 and the second due in January 2013. On March 11, 2011, Arena GmbH amended its agreements with Siegfried, effective January 1, 2011, whereby, among other changes, Arena GmbH agreed to pay to Siegfried these remaining two installments in June 2011 and October 2011, respectively. The amounts paid will be affected by the exchange rate between the Swiss franc and the US dollar when the cash payments are made.

In July 2009, we received net proceeds of \$95.6 million from the issuance of a note, warrants and related financial instruments to Deerfield. Upon the closing of a public offering also in July 2009, we were required to repay the first scheduled payment of \$10.0 million of the Deerfield loan. As part of a registered direct public offering to Deerfield in August 2010, we agreed to prepay \$30.0 million that we otherwise would have been required to repay in July 2012. At December 31, 2010, the remaining principal repayments on the Deerfield loan were scheduled as follows: \$20.0 million in July 2011 and \$40.0 million in June 2013; however, in January 2011, we prepaid to Deerfield the \$20.0 million principal repayment that was due in July 2011. At any time we may prepay any or all of the outstanding principal at par, and we may be required to make the remaining repayment earlier in connection with certain equity issuances. In addition, we are required to make mandatory prepayments of the loan under certain circumstances. Our consolidated balance sheet at December 31, 2010 reflects a balance of \$37.8 million for our note payable to Deerfield due to the requirement to separately value the components of

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the note, warrants and related financial instruments. As of December 31, 2010, we expect interest expense of \$8.6 million to be paid in cash over the remaining term of the loan; however this amount was reduced by \$0.7 million due to our January 2011 principal prepayment of \$20.0 million.

In determining the amount of our purchase obligations for contracts, we have included only the minimum obligation we have under our contracts (which analysis often assumed that such contracts were terminated on December 31, 2010) and did not include any amount that was previously paid, accrued, expensed or associated with a contingent event, such as a change in control or termination of a key employee.

### *Off-Balance Sheet Arrangements*

We do not have, and did not have as of December 31, 2010, any off-balance sheet arrangements that have or are reasonably likely to have a current or future material effect on our financial condition, results of operations, liquidity, capital expenditures or capital resources.

## **COLLABORATIONS**

### **Eisai Inc.**

In July 2010, our wholly owned subsidiary, Arena GmbH, entered into a marketing and supply agreement with Eisai. Under this agreement, Arena GmbH granted Eisai exclusive rights to commercialize lorcaserin in the United States and its territories and possessions subject to FDA approval of the lorcaserin NDA. As part of the agreement, Arena GmbH is obligated to manufacture lorcaserin at our facility in Switzerland, and Eisai is obligated to purchase all of its requirements of lorcaserin from Arena GmbH.

We received a non-refundable, upfront payment of \$50.0 million from Eisai, and, following regulatory approval of lorcaserin and upon the delivery of product supply for launch, may receive up to an additional \$60.0 million depending on the label. We recorded the \$50.0 million upfront payment as deferred revenues and will recognize it as revenue ratably over 13 years, which represents the period in which we expect to have significant involvement. Accordingly, at December 31, 2010, our consolidated balance sheet included \$3.8 million and \$44.2 million for the current and non-current portion, respectively, of such deferred revenues. We recognized revenue of \$1.9 million in 2010 related to the marketing and supply agreement with Eisai.

We are obligated to sell lorcaserin to Eisai for a purchase price starting at 31.5% of Eisai's annual net product sales, and the purchase price will increase on a tiered basis to 36.5% on the portion of annual net product sales exceeding \$750.0 million, subject to reduction in the event of generic competition and certain other circumstances. We are also eligible to receive up to an aggregate of \$1.19 billion in purchase price adjustment payments based on Eisai's annual net sales of lorcaserin, with the first and last amounts payable with annual net sales of \$250.0 million and \$2.5 billion, respectively. Of these purchase price adjustment payments, Eisai is obligated to pay us a total of \$330.0 million for annual net sales of up to \$1.0 billion. We are also eligible to receive up to an additional \$70.0 million in regulatory and development milestone payments.

Eisai and we will share equally the development expenses for the additional development work required by the FDA prior to approval of our NDA for lorcaserin. If the FDA requires development work following approval of lorcaserin, Eisai will bear 90% and we will bear 10% of such expenses, except that Eisai and we will share equally the costs of certain pediatric or adolescent studies.

Eisai and we have agreed to not commercialize outside of our marketing and supply agreement any product that competes with lorcaserin in the United States. Our marketing and supply agreement includes a stand-still provision limiting Eisai's ability to acquire our securities and assets.

Unless terminated earlier, our marketing and supply agreement will continue in effect until terminated by Eisai following the later of the expiration of all issued lorcaserin patents for the United States and 12 years after

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the first commercial sale of lorcaserin in the United States. Either party has the right to terminate this agreement early in certain circumstances, including (i) if the other party is in material breach, (ii) for certain commercialization concerns and (iii) for certain intellectual property infringement. Eisai also has the right to terminate this agreement early in certain circumstances, including (a) if sales of generic equivalents of lorcaserin in the United States exceed sales of lorcaserin in the United States (based on volume) and (b) if Eisai is acquired by a company that has a product that competes with lorcaserin.

### **Ortho-McNeil-Janssen Pharmaceuticals, Inc.**

Our collaboration and license agreement with Ortho-McNeil-Janssen terminated in December 2010. Upon termination, all rights to the compounds developed under the collaboration, and related intellectual property and other information (including the investigational new drug, or IND, application relating to APD597) reverted to us. We entered into the collaboration in December 2004 to further develop compounds for the potential treatment of type 2 diabetes and other disorders. Under the collaboration, Ortho-McNeil-Janssen advanced APD668 and APD597, first and second generation GPR119 agonists for the treatment of type 2 diabetes, respectively, into clinical trials.

From the inception of this collaboration through December 31, 2010, we have received \$27.5 million from Ortho-McNeil-Janssen in upfront and milestone payments, \$7.2 million in research funding and \$20.1 million for patent activities and additional sponsored research. In 2010, we recognized \$3.2 million of revenues under this agreement, all of which was reimbursement for patent activities. In 2009, we recognized revenues of \$3.8 million, of which \$3.7 million was reimbursement for patent activities and \$0.1 million was for additional sponsored research. In 2008, we recognized revenues of \$2.3 million, all of which was reimbursement for patent activities.

### **Merck & Co., Inc.**

Our collaboration with Merck terminated in March 2010. Upon termination, all licenses granted to Merck under the agreement became non-exclusive as between Merck and us. We initiated the collaboration with Merck in October 2002 on three GPCRs to develop therapeutics for atherosclerosis and other disorders. Under the collaboration, Merck advanced MK-0354, a first generation niacin receptor agonist, and MK-1903, a second generation niacin receptor agonist, into Phase 2 trials.

From the inception of this collaboration through its termination, we recorded \$18.0 million from Merck in upfront and milestone payments, \$27.5 million in research funding and \$0.5 million for patent activities, as well as \$8.5 million from the sale of shares of our common stock. We recognized nominal amounts of revenue under the Merck agreement, all of which was reimbursement for patent activities, in 2010, 2009 and 2008.

## **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.

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While our significant accounting policies are described in more detail in Note 1 to our consolidated financial statements, we believe the following accounting policies are critical in the preparation of our financial statements:

**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.

As compensation expense recognized is based on awards ultimately expected to vest, we reduce the expense recognized based on an estimated forfeiture rate at the time of grant. If actual forfeitures vary from estimates, we will recognize the difference in compensation expense in the period the actual forfeitures occur or when options vest.

**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 elsewhere in this Annual Report, which contain additional accounting policies and other disclosures required by GAAP.*

## **NEW ACCOUNTING GUIDANCE**

In April 2010, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2010-17, Revenue Recognition Milestone Method, which provides guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions in which one or more payments are contingent upon achieving uncertain future events. Under this guidance, we may recognize revenue contingent upon the achievement of a milestone in its entirety in the period in which the milestone is achieved, provided that the milestone meets all the criteria within the guidance to be considered substantive. However, under this guidance, we can make an accounting policy election to apply another appropriate accounting policy that results in the deferral of some portion of the arrangement consideration. This guidance is effective prospectively for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. We elected not to adopt ASU 2010-17.

In October 2009, the FASB issued ASU No. 2009-13, Multiple-Deliverable Revenue Arrangements, which provides guidance on recognizing revenue in arrangements with multiple deliverables. ASU 2009-13 addresses how to determine whether an arrangement involving multiple deliverables contains more than one unit of accounting, how such deliverables should be separated and how the consideration should be allocated to one or more units of accounting. ASU 2009-13 is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. The adoption of ASU 2009-13 effective January 1, 2011 did not have a material impact on our consolidated financial statements.

## **Item 7A. Quantitative and Qualitative Disclosures About Market Risk.**

Our primary market risk exposure as it affects our cash equivalents is interest rate risk. Our management establishes and oversees the implementation of a board-approved policy covering our investments. We manage our interest rate risk in accordance with our investment guidelines which (i) emphasize preservation of principal over other portfolio considerations, (ii) require our investments to be placed in US government, agency and government-sponsored enterprise obligations and in corporate debt instruments that are rated investment grade, (iii) establish parameters for diversification in our investment portfolio, and (iv) require investments to be placed with maturities that maintain safety and liquidity. We target our portfolio to have an average duration of no more than two years, however, due to our financial condition and the current interest rate environment, our average

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duration is significantly shorter than two years. We do not invest in derivative instruments or auction rate securities, or any financial instruments for trading purposes. We monitor our interest rate risk on a periodic basis and we ensure that our cash equivalents and short-term investments are invested in accordance with our investments guidelines. We also monitor credit ratings and the duration of our financial investments, which we believe enhances the preservation of our capital.

We model interest rate exposure by a sensitivity analysis that assumes a hypothetical parallel shift downward in the US Treasury yield curve of 100 basis points. Under these assumptions, if the yield curve were to shift lower by 100 basis points from the level existing at December 31, 2010, we would expect future interest income from our portfolio to decline by approximately \$1.5 million over the next 12 months. As of December 31, 2009, this same hypothetical reduction in interest rates would have resulted in a \$1.2 million decline in interest income over the following 12 months. The model we use is not intended to forecast actual losses in interest income, but is used as a risk estimation and investment management tool. These hypothetical changes and assumptions are likely to be different from what actually occurs in the future. Furthermore, such computations do not incorporate any actions our management may take if the hypothetical interest rate changes actually occur. As a result, the impact on actual earnings may differ from those quantified herein.

Our note payable to Deerfield is not subject to market risk due to its fixed interest rate.

We have a wholly owned subsidiary in Switzerland, which exposes us to foreign currency exchange risk. The functional currency of our subsidiary in Switzerland is the Swiss franc. Accordingly, all assets and liabilities of our subsidiary, including our note payable to Siegfried, are translated to US dollars based on the applicable exchange rate on the balance sheet date. Revenue and expense components are translated to US dollars at weighted-average exchange rates in effect during the period. Gains and losses resulting from foreign currency translation are reported as a separate component of accumulated other comprehensive gain or loss in the stockholders' equity section of our consolidated balance sheets. Foreign currency transaction gains and losses, which have not been material for us to date, are included in our results of operations. We have not hedged exposures denominated in foreign currencies, but may do so in the future.

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**Item 8. Financial Statements and Supplementary Data.**

**ARENA PHARMACEUTICALS, INC.**

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**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders

Arena Pharmaceuticals, Inc.:

We have audited the accompanying consolidated balance sheet of Arena Pharmaceuticals, Inc. and subsidiaries (the Company) as of December 31, 2010, and the related consolidated statements of operations, stockholders' equity and comprehensive loss, and cash flows for the year then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Arena Pharmaceuticals, Inc. and subsidiaries as of December 31, 2010, and the results of their operations and their cash flows for the year then ended, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 8 to the consolidated financial statements, the Company changed its method of accounting for certain warrants due to the adoption of a new accounting pronouncement in 2009.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Arena Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2010, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 15, 2011, expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ KPMG LLP

San Diego, California

March 15, 2011



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**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders of Arena Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheet of Arena Pharmaceuticals, Inc. as of December 31, 2009, and the related consolidated statements of operations, stockholders' equity and comprehensive loss, and cash flows for the years ended December 31, 2009 and 2008. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Arena Pharmaceuticals, Inc. at December 31, 2009, and the consolidated results of its operations and its cash flows for the years ended December 31, 2009 and 2008, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 8 to the consolidated financial statements, the Company changed its method of determining whether equity-linked financial instruments are indexed to the Company's own stock, with the adoption of the amendments to the FASB Accounting Standards Codification Topic 815-40, *Contracts in Entity's Own Equity*, effective January 1, 2009.

/s/ Ernst & Young LLP

San Diego, California

March 16, 2010

**Table of Contents****ARENA PHARMACEUTICALS, INC.****Consolidated Balance Sheets****(In thousands, except share and per share data)**

	December 31, 2010	December 31, 2009
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 150,669	\$ 94,733
Short-term investments, available-for-sale	0	20,716
Accounts receivable	3,499	1,415
Prepaid expenses and other current assets	2,638	4,409
<b>Total current assets</b>	<b>156,806</b>	<b>121,273</b>
Land, property and equipment, net	91,533	95,445
Acquired technology and other intangibles, net	12,031	13,123
Other non-current assets	5,992	6,437
<b>Total assets</b>	<b>\$ 266,362</b>	<b>\$ 236,278</b>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable and other accrued liabilities	\$ 5,017	\$ 9,677
Accrued compensation	4,427	3,928
Accrued clinical and preclinical study fees	1,236	2,279
Current portion of deferred revenues	3,846	4,086
Current portion of derivative liabilities	607	0
Current portion of note payable to Siegfried	3,560	0
Current portion of note payable to Deerfield <sup>1</sup>	17,175	0
Current portion of lease financing obligations	998	717
<b>Total current liabilities</b>	<b>36,866</b>	<b>20,687</b>
Deferred rent	412	564
Deferred revenues, less current portion	44,231	0
Derivative liabilities, less current portion	1,664	6,642
Note payable to Siegfried, less current portion	6,801	9,143
Note payable to Deerfield, less current portion <sup>1</sup>	20,602	47,906
Lease financing obligations, less current portion	75,771	76,769
<b>Commitments and contingencies and subsequent events</b>		
Stockholders' equity:		
Series A preferred stock, \$.0001 par value: 350,000 shares authorized at December 31, 2010 and 2009; no shares issued and outstanding at December 31, 2010 and 2009	0	0
Common stock, \$.0001 par value: 242,500,000 shares authorized at December 31, 2010 and 2009; 121,515,805 and 92,813,899 shares issued and outstanding at December 31, 2010 and 2009, respectively	12	10
Additional paid-in capital	1,087,228	961,269
Treasury stock, at cost 3,000,000 shares at December 31, 2010 and 2009	(23,070)	(23,070)
Accumulated other comprehensive income	4,966	945
Accumulated deficit	(989,121)	(864,587)
<b>Total stockholders' equity</b>	<b>80,015</b>	<b>74,567</b>

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Total liabilities and stockholders' equity	\$ 266,362	\$ 236,278
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<sup>1</sup> The outstanding principal balance of the note payable to Deerfield was \$60.0 million and \$90.0 million at December 31, 2010 and 2009, respectively. See Note 7.

See accompanying notes to consolidated financial statements.

**Table of Contents****ARENA PHARMACEUTICALS, INC.****Consolidated Statements of Operations****(In thousands, except share and per share data)**

	2010	Years ended December 31, 2009	2008
<b>Revenues:</b>			
Manufacturing services	\$ 7,057	\$ 6,579	\$ 7,434
Collaborative agreements	9,556	3,808	2,375
Total revenues	16,613	10,387	9,809
<b>Operating Expenses:</b>			
Cost of manufacturing services	7,414	6,536	8,515
Research and development	75,459	110,159	204,374
General and administrative	27,936	25,247	30,535
Restructuring charges	0	3,324	0
Amortization of acquired technology and other intangibles	2,159	3,508	2,314
Total operating expenses	112,968	148,774	245,738
Loss from operations	(96,355)	(138,387)	(235,929)
<b>Interest and Other Income (Expense):</b>			
Interest income	469	689	7,370
Interest expense	(21,681)	(18,718)	(5,454)
Gain from valuation of derivative liabilities	4,371	5,418	0
Warrant settlement provision	0	0	(2,236)
Loss on extinguishment of debt	(12,354)	(2,479)	0
Other	1,016	273	(1,324)
Total interest and other expense, net	(28,179)	(14,817)	(1,644)
Net loss	(124,534)	(153,204)	(237,573)
Dividends on redeemable convertible preferred stock	0	0	(1,912)
Net loss allocable to common stockholders	\$ (124,534)	\$ (153,204)	\$ (239,485)
Net loss per share allocable to common stockholders, basic	\$ (1.14)	\$ (1.82)	\$ (3.24)
Net loss per share allocable to common stockholders, diluted	\$ (1.14)	\$ (1.82)	\$ (3.24)
Shares used in calculating net loss per share allocable to common stockholders, basic	109,573,177	84,341,362	73,840,716
Shares used in calculating net loss per share allocable to common stockholders, diluted	109,573,177	84,341,362	73,840,716

See accompanying notes to consolidated financial statements.



**Table of Contents****ARENA PHARMACEUTICALS, INC.****Consolidated Statements of Stockholders Equity and Comprehensive Loss**

(In thousands, except share data)

	Common Stock		Additional Paid-In Capital	Treasury Stock	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders Equity
	Shares	Amount					
<b>Balance at December 31, 2007</b>	<b>72,260,254</b>	<b>\$ 8</b>	<b>\$ 838,913</b>	<b>\$ (23,070)</b>	<b>\$ (23)</b>	<b>\$ (479,451)</b>	<b>\$ 336,377</b>
Issuance of common stock upon exercise of options	28,625		133				133
Issuance of common stock under employee stock purchase plan	357,101		1,600				1,600
Issuance of common stock to Siegfried	1,488,482		8,000				8,000
Share-based compensation expense, net of forfeitures			8,375				8,375
Compensation expense related to restricted stock			117				117
Issuance of warrants in settlement			2,236				2,236
Dividends on redeemable convertible preferred stock						(1,912)	(1,912)
Net loss						(237,573)	(237,573)
Net unrealized gain on available-for-sale securities and investments					37		37
Translation gain					242		242
Net comprehensive loss							(237,294)
<b>Balance at December 31, 2008</b>	<b>74,134,462</b>	<b>8</b>	<b>859,374</b>	<b>(23,070)</b>	<b>256</b>	<b>(718,936)</b>	<b>117,632</b>
Cumulative effect of adoption of new accounting standard			(9,671)			7,553	(2,118)
Issuance of common stock upon exercise of options	63,500		38				38
Issuance of common stock under employee stock purchase plans	364,096		949				949
Issuance of common stock under equity financing arrangement	5,745,591	1	14,654				14,655
Issuance of common stock in public offering, net of offering costs of \$2,400	12,500,000	1	49,724				49,725
Issuance of warrants to Deerfield			39,052				39,052
Share-based compensation expense, net of forfeitures			7,149				7,149
Restricted shares released from deferred compensation plan	6,250						
Net loss						(153,204)	(153,204)
Net unrealized gain on available-for-sale securities and investments					155		155
Translation gain					534		534
Net comprehensive loss							(152,515)
<b>Balance at December 31, 2009</b>	<b>92,813,899</b>	<b>10</b>	<b>961,269</b>	<b>(23,070)</b>	<b>945</b>	<b>(864,587)</b>	<b>74,567</b>
Issuance of common stock upon exercise of options	51,655		55				55
Issuance of common stock under employee stock purchase plan	399,095		766				766
Issuance of common stock under equity financing arrangement	8,278,432		24,211				24,211

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Issuance of common stock to Deerfield	19,955,224	2	95,432						95,434
Share-based compensation expense, net of forfeitures			5,495						5,495
Restricted shares released from deferred compensation plan	17,500								
Net loss							(124,534)		(124,534)
Net unrealized loss on available-for-sale securities and investments						(283)			(283)
Translation gain						4,304			4,304
Net comprehensive loss									(120,513)
<b>Balance at December 31, 2010</b>	<b>121,515,805</b>	<b>\$ 12</b>	<b>\$ 1,087,228</b>	<b>\$ (23,070)</b>	<b>\$ 4,966</b>	<b>\$ (989,121)</b>	<b>\$</b>	<b>\$</b>	<b>80,015</b>

See accompanying notes to consolidated financial statements.

**Table of Contents****ARENA PHARMACEUTICALS, INC.****Consolidated Statements of Cash Flows****(In thousands)**

	<b>Years ended December 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
<b>Operating Activities</b>			
Net loss	\$ (124,534)	\$ (153,204)	\$ (237,573)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	10,393	11,018	11,665
Amortization of acquired technology and other intangibles	2,159	3,508	2,314
Share-based compensation	5,495	7,149	8,492
Deferred income tax provision (benefit)	0	(627)	534
Gain from valuation of derivative liabilities	(4,371)	(5,418)	0
Warrant settlement provision	0	0	2,236
Investment write-down	0	0	1,607
Amortization of short-term investment premium	0	69	333
Amortization of prepaid financing costs	545	338	333
Accretion of note payable to Deerfield	7,517	7,555	0
Loss on extinguishment of debt	12,354	2,479	0
Accretion of note payable to Siegfried	269	251	239
(Gain)/Loss on disposal or sale of equipment	(14)	313	(37)
Changes in assets and liabilities:			
Accounts receivable	(1,931)	430	61
Prepaid expenses and other assets	1,608	(929)	4,119
Accounts payable and accrued liabilities	(5,644)	(28,765)	14,338
Deferred revenues	43,991	37	0
Deferred rent	(152)	(129)	(100)
Net cash used in operating activities	(52,315)	(155,925)	(191,439)
<b>Investing Activities</b>			
Purchases of short-term investments, available-for-sale	(1,231)	(20,433)	(65,023)
Proceeds from sales/maturities of short-term investments, available-for-sale	21,664	36,696	39,123
Purchase of drug product facility	0	0	(19,573)
Purchases of land, property and equipment	(4,211)	(5,331)	(23,217)
Proceeds from sale of equipment	47	263	38
Other non-current assets	48	170	179
Net cash provided by (used in) investing activities	16,317	11,365	(68,473)
<b>Financing Activities</b>			
Principal payments on lease financing obligations	(717)	(581)	(240)
Proceeds from lease financing	0	15,000	1,000
Proceeds from issuance of note payable and related financial instruments to Deerfield	0	96,865	0
Principal payments on note payable to Deerfield	(30,000)	(10,000)	0
Redemption of redeemable convertible preferred stock	0	0	(55,834)
Proceeds from issuance of common stock	120,466	65,368	1,733
Net cash provided by (used in) financing activities	89,749	166,652	(53,341)
Effect of exchange rate changes on cash	2,185	(688)	(407)
Net increase (decrease) in cash and cash equivalents	55,936	21,404	(313,660)
Cash and cash equivalents at beginning of year	94,733	73,329	386,989
Cash and cash equivalents at end of year	\$ 150,669	\$ 94,733	\$ 73,329

**Supplemental Disclosure Of Cash Flow Information:**



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Interest paid, net of no capitalized interest in 2010 and 2009, and \$860 in 2008	\$ 13,434	\$ 10,297	\$ 5,851
Unrealized gain on short-term investments, available-for-sale	\$ 0	\$ 248	\$ 37
<b>Supplemental Disclosure Of Non-Cash Investing and Financing Information:</b>			
Purchases of land, property and equipment included in accounts payable and accrued liabilities	\$ 12	\$ 79	\$ 1,776

See accompanying notes to consolidated financial statements.

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**ARENA PHARMACEUTICALS, INC.**

**Notes to Consolidated Financial Statements**

**(1) The Company and Summary of Significant Accounting Policies**

**The Company**

Arena Pharmaceuticals, Inc., or Arena, was incorporated on April 14, 1997, and commenced operations in July 1997. We are a clinical-stage biopharmaceutical company with a pipeline of internally discovered small molecule drug candidates that target G protein-coupled receptors, or GPCRs, and are being developed internally or with a collaborator. We operate in one business segment. In October 2010, the US Food and Drug Administration, or FDA, issued a Complete Response Letter, or CRL, regarding our New Drug Application, or NDA, for our most advanced drug candidate, lorcaserin hydrochloride, or lorcaserin, which is intended for weight management. 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. The FDA also described nonclinical and clinical reasons for its decision and provided recommendations relating to addressing such issues. In December 2010, we completed our end-of-review meeting with the FDA, which included a discussion of the FDA's position on issues identified in the CRL and our plan to respond to the CRL, and we have had additional communications with the FDA relating to the lorcaserin NDA, the requirements for resubmission of the NDA and related activities.

**Basis of Presentation**

The accompanying consolidated financial statements reflect all of our activities, including those of our wholly owned subsidiaries. All material intercompany accounts and transactions have been eliminated in consolidation.

During the second quarter of 2010, we identified an error in our consolidated financial statements as of and for the year ended December 31, 2009 and the three months ended March 31, 2010, which error was incorrectly applying the effective interest method to the accretion component of the debt discount on our note payable to Deerfield. As a result of the error, we overstated interest expense by \$3.0 million and \$1.3 million for the year ended December 31, 2009 and the three months ended March 31, 2010, respectively. The total interest expense on this note is comprised of such accretion and the 7.75% coupon rate applied to the outstanding and undiscounted principal balance. In accordance with relevant guidance, we evaluated the materiality of the error from a qualitative and quantitative perspective. Based on such evaluation, we concluded that correcting the cumulative error would be immaterial to the full year results for 2010 and correcting the error would not have had a material impact on any individual prior period financial statements or affect the trend of financial results. Accordingly, we recorded a non-cash adjustment during the second quarter of 2010 to reduce both the cumulative interest expense and the note payable to Deerfield by \$4.3 million.

We have accumulated a large deficit since inception, and we expect that our losses will continue to be substantial for at least the short term. As of December 31, 2010, we had \$150.7 million in cash and cash equivalents, which we believe will be sufficient to fund our operations for at least the next 12 months.

**Financial Statement Preparation**

The preparation of financial statements in conformity with US generally accepted accounting principles, or GAAP, requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. We use estimates for certain accruals including clinical and preclinical study fees and expenses, share-based compensation, and valuations of derivative liabilities, long-lived assets and contingencies, among others. Actual results could differ from those estimates.

**Reclassifications**

Certain prior year amounts have been reclassified to conform to the current year presentation.

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### **Cash and Cash Equivalents**

Cash and cash equivalents consist of cash and highly liquid investments with remaining maturities of three months or less when purchased.

### **Short-term Investments, Available-for-Sale**

We define short-term investments as income-yielding securities that can be readily converted to cash, and classify such investments as available-for-sale. We carry these securities at fair value, and report unrealized gains and losses as a separate component of accumulated other comprehensive income or loss. Realized gains and losses and declines in securities judged to be other than temporary are included in other income or expense. Securities sold are based on the specific identification method. Interest and dividends on available-for-sale securities are included in interest income.

### **Fair Value of Financial Instruments**

Cash and cash equivalents, accounts receivable, prepaid expenses and other current assets, accounts payable and accrued liabilities are carried at cost, which we believe approximates fair value due to the short-term maturity of these instruments. Short-term investments and derivative liabilities are carried at fair value. Based on borrowing rates currently available to us for loans with similar terms, we believe the aggregate fair value and carrying value of the lease financing obligations, note payable to Siegfried and note payable to Deerfield were \$110.6 million and \$124.9 million, respectively, at December 31, 2010. As of December 31, 2009, we determined that the carrying value of the lease financing obligations, note payable to Siegfried and note payable to Deerfield approximated fair value, based on borrowing rates then available to us for loans with similar terms.

### **Concentration of Credit Risk and Major Customers**

Financial instruments, which potentially subject us to concentrations of credit risk, consist primarily of cash, cash equivalents and short-term investments. We limit our exposure to credit loss by placing our cash and investments in US government, agency and government-sponsored enterprise obligations and in corporate debt instruments that are rated investment grade, in accordance with our board-approved investment policy.

We manufacture drug products for Siegfried Ltd, or Siegfried, under a manufacturing services agreement, and all of our manufacturing services revenues are attributable to Siegfried. For the year ended December 31, 2010, 43% of our total revenues were attributable to Siegfried, while 24%, 19% and 12% were attributable to TaiGen Biotechnology Co., Ltd., Ortho-McNeil-Janssen Pharmaceuticals, Inc., or Ortho-McNeil-Janssen, and Eisai Inc., or Eisai, respectively. For the year ended December 31, 2009, 63% of our total revenues were attributable to Siegfried, while 36% were attributable to Ortho-McNeil-Janssen. For the year ended December 31, 2008, 76% of our total revenues were attributable to Siegfried, while 24% were attributable to Ortho-McNeil-Janssen. Ortho-McNeil-Janssen accounted for 35% of our accounts receivable as of December 31, 2010 and 2009 and 39% as of December 31, 2008, while 65% of our accounts receivable as of December 31, 2010 and 2009 and 61% as of December 31, 2008 were attributable to Siegfried.

### **Property and Equipment**

Property and equipment are stated at cost and depreciated over the estimated useful lives of the assets (generally three to 15 years) using the straight-line method. Buildings are stated at cost and depreciated over an estimated useful life of approximately 20 years using the straight-line method. Leasehold improvements are stated at cost and amortized over the shorter of the estimated useful lives of the assets or the lease term. Capital improvements are stated at cost and amortized over the estimated useful lives of the underlying assets.

### **Acquired Technology and Other Intangibles**

We have intangible assets in connection with certain assets we acquired from Siegfried in January 2008, including manufacturing facility production licenses and an assembled workforce, as well as our February 2001

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acquisition of Bunsen Rush Laboratories, Inc., or Bunsen Rush, and its Melanophore technology. These assets are measured based on their fair value at acquisition. The useful life of our intangible assets is determined based on the period over which the asset is expected to contribute directly or indirectly to our future cash flows. We amortize our intangible assets using the straight-line method over estimated useful lives ranging from two to 20 years.

We will continue to evaluate the carrying value of the Melanophore technology and manufacturing facility production licenses. If, in the future, we determine that any of our intangible assets have become impaired or such assets are no longer being used, we may record a write-down of the carrying value or accelerate such amortization.

### **Long-lived Assets**

If indicators of impairment exist, we assess the recoverability of the affected long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted cash flow projections. If impairment is indicated, we measure the impairment loss by comparing the fair value of the asset, estimated using discounted cash flows expected to be generated from the asset, to the carrying value.

### **Deferred Rent**

For financial reporting purposes, rent expense is recognized on a straight-line basis over the term of the lease. The difference between rent expense and amounts paid under lease agreements is recorded as deferred rent in the liability section of our consolidated balance sheets.

### **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 anti-dilution 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, yield, probability of change in control and risk-free interest rate.

### **Foreign Currency Translation**

The functional currency of our wholly owned subsidiary in Switzerland is the Swiss franc. Accordingly, all assets and liabilities of this subsidiary are translated to US dollars based on the applicable exchange rate on the balance sheet date. Revenue and expense components are translated to US dollars at weighted-average exchange rates in effect during the period. Gains and losses resulting from foreign currency translation are reported as a separate component of accumulated other comprehensive income or loss in the stockholders' equity section of our consolidated balance sheets. Foreign currency transaction gains and losses are included in our results of operations and, to date, have not been material.

### **Share-based Compensation**

Compensation expense for all share-based awards, which we recognize on a straight-line basis over the vesting period, is estimated based on the grant-date fair value using the Black-Scholes option pricing model. We

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estimate forfeitures at the time of grant and revise our estimate in subsequent periods if actual forfeitures differ from those estimates. Such compensation expense is included in the applicable expense line item on our consolidated statements of operations.

We measure the value of restricted stock awards based on the fair value of the stock on the grant date, and increase additional paid-in capital as compensation expense is recognized over the applicable vesting period. The restrictions generally lapse in equal annual installments over a vesting period of two, three or four years.

We recognized total share-based compensation expense for all share-based awards of \$5.5 million, \$7.1 million and \$8.5 million during the years ended December 31, 2010, 2009 and 2008, respectively.

## **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. 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 statements of operations.

## **Research and Development Costs**

Research and development expenses, which consist primarily of salaries and other personnel costs, costs associated with external clinical and preclinical study fees, manufacturing costs for non-commercial products and other related expenses, and the development of earlier-stage programs and technologies, are expensed to operations as incurred when these expenditures relate to our research and development efforts and have no alternative future uses.

## **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.

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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 recognized 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.

**Patent Costs**

We record costs related to filing and prosecuting patent applications in general and administrative expenses as incurred, as recoverability of such expenditures is uncertain.

**Comprehensive Income (Loss)**

We report all components of comprehensive income (loss), including foreign currency translation gain and loss and unrealized gains and losses on investment securities, in the financial statements in the period in which they are recognized. Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources.

**Net Loss Per Share**

We compute basic and diluted net loss per share using the weighted-average number of shares of common stock outstanding during the period, less any shares subject to repurchase or forfeiture. There were no shares of our common stock subject to repurchase or forfeiture for the years ended December 31, 2010 or 2009. There were 29,000 shares of common stock excluded from our calculation of basic and diluted net loss per share because they were subject to repurchase or forfeiture for the year ended December 31, 2008.

Because we are in a net loss position, we have excluded outstanding unvested performance-based restricted stock unit awards, which are subject to forfeiture, stock options and warrants, as well as unvested restricted stock in our deferred compensation plan, from our calculation of diluted net loss per share because these securities are antidilutive for all years presented. The table below presents our securities that would otherwise be included in our diluted net loss per share at December 31, 2010, 2009 and 2008.

	<b>December 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
Warrants	30,445,127	30,138,263	1,936,200
Stock options	8,358,594	7,226,824	6,556,630
Performance-based restricted stock unit awards	1,666,650	1,714,350	1,950,100
Unvested restricted stock	84,169	101,669	107,919
<b>Total</b>	<b>40,554,540</b>	<b>39,181,106</b>	<b>10,550,849</b>

Had they been dilutive, these securities would have been included in our computation of diluted net loss per share.

**New Accounting Guidance**

In April 2010, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2010-17, Revenue Recognition Milestone Method, which provides guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions in which one or more payments are contingent upon achieving uncertain future events. Under this guidance, we may recognize revenue contingent upon the achievement of a milestone in

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its entirety in the period in which the milestone is achieved, provided that the milestone meets all the criteria within the guidance to be considered substantive. However, under this guidance, we can make an accounting policy election to apply another appropriate accounting policy that results in the deferral of some portion of the arrangement consideration. This guidance is effective prospectively for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. We elected not to adopt ASU 2010-17.

In October 2009, the FASB issued ASU No. 2009-13, Multiple-Deliverable Revenue Arrangements, which provides guidance on recognizing revenue in arrangements with multiple deliverables. ASU 2009-13 addresses how to determine whether an arrangement involving multiple deliverables contains more than one unit of accounting, how such deliverables should be separated and how the consideration should be allocated to one or more units of accounting. ASU 2009-13 is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. The adoption of ASU 2009-13 effective January 1, 2011 did not have a material impact on our consolidated financial statements.

**(2) Available-For-Sale Securities**

At December 31, 2010, we had no available-for-sale securities. Our available-for-sale securities at December 31, 2009 consisted of the following, in thousands:

	Maturity in Years	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
<b>December 31, 2009</b>					
US government and agency obligations	Less than 1	\$ 20,433	\$ 404	\$ (121)	\$ 20,716
Total available-for-sale securities		\$ 20,433	\$ 404	\$ (121)	\$ 20,716

**(3) Fair Value Disclosures**

We measure our financial assets and liabilities at fair value, which is defined as the exit price, or the amount that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date.

We use the following three-level valuation hierarchy that maximizes the use of observable inputs and minimizes the use of unobservable inputs to value our financial assets and liabilities:

- Level 1 Observable inputs such as unadjusted quoted prices in active markets for identical instruments.
- Level 2 Quoted prices for similar instruments in active markets or inputs that are observable for the asset or liability, either directly or indirectly.
- Level 3 Unobservable inputs based on our own assumptions.

The following table presents our valuation hierarchy for our financial assets and liabilities that are measured at fair value on a recurring basis as of December 31, 2010, in thousands:

	Fair Value Measurements at December 31, 2010			
	Balance at December 31, 2010	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<i>Assets:</i>				
Money market funds and cash equivalents(1)	\$ 138,195	\$ 138,195	\$ 0	\$ 0
<i>Liabilities:</i>				
Warrants and other derivative instruments	\$ 2,271	\$ 0	\$ 0	\$ 2,271

- (1) Included in cash and cash equivalents on our consolidated balance sheet.



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The following table presents our valuation hierarchy for our financial assets and liabilities that are measured at fair value on a recurring basis as of December 31, 2009, in thousands:

	Fair Value Measurements at December 31, 2009			
	Balance at December 31, 2009	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<i>Assets:</i>				
Money market funds (1)	\$ 86,857	\$ 86,857	\$ 0	\$ 0
US government and agency obligations (2)	20,716	20,716	0	0
<i>Liabilities:</i>				
Warrants and other derivative instruments	\$ 6,642	\$ 0	\$ 0	\$ 6,642

(1) Included in cash and cash equivalents on our consolidated balance sheet.

(2) Included in short-term investments, available-for-sale on our consolidated balance sheet.

The following table presents the activity for our derivative liabilities, which are classified as Level 3 in our valuation hierarchy, during the years ended December 31, 2010 and 2009, in thousands:

	December 31,	
	2010	2009
Beginning balance	\$ 6,642	\$ 2,118
Issuance of Deerfield derivative liabilities	0	9,942
Gain from change in valuation of derivative liabilities	(4,371)	(5,418)
Ending balance	\$ 2,271	\$ 6,642

**(4) Land, Property and Equipment**

Land, property and equipment consisted of the following, in thousands:

	December 31,	
	2010	2009
Land	\$ 10,854	\$ 10,854
Building and capital improvements	66,778	67,004
Leasehold improvements	19,272	19,208
Machinery and equipment	49,987	47,079
Computers and software	8,786	7,783
Furniture and office equipment	2,573	2,514
	158,250	154,442
Less accumulated depreciation and amortization	(66,717)	(58,997)
Land, property and equipment, net	\$ 91,533	\$ 95,445

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Depreciation expense was \$8.3 million, \$8.8 million and \$8.0 million for the years ended December 31, 2010, 2009 and 2008, respectively. We capitalized interest of \$0.9 million related to construction of a facility during the year ended December 31, 2008, and included it in leasehold improvements.

### **(5) Acquired Technology and Other Intangibles**

In February 2001, we acquired Bunsen Rush for \$15.0 million in cash and assumed \$0.4 million in liabilities. We allocated \$15.4 million to the patented Melanophore technology, our primary screening

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technology, acquired in such transaction. We are amortizing the Melanophore screening technology over its estimated useful life of 10 years, which we determined based on an analysis, as of the acquisition date, of the conditions in, and the economic outlook for, the pharmaceutical and biotechnology industries and the patent life of the technology.

In January 2008, we acquired from Siegfried certain assets, including manufacturing facility production licenses and an assembled workforce originally valued at \$12.1 million and \$1.6 million, respectively. We amortized the acquired workforce over its estimated benefit of two years, which was determined based on an analysis as of the acquisition date. The manufacturing facility production licenses, which are necessary for us to produce and package tablets and other dosage forms in such facility, were originally believed to have an indefinite useful life as of the acquisition date. We further evaluated the manufacturing facility production licenses and, in 2009, determined that an estimated useful life of 20 years as of the acquisition date was more appropriate. Due to the relatively nominal amount of amortization related to the manufacturing facility production licenses that would have been expensed in 2008 had it been treated as an amortizing asset, we recorded both the 2008 and 2009 amortization expense in 2009. This amortization also resulted in the reversal of \$0.5 million of tax expense recorded in 2008 for a combined immaterial net increase to our net loss of \$66,000 in 2009.

Acquired technology and other intangibles, net, consisted of the following at December 31, 2010 and 2009, in thousands:

	<b>Gross</b>		
	<b>Carrying</b>	<b>Accumulated</b>	<b>Net</b>
<b>December 31, 2010</b>	<b>Amount</b>	<b>Amortization</b>	
Acquired Melanophore screening technology	\$ 15,378	\$ (15,114)	\$ 264
Acquired manufacturing facility production licenses	13,844	(2,077)	11,767
Acquired workforce	1,793	(1,793)	0
Total acquired technology and other intangibles, net	\$ 31,015	\$ (18,984)	\$ 12,031

	<b>Gross</b>		
	<b>Carrying</b>	<b>Accumulated</b>	<b>Net</b>
<b>December 31, 2009</b>	<b>Amount</b>	<b>Amortization</b>	
Acquired Melanophore screening technology	\$ 15,378	\$ (13,577)	\$ 1,801
Acquired manufacturing facility production licenses	12,580	(1,258)	11,322
Acquired workforce	1,629	(1,629)	0
Total acquired technology and other intangibles, net	\$ 29,587	\$ (16,464)	\$ 13,123

We recognized amortization expense of \$1.5 million in each of the years ended December 31, 2010, 2009 and 2008 for the acquired Melanophore technology, \$0.6 million and \$1.3 million in the years ended December 31, 2010 and 2009, respectively, for the manufacturing facility production licenses and \$0.8 million for both of the years ended December 31, 2009 and 2008 for the acquired workforce. Using the exchange rate in effect on December 31, 2010, we expect to record amortization expense of \$0.7 million per year through 2027 for the manufacturing facility production licenses.

**Table of Contents****(6) Commitments****Leases**

The following table summarizes our significant real property leasing arrangements and essential provisions as of December 31, 2010:

		<b>Description of Arrangements</b>
6166 Nancy Ridge Drive, San Diego, California	Lease	In 1997, we began leasing this property under a lease that included an option to buy the property for \$2.1 million. In 1998, we assigned the option to another company in exchange for \$0.7 million in cash, and such company exercised the option and leased the property to us under a lease that expires in 2013. The \$0.7 million is being recognized on a straight-line basis as a reduction in the rent expense on the underlying lease. We have two five-year options to extend the lease term beyond 2013. The new lease terms stipulate annual increases in monthly rental payments of 2.75% beginning in April 2000.
6122-6124-6126 Nancy Ridge Drive, San Diego, California	Lease with option to purchase	In 2002, we leased a property located at 6124-6126 Nancy Ridge Drive. Under the terms of this lease, effective April 2003, monthly rental payments increased by 2% and are subject to a 2% annual increase thereafter. In 2005, we amended this lease to include additional square footage in a contiguous building, 6122 Nancy Ridge Drive. As discussed in the below section on 6114, 6118, 6154 Nancy Ridge Drive, we assigned our option to buy this entire building for \$7.9 million when the lease ends in March 2012, and have an option to purchase the property back.
6138-6150 Nancy Ridge Drive, San Diego, California	Lease with option to purchase	In 2003, we completed the sale and leaseback of this property. The sales price for this property was \$13.0 million and net proceeds to us were \$12.6 million. We have accounted for this transaction using the financing method because our option to repurchase this property in the future is considered continued involvement requiring such method. Under the financing method, the book value of the property and related accumulated depreciation remain on our balance sheet and no sale is recognized. Instead, the sales price of the property is recorded as a financing obligation and a portion of each lease payment is recorded as interest expense. The term of the lease, which became effective in December 2003, is 15 years, with monthly rental payments increasing by 2.5% annually, beginning in January 2005. We have the right to repurchase this property through year 14 of the lease. We recognized interest expense of \$1.2 million in both of the years ended December 31, 2010 and 2009 and \$1.3 million in the year ended December 31, 2008 related to this lease. At December 31, 2010, the total financing obligation on our consolidated balance sheets related to this transaction was \$11.6 million.

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		<b>Description of Arrangements</b>
6114, 6118, 6154 Nancy Ridge Drive, San Diego, California	Lease with option to purchase	In May 2007, we completed the sale and leaseback of these properties. The total consideration for these properties and the assignment of the option to purchase the property located at 6122-6124-6126 Nancy Ridge Drive was \$50.1 million, resulting in net proceeds to us of \$48.5 million after financing costs and commissions. Concurrently with the closing of the transaction, we leased back the three properties under leases with 20-year terms and two consecutive options to extend such terms for five years each. In addition, subject to certain restrictions, we have the option to repurchase all of the properties included in the transaction on the 10 <sup>th</sup> , 15 <sup>th</sup> or 20 <sup>th</sup> anniversary of the execution date of the leases, and earlier if the leases are terminated under certain circumstances. We have accounted for this transaction using the financing method because our option to repurchase this property in the future is considered continued involvement requiring such method. Initial base rent for the three properties (net of taxes, insurance and maintenance costs (i.e. triple net) for which we are responsible) that were purchased as part of this transaction is an aggregate of \$4.5 million annually, subject to an annual increase of 2.5% and other specified adjustments. We recognized interest expense of \$6.1 million, \$6.0 million and \$3.9 million in the years ended December 31, 2010, 2009 and 2008, respectively, related to this transaction. The interest expense recognized in the year ended December 31, 2008 included \$0.9 million of capitalized interest related to the expansion of this facility. At December 31, 2010, the total financing obligation related to this transaction was \$65.2 million.
Zofingen, Switzerland	Lease	We lease from Siegfried approximately 17,000 square feet in various facilities that can be terminated with 12 months written notice under an agreement that expires in 2032. The agreement stipulates that the annual rental payments are indexed to the Swiss Consumer Price Index after 2008.

In accordance with the lease terms for three of the above-listed properties, we are required to maintain deposits for the benefit of the landlord throughout the term of the leases. A total of \$1.4 million was recorded in other non-current assets on our consolidated balance sheets as of December 31, 2010 and 2009 related to such leases.

We recognize rent expense on a straight-line basis over the term of each lease. Rent expense was \$1.2 million in each of the years ended December 31, 2010, 2009 and 2008.

We expect interest expense from December 31, 2010 through the terms of the leases related to our facilities to total \$78.4 million. As of December 31, 2010, the total financing obligation for these facilities was \$76.8 million. The aggregate residual value of the facilities at the end of the lease terms is \$10.0 million.

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Annual future obligations as of December 31, 2010 are as follows, in thousands:

Year ending December 31,	Financing Obligations	Operating Leases
2011	\$ 7,512	\$ 1,351
2012	8,391	890
2013	8,601	256
2014	8,816	0
2015	9,036	0
Thereafter	102,868	0
<b>Total minimum lease payments</b>	<b>145,224</b>	<b>\$ 2,497</b>
Less amounts representing interest	(78,445)	
Add amounts representing residual value	9,990	
Lease financing obligations	76,769	
Less current portion	(998)	
	<b>\$ 75,771</b>	

**(7) Note Payable to Deerfield**

In July 2009, pursuant to a Facility Agreement we entered into in June 2009 with 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, Deerfield provided us with a \$100.0 million secured loan and we issued Deerfield warrants to purchase an aggregate of 28,000,000 shares of our common stock at an exercise price of \$5.42 per share. We refer to these warrants as the 2009 Warrants. We received net proceeds of \$95.6 million from this loan.

On or before June 17, 2011, Deerfield may make a one-time election, which we refer to as the Deerfield Additional Loan Election, to loan us up to an additional \$20.0 million under the Facility Agreement, with the additional loan maturing on the same date as the original loan, June 17, 2013. For each additional \$1.0 million that Deerfield loans us under the Facility Agreement, we will issue Deerfield warrants for 280,000 shares of common stock at an exercise price of \$5.42 per share. All of the warrants issued or issuable in connection with the Facility Agreement are exercisable until June 17, 2013.

Under certain circumstances, Deerfield also has the right to require us to accelerate principal payments under the loan. At any time we may prepay any or all of the outstanding principal at par, and we may be required to make the scheduled repayments earlier in connection with certain equity issuances.

In accordance with relevant guidance, we separately valued four components under the Facility Agreement at the July 2009 issuance date as follows:

- (1) The \$100.0 million loan was valued at \$47.9 million on a relative fair value basis, and was recorded as a long-term liability on our consolidated balance sheet.
- (2) The 2009 Warrants to purchase an aggregate of 28,000,000 shares of our common stock, net of issuance costs, were valued at \$39.1 million on a relative fair value basis. The relative fair value of these warrants was recorded as additional paid-in capital on our consolidated balance sheet, and the resulting debt discount is being accreted to interest expense over the term of the loan or until paid using the effective interest rate method. These warrants were valued at the date of issuance using an option pricing model and the following assumptions: expected life of 3.95 years, risk-free interest rate of 2.0%, expected volatility of 66% and no dividend yield.

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Because these warrants are eligible for equity classification, no adjustments to the recorded value will be made on an ongoing basis.

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- (3) The Deerfield Additional Loan Election, including the 5,600,000 contingently issuable warrants to purchase up to 5,600,000 shares of our common stock, was valued at \$9.5 million. The Deerfield Additional Loan Election was classified as a liability on our consolidated balance sheet and, accordingly, will be revalued on each subsequent balance sheet date until it is exercised or expires, with any changes in the fair value between reporting periods recorded in the interest and other income (expense) section of our consolidated statements of operations (see Note 8). This allocation of proceeds under the Facility Agreement resulted in additional debt discount that is being accreted to interest expense over the term of the loan or until paid using the effective interest rate method.
- (4) Deerfield's ability to accelerate principal payments under the loan was valued at \$0.5 million. The acceleration right was classified as a liability on our consolidated balance sheet and, accordingly, will be revalued on each subsequent balance sheet date until it is exercised or expires, with any changes in the fair value between reporting periods recorded in the interest and other income (expense) section of our consolidated statements of operations (see Note 8). This allocation of proceeds under the Facility Agreement resulted in additional debt discount that is being accreted to interest expense over the term of the loan or until paid using the effective interest rate method.

The difference between the total recorded value of the note payable to Deerfield of \$37.8 million and the \$60.0 million outstanding principal balance of the loan as of December 31, 2010 represents the remaining debt discount, which will be accreted to interest expense over the remaining term of the loan or until paid. At December 31, 2009, the total recorded value of the note payable to Deerfield was \$47.9 million while the outstanding principal balance of the loan was \$90.0 million.

The loan matures on June 17, 2013, and the outstanding principal accrues interest at a rate of 7.75% per annum on the stated principal balance, payable quarterly in arrears. Total interest expense of \$14.0 million and \$11.2 million, including accretion of the debt discount attributable to the warrants and the other derivative financial instruments and amortization of capitalized issuance costs, was recognized in connection with this loan for the years ended December 31, 2010 and 2009, respectively. The non-cash correction of prior period errors described in Note 1 resulted in a \$3.0 million decrease to interest expense in the year ended December 31, 2010. We expect interest expense of \$8.6 million to be paid in cash from December 31, 2010 through the remaining term of the loan. The effective annual interest rate on the loan is 38.4%.

As a result of the closing of our public offering of common stock in July 2009, we were required to repay Deerfield \$10.0 million that was originally due in July 2010. In connection with this \$10.0 million repayment, we retired a proportional share of the debt discount and issuance costs directly related to the repaid debt and recognized a non-cash loss on extinguishment of debt of \$2.5 million in 2009.

In June 2010, we entered into a Purchase and Exchange Agreement, or Purchase Agreement, with Deerfield, pursuant to which we sold Deerfield 11,000,000 shares of our common stock at a price of \$3.23 per share, resulting in net proceeds to us of \$35.5 million. Also pursuant to the Purchase Agreement, we exchanged 2009 Warrants to purchase an aggregate of 16,200,000 shares of our common stock at an exercise price of \$5.42 per share for new warrants, which we refer to as the New Warrants, to purchase a like number of shares of our common stock at an exercise price of \$3.45 per share. The New Warrants will remain exercisable until June 17, 2013, which is the same date the 2009 Warrants expire. Other than the exercise price and certain provisions related to cashless exercise and early termination of the warrants, the New Warrants contain substantially the same terms as the 2009 Warrants.

We valued the New Warrants at their June 7, 2010 issuance date using an option pricing model and the following assumptions: expected life of 3.03 years, risk-free interest rate of 1.2%, expected volatility of 72% and no dividend yield. We determined that the incremental value of the New Warrants was \$5.5 million, which was recorded as a component of the stock issuance and warrant exchange under the Purchase Agreement in the stockholders' equity section of our consolidated balance sheet. Because the New Warrants are eligible for equity classification, no adjustments to the recorded value will be made on an ongoing basis.



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In August 2010, we sold 8,955,224 shares of our common stock at a price of \$6.70 per share in a registered direct public offering to Deerfield. As part of this transaction, we entered into an amendment to the Facility Agreement, pursuant to which \$30.0 million of the proceeds from this transaction was used to prepay the portion of the principal amount that we otherwise would have been required to repay in July 2012. Net proceeds to us from this transaction, after prepayment of the \$30.0 million, were approximately \$30.0 million. In connection with this \$30.0 million prepayment, we retired a proportional share of the debt discount and issuance costs directly related to the repaid debt and recognized a non-cash loss on extinguishment of debt of \$12.4 million in 2010. In accordance with relevant guidance, we also evaluated whether this amendment constituted an extinguishment of debt resulting in extinguishment accounting or modification accounting. Based on our analysis, we determined that this amendment was not a substantial modification and, accordingly, we accounted for this amendment under modification accounting. Had extinguishment accounting been required, we would have recognized a gain or loss based on the difference between the carrying value of our note payable to Deerfield and its fair value.

At December 31, 2010, of the total \$60.0 million of principal then outstanding on the Deerfield loan, \$20.0 million was due in July 2011 and the remaining \$40.0 million was due in June 2013. See Note 16 regarding the principal prepayment made subsequent to December 31, 2010.

**(8) Derivative Liabilities**

In June 2006 and August 2008, we issued seven-year warrants, which we refer to as the Series B warrants, to purchase 829,856 and 1,106,344 shares of our common stock, respectively, at an exercise price of \$15.49 and \$7.71 per share, respectively. The Series B warrants are related to our Series B Convertible Preferred Stock, which we redeemed in 2008 and is no longer outstanding. The warrants contain an anti-dilution provision and, as a result of subsequent equity issuances at prices below the adjustment price of \$6.72 defined in the warrants, as of December 31, 2010, the number of shares issuable upon exercise of the outstanding June 2006 and August 2008 Series B Warrants was increased to 1,046,781 and 1,398,346, respectively, and the exercise price was reduced to \$12.28 and \$6.10 per share, respectively.

In January 2009, we adopted amendments to the authoritative guidance related to contracts in an entity's own equity. These amendments provide a two-step model to be applied in determining whether a financial instrument or an embedded feature in a financial instrument is indexed to an entity's own stock that would qualify such financial instruments or embedded features for a scope exception. This scope exception specifies that a contract that would otherwise meet the definition of a derivative financial instrument would not be considered as such if the contract is both (i) indexed to the entity's own stock and (ii) classified in the stockholders' equity section of the balance sheet. Our adoption of these amendments resulted in the determination that our Series B warrants are ineligible for equity classification as a result of the anti-dilution provisions in the Series B Warrants that may result in an adjustment to the warrant exercise price. As such, upon adoption of these amendments, we recorded a \$9.7 million adjustment to equity, a \$2.1 million liability for the fair value of the Series B Warrants and a \$7.6 million adjustment to the opening accumulated deficit balance as a cumulative effect of a change in accounting principle. We have revalued these warrants on each subsequent balance sheet date, and will continue to do so until they are exercised or expire, with any changes in the fair value between reporting periods recorded as other income or expense. The June 2006 Series B Warrants were valued at December 31, 2010 using an option pricing model and the following assumptions: expected life of 2.50 years, risk-free interest rate of 0.8%, expected volatility of 96% and no dividend yield, and at December 31, 2009 using the following assumptions: expected life of 3.50 years, risk-free interest rate of 2.0%, expected volatility of 68% and no dividend yield. The August 2008 Series B Warrants were valued at December 31, 2010 using an option pricing model and the following assumptions: expected life of 4.62 years, risk-free interest rate of 1.8%, expected volatility of 83% and no dividend yield, and at December 31, 2009 using the following assumptions: expected life of 5.62 years, risk-free interest rate of 2.9%, expected volatility of 61% and no dividend yield.

We separately valued the Deerfield Additional Loan Election, including the 5,600,000 contingently issuable warrants to purchase up to 5,600,000 shares of our common stock, as of the July 6, 2009 issuance date of the

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Deerfield loan (see Note 7). The value of the Deerfield Additional Loan Election is classified as a liability on our consolidated balance sheet and, accordingly, will be revalued on each subsequent balance sheet date until it is exercised or expires, with any changes in the fair value between reporting periods recorded as other income or expense. In July 2009, the Deerfield Additional Loan Election was valued using an option pricing model and the following assumptions: expected life of 1.45 to 1.95 years, risk-free interest rate of 2.0%, expected volatility of 66% and no dividend yield. At December 31, 2010, the Deerfield Additional Loan Election was revalued using an option pricing model and the following assumptions: expected life of 0.46 years, risk-free interest rate of 0.8%, expected volatility of 97% and no dividend yield, and at December 31, 2009 using the following assumptions: expected life of 2 to 3 years, risk-free interest rate of 1.9%, expected volatility of 69% and no dividend yield.

We also separately valued Deerfield's right to require us to accelerate principal payments of the loan under certain circumstances at \$0.5 million as of the July 6, 2009 issuance date (see Note 7). The value of this acceleration right is classified as a liability on our consolidated balance sheet and, accordingly, will be revalued on each subsequent balance sheet date until it is exercised or expires, with any changes in the fair value between reporting periods recorded as other income or expense. At each reporting date, this acceleration right was valued using a discounted cash flow model.

Our derivative liabilities consisted of the following, as of December 31, 2010 and 2009, in thousands:

	<b>December 31</b>	
	<b>2010</b>	<b>2009</b>
Deerfield Additional Loan Election	\$ 607	\$ 0
Total current derivative liabilities	607	0
Deerfield Additional Loan Election	0	3,831
Series B Warrants	1,234	2,386
Deerfield acceleration right	430	425
Total long-term derivative liabilities	1,664	6,642
Total derivative liabilities	\$ 2,271	\$ 6,642

The change in the fair value of our derivative liabilities is recorded in the interest and other income (expense) section of our consolidated statements of operations. The following table presents the gain (loss) we recognized in the years ended December 31, 2010 and 2009, in thousands:

	<b>December 31</b>	
	<b>2010</b>	<b>2009</b>
Deerfield Additional Loan Election	\$ 3,224	\$ 5,652
Series B Warrants	1,152	(268)
Deerfield acceleration right	(5)	34
Total gain due to revaluation of derivative liabilities	\$ 4,371	\$ 5,418

**(9) Asset Acquisition from Siegfried Ltd and Related Agreements**

In January 2008, we acquired from Siegfried certain drug product facility assets, including manufacturing facility production licenses, fixtures, equipment, other personal property and real estate assets in Zofingen, Switzerland, under an Asset Purchase Agreement between Siegfried and Arena GmbH. These assets are being used to manufacture lorcaserin and certain drug products for Siegfried. This transaction was determined not to be an acquisition of a business since a self-sustaining integrated set of activities and assets was not acquired. Accordingly, goodwill was not recognized and the assets acquired were recorded based on their relative fair value.



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The purchase price under such agreement, in Swiss francs, was CHF 31.8 million in cash and 1,488,482 shares of our common stock valued at \$8.0 million, which were issued to Siegfried in January 2008. We paid CHF 21.8 million, or \$19.6 million, of the cash purchase price in January 2008, and will pay the remaining CHF 10.0 million cash portion of the purchase price in three equal installments in January 2011, January 2012 and January 2013. See Note 16 regarding Arena GmbH's agreement subsequent to December 31, 2010 to repay the installments due in January 2012 and January 2013 in 2011. Our consolidated balance sheet at December 31, 2010 and 2009 included a total of \$10.4 million and \$9.1 million, respectively, for the US dollar equivalent representing the then-present value of this liability.

This transaction, including the cash payment made in January 2008, the value of the common stock when it was issued and the present value of the remaining cash payments, was recorded as follows, in thousands, translated into US dollars at the exchange rate in effect when the transaction closed on January 9, 2008:

<b>Tangible assets</b>	
Fixtures, equipment and personal property	\$ 16,760
Real estate	5,659
<b>Total tangible assets</b>	<b>\$ 22,419</b>
<b>Intangible assets</b>	
Manufacturing facility production licenses	11,620
Acquired workforce	1,505
<b>Total intangible assets</b>	<b>13,125</b>
<b>Total assets acquired</b>	<b>\$ 35,544</b>

At December 31, 2010 and 2009, the balances of these acquired assets are translated into US dollars at the applicable exchange rate on the balance sheet date.

In connection with this transaction, we and Siegfried also entered into a long-term supply agreement for the active pharmaceutical ingredient of lorcaserin, a manufacturing services agreement and a technical services agreement.

Pursuant to the manufacturing services agreement, we recognized revenue of \$7.1 million, \$6.6 million and \$7.4 million in the years ended December 31, 2010, 2009 and 2008, respectively, for manufacturing drug products for Siegfried. Upon Siegfried's acceptance of drug products manufactured by us, we recognize manufacturing services revenues at agreed upon prices for such drug products. The related cost to manufacture the drug products was \$7.4 million, \$6.5 million and \$8.5 million in the years ended December 31, 2010, 2009 and 2008, respectively.

We also recognized expenses of \$2.5 million for services incurred under the technical services agreement in the year ended December 31, 2010 and \$2.3 million in both of the years ended December 31, 2009 and 2008. The technical services agreement provides us with administrative and other services to operate the facility. We determined that we are receiving an identifiable benefit for these services and are recording such fees in the operating expense section of the accompanying consolidated statements of operations.

**(10) Stockholders' Equity****Preferred Stock**

In October 2002, and in conjunction with the stockholders' rights plan (see "Stockholders' Rights Plan" below in this note), our board of directors created a series of preferred stock, consisting of 350,000 shares with a par value of \$.0001 per share, designated as Series A Junior Participating Preferred Stock, or the Series A Preferred Stock. Such number of shares may be increased or decreased by our board of directors, provided that

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no decrease shall reduce the number of shares of Series A Preferred Stock to a number less than the number of shares then outstanding, plus the number of shares reserved for issuance upon the exercise of outstanding options, rights or warrants or upon the conversion of any of our outstanding securities convertible into Series A Preferred Stock. As of December 31, 2010 and 2009, no shares of Series A Preferred Stock were issued or outstanding.

### **Treasury Stock**

In October 2003, Biotechnology Value Fund, L.P. and certain of its affiliates accepted our offer of \$23.1 million to purchase from them 3,000,000 shares of our common stock at a cash price of \$7.69 per share, which shares are recorded on our consolidated balance sheets as treasury stock.

### **Warrants**

In July 2009, we issued to Deerfield the 2009 Warrants to purchase an aggregate of 28,000,000 shares of our common stock at an exercise price of \$5.42 per share in connection with our receipt of a \$100.0 million loan. We valued the 2009 Warrants, which are recorded as additional paid-in capital on our consolidated balance sheet, at \$39.1 million on a relative fair value basis as of the July 6, 2009 issuance date, net of allocated issuance costs (see Note 7).

As part of our June 2010 sale of common stock to Deerfield that resulted in net proceeds to us of \$35.5 million (see Note 7), we exchanged 16,200,000 of the 2009 Warrants to purchase shares of our common stock at an exercise price of \$5.42 per share for the New Warrants to purchase a like number of shares of our common stock at an exercise price of \$3.45 per share. We valued the incremental value of the New Warrants at \$5.5 million as of the June 7, 2010 issuance date (see Note 7).

In June 2006 and August 2008, we issued our Series B Warrants (see Note 7). These warrants contain an anti-dilution provision and, as a result of subsequent equity issuances at prices below the adjustment price of \$6.72 defined in the warrants, as of December 31, 2010 the outstanding June 2006 and August 2008 Series B Warrants were exerc