

ARENA PHARMACEUTICALS INC

Form 10-K

March 03, 2014

[Table of Contents](#)

**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, 2013

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)

Edgar Filing: ARENA PHARMACEUTICALS INC - Form 10-K

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)  
**6154 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:**

Title of each class	Name of each exchange on which registered
Common Stock, \$0.0001 par value	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 \$1.7 billion as of June 30, 2013, based on the last sale price of the registrant's common stock as reported on the NASDAQ Global Select Market on such date. For purposes of this calculation, shares of the registrant's common stock held by directors and executive officers have been excluded. This

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

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 February 24, 2014, there were 219,259,995 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 2014, 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, 2013.

**Table of Contents**

**ARENA PHARMACEUTICALS, INC.**

**TABLE OF CONTENTS**

<i><b>PART I</b></i>		
Item 1.	<b><u>Business</u></b>	2
Item 1A.	<b><u>Risk Factors</u></b>	28
Item 1B.	<b><u>Unresolved Staff Comments</u></b>	60
Item 2.	<b><u>Properties</u></b>	60
Item 3.	<b><u>Legal Proceedings</u></b>	61
Item 4.	<b><u>Mine Safety Disclosures</u></b>	61
<i><b>PART II</b></i>		
Item 5.	<b><u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u></b>	62
Item 6.	<b><u>Selected Financial Data</u></b>	64
Item 7.	<b><u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u></b>	65
Item 7A.	<b><u>Quantitative and Qualitative Disclosures About Market Risk</u></b>	85
Item 8.	<b><u>Financial Statements and Supplementary Data</u></b>	86
Item 9.	<b><u>Changes in and Disagreements With Accountants on Accounting and Financial Disclosure</u></b>	120
Item 9A.	<b><u>Controls and Procedures</u></b>	120
Item 9B.	<b><u>Other Information</u></b>	122
<i><b>PART III</b></i>		
Item 10.	<b><u>Directors, Executive Officers and Corporate Governance</u></b>	123
Item 11.	<b><u>Executive Compensation</u></b>	123
Item 12.	<b><u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u></b>	123
Item 13.	<b><u>Certain Relationships and Related Transactions, and Director Independence</u></b>	124
Item 14.	<b><u>Principal Accountant Fees and Services</u></b>	124
<i><b>PART IV</b></i>		
Item 15.	<b><u>Exhibits, Financial Statement Schedules</u></b>	125

**Table of Contents**

**INFORMATION RELATING TO FORWARD-LOOKING STATEMENTS**

This Annual Report on Form 10-K, or Annual Report, 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. 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. For such statements, we claim the protection of the Private Securities Litigation Reform Act of 1995. Readers of this Annual Report are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the time this Annual Report 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. 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 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. BELVIQ® is a registered trademark of Arena Pharmaceuticals GmbH. Any other brand names or trademarks appearing in this Annual Report are the property of their respective holders.

In this Annual Report, 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.

BELVIQ® (pronounced BEL-VEEK) is the trade name for the finished drug product containing the active pharmaceutical ingredient lorcaserin hydrochloride, or lorcaserin, that is marketed for chronic weight management in the United States. Lorcaserin may in the future be marketed in the United States or in other countries under a different trade name for chronic weight management. Lorcaserin may also be marketed under a different trade name for a different indication, in a different formulation or in combination with another drug. In this report, we use BELVIQ to refer to the finished drug product containing lorcaserin and/or, depending on the context, the active pharmaceutical ingredient lorcaserin, and without regard to the current or potential indication, formulation or combination.

---

**Table of Contents**

**PART I**

**Item 1. Business.  
Overview**

We are a biopharmaceutical company focused on discovering, developing and commercializing novel drugs that target G protein-coupled receptors, or GPCRs, to address unmet medical needs. BELVIQ® (lorcaserin HCl), our internally discovered drug for chronic weight management, is our first and only drug approved by any regulatory agency for marketing. BELVIQ was approved by the US Food and Drug Administration, or FDA, for marketing in the United States, and was made available by prescription in June 2013 to adults who are overweight with a comorbidity or obese. As described below, there are pending applications for the regulatory approval of BELVIQ for marketing in a number of additional countries under our collaborations. In addition to BELVIQ, we have drug candidates and compounds at various stages of research and development.

The key elements of our strategy are as follows:

**Make BELVIQ Available to Patients for Chronic Weight Management.** We have agreements with pharmaceutical companies that provide them rights and responsibilities to seek regulatory approval and commercialize BELVIQ for chronic weight management throughout most of the world. Our Swiss subsidiary, Arena Pharmaceuticals GmbH, or Arena GmbH, will manufacture BELVIQ and supply BELVIQ to our collaborators for commercialization in the United States and, subject to applicable regulatory approval, additional countries in the future.

**Pursue Additional BELVIQ Opportunities.** We will explore with our collaborators or independently additional indications, formulations and combinations for BELVIQ.

**Advance our Pipeline and GPCR Research.** We will advance our pipeline of drug candidates independently and through collaborations with pharmaceutical companies. In addition, our technologies, our drug discovery infrastructure and our scientists integrated approach to research have allowed us to identify and develop BELVIQ as well as a number of other novel compounds. We will continue our research and development efforts to identify additional GPCR targets and discover and advance new compounds.

Eisai is responsible for marketing and distributing BELVIQ in the United States under Arena GmbH's marketing and supply agreement with Eisai Inc., and Eisai Inc.'s parent company, Eisai Co., Ltd., which we refer to collectively with Eisai Inc. as Eisai. Under such agreement, Arena GmbH also granted Eisai exclusive commercialization rights for BELVIQ in all of the other countries in the world, except for South Korea, Taiwan, Australia, New Zealand and Israel. In addition, Arena GmbH has marketing and supply agreements with Ildong Pharmaceutical Co., Ltd., or Ildong, for BELVIQ in South Korea, and with CY Biotech Company Limited, or CYB, in Taiwan. We intend to enter into additional collaborations for the potential regulatory approval and commercialization of BELVIQ in Australia, New Zealand and Israel.

The marketing of BELVIQ is subject to applicable regulatory approval, and, in general, our collaborators are responsible for regulatory activities related to obtaining marketing approval of BELVIQ in the territories covered under the respective agreement. We or our collaborators have filed for regulatory approval in a number of countries, and we expect our collaborators to file for regulatory approval in additional countries in the future.

We have composition of matter patents for BELVIQ issued in major jurisdictions globally that, in most cases, are capable of continuing into 2023. We have filed applications for patent extension in the United States, which, if granted, will extend the patent term for BELVIQ into 2026 and potentially into 2027.

As part of our research and development efforts, we are exploring BELVIQ for possible new indications, using different formulations, and in combination with other drugs. We and Eisai have initially prioritized the development areas of smoking cessation, a once-daily formulation, and co-administration with phentermine, as well as exploring, including as part of the FDA-required cardiovascular outcomes trial, or CVOT, BELVIQ's effect on conversion to type 2 diabetes and improvements in cardiovascular outcomes.



**Table of Contents**

In addition to BELVIQ, we also intend to utilize our GPCR focus and expertise to advance other of our internally discovered compounds and drug candidates, which include the following clinical-stage, orally available candidates:

APD811, an agonist of the prostacyclin receptor intended for the treatment of pulmonary arterial hypertension, has completed single- and multiple-ascending dose Phase 1 trials and is expected to begin a Phase 2 trial in the first half of 2014.

Temanogrel, an inverse agonist of the serotonin 2A receptor intended for the treatment of thrombotic diseases, has completed single- and multiple-ascending dose Phase 1 trials. Under our Co-Development and License Agreement with Ildong, we expect Ildong to fund and complete an additional Phase 1 trial in healthy volunteers and potentially a Phase 2a proof-of-concept trial in patients. We expect Ildong to initiate the Phase 1 trial in the first quarter of 2014 to evaluate the safety of co-administration of temanogrel with aspirin and clopidogrel.

APD334, an agonist of the sphingosine 1-phosphate subtype 1, or S1P<sub>1</sub>, receptor intended for the treatment of a number of conditions related to autoimmune diseases, has completed a Phase 1 trial evaluating single-ascending doses of APD334. We plan to initiate a Phase 1 multiple-ascending dose trial of APD334 in 2014.

APD371 is an agonist of the cannabinoid 2, or CB<sub>2</sub>, receptor intended for the treatment of pain. We have initiated a Phase 1 single-ascending dose trial of APD371.

We have commercial rights for our programs and drug candidates, except for Eisai's rights with respect to BELVIQ, Ildong's rights with respect to BELVIQ and temanogrel, and CYB's rights with respect to BELVIQ.

Arena Pharmaceuticals, Inc., incorporated in the state of Delaware in April 1997, and is located in San Diego, California. Our operations outside of the United States are primarily located at Arena GmbH in Zofingen, Switzerland. Activities conducted at Arena GmbH include manufacturing, quality control, quality assurance, development of manufacturing processes, qualifying suppliers and otherwise managing aspects of the supply chain, regulatory compliance, distribution of finished products, alliance management, and strategic planning and development. Arena GmbH and its wholly owned subsidiary, API Development LTD, also hold certain intellectual property rights for BELVIQ.



**Table of Contents****Our Research and Development Programs**

Our proprietary GPCR-based technologies and our validated drug discovery and development capabilities and approach enable us to internally discover and develop drug candidates. We periodically conduct a review of our programs to prioritize the use of our resources, and we are currently focusing our resources and activities on BELVIQ and the other clinical-stage programs in the table below, as well as on earlier-stage programs that span several therapeutic areas.

<b>Drug Candidate</b>	<b>Indication/Endpoint</b>	<b>Status</b>
<b>Lorcaserin*</b>	Impact on Cardiovascular Outcomes/Conversion to Type 2 Diabetes	Included as Part of Ongoing CVOT
<b>Lorcaserin*</b>	Smoking Cessation	Upcoming Phase 2 Trial
<b>Lorcaserin*</b>	Weight Management	Ongoing Pilot Study
<b>Co-Administration with Phentermine</b>		
<b>Lorcaserin* Extended-</b>	Multiple	Completed Initial Pharmacokinetic Study
<b>Release Formulation</b>		
<b>APD811</b>	Pulmonary Arterial Hypertension	Upcoming Phase 2 Trial
<b>Temanogrel</b>	Thrombotic Diseases	Upcoming Additional Phase 1 Multiple-Ascending Dose Trial
<b>APD334</b>	Autoimmune Diseases	Upcoming Phase 1 Multiple-Ascending Dose Trial
<b>APD371</b>	Pain	Ongoing Phase 1 Single-Ascending Dose Trial

\* Lorcaserin is marketed in the United States for chronic weight management under the trade name BELVIQ. With the exception of this table, in this report, we generally use BELVIQ to refer to the finished drug product containing lorcaserin and/or, depending on the context, the active pharmaceutical ingredient lorcaserin, and without regard to the current or potential indication, formulation or combination.

**Clinical-Stage Programs*****BELVIQ for Chronic Weight Management***

According to the Centers for Disease Control and Prevention, more than one-third of US adults (35.7%) were obese in 2009-2010. 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), quality of life and functional capacity, and a significant reduction in the incidence of type 2 diabetes.

***FDA Approval of BELVIQ and Availability in the United States***

In June 2012, the FDA approved our internally discovered drug, BELVIQ, for chronic weight management in adults who are overweight with a comorbidity or obese. The FDA's approval was subject to the scheduling of BELVIQ by the US Drug Enforcement Administration, or DEA. Following such scheduling, in June 2013, our collaborator, Eisai, made BELVIQ available in the United States to patients by prescription. Eisai is focused on physician awareness and education efforts, securing broad reimbursement coverage, and creating patient awareness and access for BELVIQ. The BELVIQ sales force totaled approximately 400 representatives at around the end of 2013, reimbursement coverage for BELVIQ has increased since BELVIQ's launch, Eisai is in discussions to further improve such coverage, and Eisai has a patient awareness and support campaign intended to complement its physician awareness efforts.

BELVIQ is believed to decrease food consumption and promote satiety by selectively activating serotonin 2C receptors in the brain. Activation of these receptors may help a person eat less and feel full after eating smaller amounts of food.

---

## **Table of Contents**

In the United States, BELVIQ is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index, or BMI, of:

30 kg/m<sup>2</sup> or greater (obese), or

27 kg/m<sup>2</sup> or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidemia, type 2 diabetes).

Limitations of Use:

The safety and efficacy of coadministration of BELVIQ with other products intended for weight loss, including prescription drugs (e.g., phentermine), over-the-counter drugs, and herbal preparations, have not been established.

The effect of BELVIQ on cardiovascular morbidity and mortality has not been established.

### *US Postmarketing Requirements*

As part of the US approval of BELVIQ, the FDA is requiring the evaluation of the effect of long-term treatment with BELVIQ on the incidence of major adverse cardiovascular events, or MACE, in overweight and obese patients with cardiovascular disease or multiple cardiovascular risk factors, as well as to conduct postmarketing studies to assess the safety and efficacy of BELVIQ for weight management in obese pediatric patients.

Eisai initiated enrollment in January 2014 of approximately 12,000 patients in the CVOT, which is also referred to as CAMELLIA (Cardiovascular And Metabolic Effects of Lorcaserin In Overweight And Obese Patients). CAMELLIA is a randomized, double-blind, placebo-controlled trial that will enroll patients with cardiovascular disease or multiple cardiovascular risk factors. The trial is expected to run for approximately five years.

The FDA required portion of CAMELLIA is designed to evaluate BELVIQ's effect on the incidence of MACE (non-fatal myocardial infarction, non-fatal stroke and cardiovascular death) compared to placebo, with a non-inferiority margin for the hazard ratio of 1.4. In addition, as part of the non-FDA required portion of the trial, CAMELLIA will also evaluate whether BELVIQ reduces the incidence of conversion to type 2 diabetes in patients without type 2 diabetes at baseline and the incidence of MACE+ (MACE or hospitalization for unstable angina or heart failure, or any coronary revascularization), both as compared to placebo. CAMELLIA will include echocardiograms in a subset of the patients.

As the first of four postmarketing commitments related to adolescent and pediatric patients, we have completed dosing in a pharmacokinetic study of BELVIQ in adolescents, and results are pending. Eight adolescent boys and girls, aged 12-17, with a BMI of greater than or equal to the 95<sup>th</sup> percentile for age and sex, but less than or equal to 44 kg/m<sup>2</sup>, were administered a single 10 mg dose of BELVIQ.

### *BELVIQ Collaborations and Regulatory Activity*

Arena GmbH has granted Eisai exclusive commercialization rights for BELVIQ to all of the countries in the world, except for South Korea, Taiwan, Australia, New Zealand and Israel. Arena GmbH also has marketing and supply agreements with Ildong for BELVIQ in South Korea, and with CYB in Taiwan. We intend to enter into additional collaborative agreements for the potential regulatory approval and commercialization of BELVIQ in Australia, New Zealand and Israel.

The marketing of BELVIQ is subject to applicable regulatory approval. BELVIQ has been approved for marketing in the United States, but currently not in any other country. In general, our collaborators are responsible for seeking regulatory approval in the territories covered under the respective agreement. Eisai



---

**Table of Contents**

filed applications for regulatory approval of BELVIQ in Mexico and Canada in March and June of 2013, respectively, and in Brazil in February 2014. In November 2013, Ildong submitted an application for regulatory approval of BELVIQ in South Korea. We previously filed applications for marketing approval of BELVIQ with the regulatory authorities for the European Union and Switzerland, and these regulatory authorities notified us that we had not yet satisfactorily addressed their concerns and that our applications would not be approved. We expect to continue to work with Eisai in pursuing regulatory approvals for BELVIQ in Europe and other territories outside the United States. In addition, CYB intends to file an application for regulatory approval of BELVIQ in Taiwan.

*Eisai Collaboration*

In November 2013, Arena GmbH, Eisai Inc., and Eisai Inc.'s parent company, Eisai Co., Ltd., entered into the Second Amended and Restated Marketing and Supply Agreement, or Eisai Agreement, which amended and restated the previous agreement and expanded Eisai's exclusive commercialization rights for BELVIQ to all of the countries in the world, except for South Korea, Taiwan, Australia, New Zealand and Israel. Eisai's commercialization rights are subject to applicable regulatory approval.

Arena GmbH and Eisai entered into the original Marketing and Supply Agreement in July 2010, under which we granted Eisai Inc. exclusive commercialization rights for BELVIQ solely in the United States and its territories and possessions. In May 2012, Arena GmbH and Eisai Inc. amended and restated such agreement by entering into the Amended and Restated Marketing and Supply Agreement, which expanded Eisai Inc.'s exclusive commercialization rights to include most of North and South America.

*Upfront and Milestone Payments*

In connection with entering into the Eisai Agreement, we received from Eisai an upfront payment of \$60.0 million. This payment is in addition to the \$50.0 million and \$5.0 million in upfront payments we received from Eisai in connection with entering into the original agreement and the first amended agreement, respectively. We are also eligible to receive up to an aggregate of \$176.5 million in additional regulatory and development milestone payments. These milestone payments include an aggregate of \$53.5 million in such potential milestone payments that remained available for us to achieve under the first amended agreement and an aggregate of \$123.0 million in additional potential milestone payments under the Eisai Agreement.

*Product Purchase Price and Purchase Price Adjustment Payments*

We manufacture BELVIQ at our facility in Switzerland, and sell BELVIQ to Eisai for Eisai's commercialization in the United States and, subject to applicable regulatory approval, in the other territories under the Eisai Agreement (other than Europe, China and Japan) for a purchase price starting at 31.5% and 30.75%, respectively (and starting at 27.5% in Europe, China and Japan), of Eisai's aggregate annual net product sales. The purchase price will increase on a tiered basis in the United States and the other territories (other than Europe, China and Japan) to as high as 36.5% and 35.75%, respectively, on the portion of Eisai's annual aggregate net product sales exceeding \$750.0 million in all territories other than Europe, China and Japan. The purchase price will increase to 35% in Europe, China and Japan on the portion of Eisai's annual aggregate net product sales exceeding \$500.0 million in such territories. The purchase price is subject to reduction (for sales in a particular country), including in the event of generic competition in the applicable country.

In addition to payments for purchases of BELVIQ, we are eligible to receive up to an aggregate of \$1.56 billion in one-time purchase price adjustment payments and other payments. These payments include up to an aggregate of \$1.19 billion that are based on Eisai's annual net product sales of BELVIQ in all of the territories under the Eisai Agreement on an aggregate basis, with the first and last amounts payable with annual net product sales of \$250.0 million and \$2.5 billion, respectively. Of these payments, Eisai will pay us a total of \$330.0 million for annual net product sales of up to \$1.0 billion. The \$1.56 billion also includes \$370.0 million in

**Table of Contents**

one-time purchase price adjustment payments we are eligible to receive based on annual net product sales in the non-US territories, comprised of \$185.0 million based on Eisai's annual net product sales in the non-US territories in North and South America and \$185.0 million based on Eisai's annual net product sales in the territories outside of North and South America. The first and last amounts are payable upon first achievement of annual net product sales of \$100.0 million and \$1.0 billion, respectively, with respect to each of the following areas: (i) the non-US territories in North and South America and (ii) the territories outside of North and South America. In addition, we are also eligible to receive certain payments by Eisai if certain annual minimum sales requirements in Mexico, Canada and Brazil are not met during the first ten years after initial commercial sale in such territories.

Development Payments

The below chart summarizes the general agreement regarding cost sharing between Eisai and us for significant development activities under the Eisai Agreement. In addition, Eisai or we may from time to time conduct approved development of BELVIQ at such party's own expense. For example, Eisai is responsible for the expenses of the pilot study of 12-week duration to preliminarily assess BELVIQ and phentermine when co-administered.

**Eisai Second Amended and Restated Marketing and Supply Agreement: Cost Sharing for Development**  
**Rest of**

	<b>United States</b>	<b>North and South America</b>	<b>Remaining Territories</b>
<b>BELVIQ for weight management</b>	Not Applicable	<b>General</b>	Up to total of \$100.0 million -
<i>- Pre-approval*</i>		Eisai: 90%; Arena: 10%	Eisai: 50%; Arena: 50%
		<b>Certain stability work</b>	Thereafter, Eisai: 100%
		Eisai: 50%; Arena: 50%	
<b>BELVIQ for weight management</b>	<b>General</b> - Eisai: 90%; Arena 10%	<b>General</b>	Up to total of \$50.0 million -
<i>- Post-approval*</i>		Eisai: 90%; Arena: 10%	Eisai: 50%; Arena: 50%
	<b>Non-FDA required portion of CVOT</b>		
	Up to \$80.0 million -	<b>Certain stability work</b>	Thereafter, Eisai: 90%;
	Eisai: 50%; Arena: 50%	Eisai: 50%; Arena: 50%	Arena: 10%
	Thereafter, Eisai: 100%		
	<b>Certain pediatric studies</b>		
	Eisai: 50%; Arena: 50%		
<b>Products other than BELVIQ for weight management</b>	Up to total of \$250.0 million (as reduced by up to \$80.0 million for non-FDA required portion of CVOT) - Eisai: 50%; Arena: 50%		
<i>- Pre-approval</i>			Up to a total of \$100.0 million in the aggregate across all additional products -

**Products other than BELVIQ for weight management** Eisai: 50%; Arena: 50%

**- Post-approval** Thereafter, Eisai: 90%; Arena: 10%

\* Development required by a regulatory authority, with the exception of the non-FDA required portions of the CVOT.

*Certain Other Terms*

Eisai and we have agreed to limitations on the ability to commercialize outside of the Eisai Agreement any weight management product or addiction disorder product in the territories under the agreement. The agreement continues to include a stand-still provision limiting Eisai's ability to acquire our securities and assets.

## Table of Contents

Eisai may terminate the Eisai Agreement with respect to any country in the territory following the later of the expiration of all issued BELVIQ patents in such country and 12 years after the first commercial sale of BELVIQ in such country. Arena GmbH and Eisai each has the right to terminate the agreement early in certain circumstances in its entirety or with respect to the applicable country or product, including (a) if the other party is in material breach, (b) for commercialization concerns, and (c) for certain intellectual property infringement. Eisai also has the right to terminate the Agreement early in its entirety or with respect to each country in certain circumstances, including (i) termination in a country if sales of generic equivalents of BELVIQ in such country exceed sales of BELVIQ in that country (based on volume), and (ii) if Eisai is acquired by a company that has a product that competes with BELVIQ. In addition, Arena GmbH can terminate the agreement early in its entirety or with respect to each country in the non-US territories in North and South America in certain circumstances, including termination in each country if Eisai does not satisfy certain regulatory filing and commercialization diligence requirements in such country.

Eisai will indemnify us for losses resulting from certain third-party claims, including for (a) Eisai's negligence, willful misconduct or violation of law, but excluding product liability claims, (b) Eisai's breach of the marketing and supply agreement or related agreements, but excluding product liability claims, (c) certain uses or misuses of BELVIQ, (d) certain governmental investigations of Eisai related to BELVIQ, and (e) infringement relating to Eisai's use of certain trademarks, tag lines and logos related to BELVIQ. Arena GmbH will indemnify Eisai for losses resulting from certain third-party claims, including for (i) Arena GmbH's negligence, willful misconduct, failure to comply with law, breach of any agreement with a third party with respect to product development prior to the effective date of the original agreement with Eisai, but excluding product liability claims, (ii) Arena GmbH's negligence or willful misconduct with respect to certain uses or misuses of BELVIQ outside of the agreement, (iii) certain uses or misuses of BELVIQ after the term of the agreement, in any territory no longer under the agreement or with respect to any product after the termination of the agreement with respect to such product, (iv) Arena GmbH's negligence, willful misconduct or violation of law, but excluding product liability claims, (v) Arena GmbH's breach of the marketing and supply agreement or related agreements, but excluding product liability claims, (vi) certain infringement of intellectual rights of a third party, and (vii) infringement relating to Eisai's use of certain trademarks related to BELVIQ. In addition, Arena GmbH and Eisai will, in general, share equally in losses resulting from third-party product liability claims, except where one party's acts or omissions did not contribute to the events or circumstances leading to such product liability claim and the other party's actual willful misconduct, violation of law or breach of its obligations under the Second Amended Agreement or certain other agreements between Arena GmbH and Eisai were the sole and direct cause of the product liability claim.

### *Ildong BELVIQ Collaboration: South Korea*

In November 2012, Arena GmbH entered into a Marketing and Supply Agreement with Ildong for BELVIQ. Under the agreement, we granted Ildong exclusive rights to commercialize BELVIQ in South Korea for weight loss or weight management in obese and overweight patients, subject to regulatory approval of BELVIQ by the South Korean Ministry of Food and Drug Safety, or MFDS.

Under the agreement, we received an upfront payment of \$5.0 million, and will receive an additional \$3.0 million upon the approval of BELVIQ by the MFDS. Ildong is responsible for the development, regulatory approval and, ultimately, commercialization of BELVIQ in South Korea for weight loss or weight management in obese and overweight patients, including related costs and expenses. We will manufacture BELVIQ at our facility in Switzerland, and sell BELVIQ to Ildong for a purchase price starting at 35% of Ildong's annual net product sales. The purchase price will increase on a tiered basis up to 45% on the portion of annual net product sales exceeding \$15.0 million. If certain annual net product sales amounts are not met, we can convert Ildong's right to commercialize BELVIQ in South Korea to be non-exclusive.

Ildong has agreed not to conduct activities outside of our agreement related to the approval or commercialization of any other pharmaceutical product for weight loss, weight management or obesity in South Korea. We have agreed

## **Table of Contents**

not to conduct activities outside of our agreement related to the commercialization in South Korea of any pharmaceutical product containing BELVIQ intended for end use in weight loss or weight management in obese and overweight patients.

Ildong will indemnify us for losses resulting from certain third-party claims, including for (a) Ildong's negligence, willful misconduct or violation of law, (b) Ildong's breach of the marketing and supply agreement or related agreements, (c) certain uses or misuses of BELVIQ (including any product liability claim and other claims relating to sales or development of BELVIQ in South Korea), (d) certain governmental investigations of Ildong related to BELVIQ, and (e) infringement relating to Ildong's use of trademarks related to BELVIQ. Arena GmbH will indemnify Ildong for losses resulting from certain third-party claims, including for (i) Arena GmbH's negligence, willful misconduct or violation of law, and (ii) Arena GmbH's breach of the marketing and supply agreement or related agreements.

Unless terminated earlier, the agreement with Ildong will continue in effect until the later of the expiration of all issued patents relating to BELVIQ in South Korea and 12 years after the first commercial sale of BELVIQ in South Korea. Either party has the right to terminate the agreement early in certain circumstances, including (a) if the other party is in material breach, (b) for certain commercialization concerns, and (c) for certain intellectual property concerns. Ildong also has the right to terminate the agreement early in certain circumstances, including if we notify Ildong that Ildong's right to commercialize BELVIQ in South Korea will become non-exclusive.

### *CYB BELVIQ Collaboration: Taiwan*

In July 2013, Arena GmbH entered into an exclusive marketing and supply agreement with CYB for BELVIQ in Taiwan. Under the agreement, we granted CYB the rights to market and distribute BELVIQ in Taiwan for weight loss or weight management in obese and overweight patients, subject to regulatory approval of BELVIQ by the Taiwan Food and Drug Administration, or TFDA.

We will manufacture BELVIQ at our facility in Switzerland, and sell finished product to CYB for a purchase price at 45% of CYB's annual net product sales. In addition, we received from CYB a net upfront payment of \$2.0 million, and are eligible to receive purchase price adjustment payments based on CYB's annual net product sales, as well as a milestone payment upon approval of the first additional indication for BELVIQ by the TFDA. CYB is responsible for the development, regulatory approval and, ultimately, marketing and distribution of BELVIQ in Taiwan, including related costs and expenses.

### *Additional Development of BELVIQ*

#### *Smoking Cessation*

We plan to initiate a Phase 2 clinical trial in the first half of 2014 to evaluate the potential of BELVIQ as a drug candidate for smoking cessation. We expect to enroll approximately 600 patients in this 12-week trial.

#### *Extended Release Once-Daily Formulation*

We have completed an initial study to evaluate the safety, tolerability and pharmacokinetic properties of different formulations of BELVIQ 20 mg extended release tablets, and selected a once-daily formulation for further development.

#### *Co-Administration with Phentermine*

In November 2013, Eisai initiated dosing in a pilot study of 12-week duration to preliminarily assess as the primary endpoint the safety of BELVIQ and phentermine when co-administered. This randomized, double-blind and parallel-group study will enroll approximately 225 overweight and obese adults. Patients will be randomized



**Table of Contents**

to one of three treatment arms in a 1:1:1 ratio, and will receive BELVIQ 10 mg twice daily, BELVIQ 10 mg twice daily in combination with phentermine 15 mg twice daily, or BELVIQ 10 mg twice daily in combination with phentermine 15 mg once daily.

Prior to initiating the 12-week pilot study, we completed a small pharmacokinetic study of single doses of BELVIQ 10 mg and phentermine 15 mg when administered in combination.

**BELVIQ Pre-Approval Development****BELVIQ Phase 3 Clinical Development**

The three trials included in our BELVIQ Phase 3 development program are summarized in the table below.

	<b>BLOOM<sup>1</sup></b>	<b>BLOSSOM<sup>2</sup></b>	<b>BLOOM-DM<sup>3</sup></b>
<b>Number of patients</b>	3,182	4,008	604
<b>Treatment groups</b>	Placebo, BELVIQ 10 mg BID	Placebo, BELVIQ 10 mg once daily, or QD, BELVIQ 10 mg BID	Placebo, BELVIQ 10 mg QD, BELVIQ 10 mg BID
<b>Patient demographics</b>	BMI <sup>3</sup> 30, or <sup>3</sup> 27 with co-morbid condition(s); average BMI of 36.2 and baseline weight of 220 pounds Average age 44 84% women Caucasian (67%) African-American (19%) Hispanic (12%)	BMI <sup>3</sup> 30, or <sup>3</sup> 27 with co-morbid condition(s); average BMI of 35.9 and baseline weight of 220 pounds Average age 44 80% women Caucasian (67%) African-American (20%) Hispanic (11%)	BMI <sup>3</sup> 27; type 2 diabetes mellitus; average BMI of 36.0 and baseline weight of 228 pounds Average age 53 54% women Caucasian (61%) African-American (21%) Hispanic (14%)
<b>Duration</b>	2 years	1 year	1 year
<b>Echocardiographic monitoring</b>	Screening, every 6 months, post-baseline	Baseline, every 6 months, post-baseline	Baseline, every 6 months, post-baseline
<b>First patient enrolled</b>	November 2006	January 2008	December 2007
<b>Last patient completed</b>	February 2009	July 2009	June 2010
<b>New Drug Application submission</b>	Original NDA 2009	Original NDA 2009	NDA resubmission 2011
<b>Location</b>	USA	USA	USA

(1) BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management)

(2) BLOSSOM (Behavioral modification and Lorcaserin Second Study for Obesity Management)

(3) BLOOM-DM (Behavioral modification and Lorcaserin for Overweight and Obesity Management in Diabetes Mellitus)

The Phase 3 trials shared the same ordered primary efficacy endpoints: 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 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 each of the trials.

## Table of Contents

In addition to routine safety monitoring, each study included echocardiographic monitoring for valvular regurgitation and pulmonary artery pressure. 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. For regulatory assessment of potential drug effects on heart valves, the FDA defined 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.

Among the pooled population enrolled in BLOOM and BLOSSOM, 22% had hypertension, 30% had dyslipidemia, 25% had impaired fasting glucose and approximately 8% reported a history of depression. In BLOOM-DM, all patients on BELVIQ 10 mg BID had type 2 diabetes, 61% had hypertension and approximately 6% reported a history of depression.

### Patient Disposition

**BLOOM.** The Week 52 completion rate was higher for patients on BELVIQ (54.9%) compared to patients on placebo (45.1%). Discontinuation rates for adverse events were 7.1% vs. 6.7% in the BELVIQ and placebo groups, respectively, for Year 1 and approximately 3.0% for each group in Year 2.

**BLOSSOM.** The Week 52 completion rate was higher for patients on BELVIQ 10 mg BID (57.2%) and 10 mg QD (59.0%) compared to patients on placebo (52.0%). Discontinuation rates for adverse events were 7.2%, 6.2% and 4.6% in the BELVIQ 10 mg BID, BELVIQ 10 mg QD and placebo groups, respectively.

**BLOOM-DM.** The Week 52 completion rate was higher for patients on BELVIQ 10 mg BID (66.0%) compared to patients on placebo (62.1%). Discontinuation rates for adverse events were 8.6% and 4.3% in the BELVIQ 10 mg BID and placebo groups, respectively.

### BELVIQ Phase 3 Results

#### Efficacy

In each of the Phase 3 trials, BELVIQ 10 mg BID was superior to placebo for each of the ordered primary endpoints using a modified intent-to-treat population with last observation carried forward imputation for missing values, or ITT-LOCF, analysis, as summarized in the table below. Patients who completed one year of study participation experienced significantly greater efficacy according to each of the three co-primary endpoints.

	BLOOM		BLOSSOM		BLOOM-DM	
	Placebo	BELVIQ 10 BID	Placebo	BELVIQ 10 BID	Placebo	BELVIQ 10 BID
<b>ITT/LOCF</b>						
% Losing <sup>3</sup> 5% weight	20.3%	47.5%	25.0%	47.2%	16.1%	37.5%
Mean weight change (%)	2.2%	5.8%	2.8%	5.9%	1.5%	4.5%
% Losing <sup>3</sup> 10% weight	7.7%	22.6%	9.7%	22.6%	4.4%	16.3%
<b>Per Protocol/Completers*</b>						
% Losing <sup>3</sup> 5% weight	32.1%	66.4%	34.9%	63.2%	17.9%	44.6%
Mean weight change (%)	3.4%	8.2%	3.9%	7.9%	1.7%	5.5%
% Losing <sup>3</sup> 10% weight	13.6%	36.2%	16.1%	35.1%	5.8%	20.8%

\* These results are reported for the per protocol populations in BLOOM and BLOSSOM, and for the completers population in BLOOM-DM. The particular statistical analysis reported for each trial was pre-specified in the statistical analysis plan for that trial.

At the end of Year 2 of BLOOM, significantly more patients who took BELVIQ for two years maintained at least 5% weight loss achieved in Year 1 than did patients who took BELVIQ during Year 1 and were changed to placebo for Year 2.

**Table of Contents**

BELVIQ demonstrated similar effects on secondary efficacy variables in BLOOM and BLOSSOM. A pooled analysis of changes from baseline to Week 52 showed significant improvements relative to placebo in waist circumference, BMI, total cholesterol, LDL cholesterol, HDL cholesterol, triglycerides, systolic blood pressure, diastolic blood pressure and heart rate. In BLOOM, significant improvements relative to placebo were also observed for hsCRP, fasting insulin and HOMA-IR (a measure of insulin resistance); these variables were not assessed in BLOSSOM. In BLOSSOM, BELVIQ significantly decreased body fat content relative to placebo; this variable was not assessed in BLOOM. In BLOOM-DM, which included only patients with type 2 diabetes, significant improvements with respect to patients on BELVIQ 10 mg BID relative to those on placebo occurred in HbA1c (-0.9% and -0.4%, respectively) and fasting glucose (-27.4 mg/dL and -11.9 mg/dL, respectively).

At baseline in BLOOM-DM, approximately 90% of patients were taking metformin and approximately 50% of patients were taking sulfonylureas with or without metformin. Weight loss and reductions in HbA1c and fasting plasma glucose were greater with BELVIQ treatment compared to placebo whether patients were treated with metformin or sulfonylureas. Fewer patients on BELVIQ 10 mg BID compared to placebo (13.3% vs. 21.8%, respectively) increased and more patients on BELVIQ 10 mg BID compared to placebo (16.8% vs. 11.5%, respectively) decreased use of anti-diabetic medication during the trial.

**Safety and Tolerability Profile*****BLOOM and BLOSSOM Pooled Analysis***

Under the BLOOM and BLOSSOM pooled analysis, the most common adverse events reported in Year 1 and their incidences for BELVIQ 10 mg BID and placebo patients, respectively, were as follows: headache (16.8% vs. 10.1%), dizziness (8.5% vs. 3.8%), fatigue (7.2% vs. 3.6%), nausea (8.3% vs. 5.3%), dry mouth (5.3% vs. 2.3%) and constipation (5.8% vs. 3.9%). Adverse events of depression, anxiety and suicidal ideation were infrequent and were reported by a similar proportion of each treatment group.

***BLOOM-DM***

In BLOOM-DM, the most common adverse events reported and their incidences for BELVIQ 10 mg BID and placebo patients, respectively, were as follows: hypoglycemia (biochemical, symptomatic or asymptomatic) (29.3% vs. 21.0%), headache (14.5% vs. 7.1%), back pain (11.7% vs. 7.9%), cough (8.2% vs. 4.4%) and fatigue (7.4% vs. 4.0%). Adverse events of depression, anxiety and suicidal ideation were infrequent and were reported by a similar proportion of each treatment group.

**Echocardiographic Analysis**

Echocardiograms were evaluated to assess whether there was an association between BELVIQ and valvular insufficiency. Incidences of new FDA-defined valvulopathy were as follows for BELVIQ 10 mg BID and placebo:

	Dose	Week 24	Week 52	Week 104
<b>BLOOM</b>	BELVIQ 10 mg BID	2.1%	2.7%	2.6%
	Placebo	1.9%	2.3%	2.7%
<b>BLOSSOM</b>	BELVIQ 10 mg BID	2.3%	2.0%	
	Placebo	1.8%	2.0%	
<b>BLOOM-DM</b>	BELVIQ 10 mg BID	2.5%	2.9%	
	Placebo	1.9%	0.5%	
<b>Pooled analysis</b>	BELVIQ 10 mg BID	2.20%	2.37%	
	Placebo	1.88%	2.04%	

***BELVIQ Prior Clinical Development***

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

---

**Table of Contents**

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. Significant weight loss was observed in both Phase 2 clinical trials. The most common adverse events occurring in the Phase 2a and Phase 2b clinical trials included headache, nausea and dizziness.

Our Phase 1 clinical trials included a three-part Phase 1a clinical trial of BELVIQ that established a maximum tolerated dose for the drug candidate and a multiple-dose Phase 1b clinical trial of BELVIQ in obese volunteers. 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 QD dose in the Phase 1a trial, a dose that resulted in euphoria and other central nervous system, or CNS, adverse effects. In each of the Phase 1a and 1b trials, serial echocardiograms supported further development of BELVIQ.

*BELVIQ Intellectual Property*

As of February 17, 2014, we owned issued patents that cover compositions of matter for the BELVIQ new chemical entity and related compounds and methods of treatment utilizing BELVIQ and related compounds in 69 jurisdictions, including the United States, Japan, Germany, France, China, Italy, Spain, Canada, the United Kingdom, Russia, Australia, India, and South Korea, and had applications pending in two other jurisdictions, of which the one with the largest pharmaceutical market was Brazil. Based on sales statistics provided by IMS Health, the jurisdictions where BELVIQ patents have been issued accounted for more than 93% of global pharmaceutical sales in 2011, while other jurisdictions where BELVIQ patents remain pending accounted for more than 2% of global pharmaceutical sales in that same year. The patents on BELVIQ issued by the US Patent and Trademark Office have serial numbers US 6,953,787; US 7,514,422; US 7,977,329; US 8,207,158; US 8,273,734; US 8,575,149; and US 8,546,379, while the corresponding patent granted by the European Patent Office has serial number EP 1 411 881 B9. Other of our BELVIQ issued patents and patent applications, including those directed to the HCl salt of BELVIQ (e.g., US 8,367,657), the hemihydrate of the HCl salt of BELVIQ as well as its crystalline forms (e.g., US 8,168,624 and EP 1 838 677 B1), and synthetic routes and intermediates useful in the manufacturing of BELVIQ, are all present in a lesser number of commercially important jurisdictions. The earliest priority date for the patents on BELVIQ 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. With respect to the United States, we have filed applications for patent extension, which, if granted, will extend the patent term for one of our BELVIQ composition of matter patents into 2026 and potentially into 2027.

As of February 17, 2014, we owned registered trademarks on the use of the name BELVIQ in Class 5 for the sale and marketing of pharmaceutical preparations for weight management, weight loss, the treatment of obesity and the maintenance of weight loss in 101 jurisdictions, including the United States, Japan, Germany, France, China, Italy, Spain, the United Kingdom, Russia, Australia and South Korea, and had trademark applications pending in 42 other jurisdictions, of which the three with the largest pharmaceutical markets were Canada, Brazil and India. The trademark on the name BELVIQ registered by the US Patent and Trademark Office has serial number US 4,080,253, while the corresponding trademark registered by the European Union's Office for Harmonization in the Internal Market has serial number CTM 010224905. Other of our BELVIQ registered trademarks and trademark applications, including those in classes 9, 16, 41 and 44 for downloadable publications, publications, educational services and medical services, respectively, directed to weight management, weight loss and the maintenance of weight loss are all present in a lesser number of commercially important jurisdictions. As of February 17, 2014, we have also filed trademark applications in Class 5 on one or more transliterations of the name BELVIQ in the local character set or alphabet of 24 jurisdictions, including Japan, China, Russia and South Korea.

## **Table of Contents**

### *APD811 Program*

APD811, an orally available agonist of the prostacyclin, or IP, receptor, is an internally discovered investigational drug candidate intended for the treatment of pulmonary arterial hypertension, or PAH. We are planning to initiate a Phase 2 clinical trial of APD811 in the first half of 2014.

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 limit physical activity, result in heart failure and reduce life expectancy. Based on data from the Registry to Evaluate Early And Long-term PAH disease management (REVEAL) of patients in the United States, there is an estimated five-year survival rate of 57% from diagnosis.

Treatment with IP agonists, which can slow disease progression and improve exercise tolerance in PAH patients, is considered standard of care for advanced PAH. Currently available IP agonists belong to the prostanoid class of molecules, and the majority of these products need to be administered frequently or continuously through intravenous, subcutaneous or inhaled delivery methods. We believe that an orally available, non-prostanoid IP agonist that provides clinical benefits similar to currently available IP agonists has the potential to improve the standard of care for PAH. APD811's oral bioavailability and approximately 20 to 26 hour half-life may provide advantages over other IP agonists, including improved receptor coverage given long half-life and the potential for once-daily oral dosing.

### *APD811 Development*

In October 2012, we initiated a multiple-dose, randomized, double-blind and placebo-controlled Phase 1 clinical trial evaluating multiple-ascending doses of APD811 in healthy volunteers. In this trial, 40 healthy volunteers received APD811 and 15 received placebo, and the safety profile of APD811 was characteristic of IP receptor agonists. One serious adverse event, transient atrial fibrillation, occurred in a single patient, and the study investigator considered it to be possibly treatment related, and the most frequent treatment-emergent adverse events were headache, nausea and jaw pain.

Prior to the multiple-dose clinical trial, in December 2010, we initiated a Phase 1 clinical trial to evaluate the safety, tolerability and pharmacokinetics of single-ascending doses of APD811. The randomized, double-blind and placebo-controlled trial evaluated 32 healthy volunteers in four cohorts of eight participants each, with six randomized to APD811 and two to placebo. APD811 was rapidly absorbed and demonstrated dose-proportional pharmacokinetic exposure over the tested dose range. Consistent with the expected pharmacology of APD811, the most common adverse events were headache, vomiting, nausea, jaw pain and flushing.

### *APD811 Intellectual Property*

As of February 17, 2014, we owned pending patent applications and patents covering compositions of matter for APD811 and related compounds and methods of treatment utilizing APD811 and related compounds, synthetic routes and intermediates useful in the manufacturing of APD811, and various solid state forms of APD811 filed in 19 jurisdictions, including the United States, Europe, Japan, China, Canada, Brazil, Russia, Australia, India, and South Korea. Based on sales statistics provided by IMS Health, the jurisdictions where APD811 patents have been filed accounted for more than 95% of global pharmaceutical sales in 2011. The earliest priority date for the patents on APD811 is 2008. The terms of any patents that may issue from these patent applications should be capable of continuing into 2029 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 later filed patent applications.

## **Table of Contents**

### ***Temanogrel Program***

Temanogrel, an orally available inverse agonist of the serotonin 2A receptor, is an internally discovered investigational drug candidate intended for the treatment of thrombotic diseases. We believe temanogrel has the potential to inhibit serotonin-mediated platelet aggregation and vasoconstriction. Temanogrel's dual mechanism may be therapeutically useful for the treatment or prevention of thrombotic diseases.

Thrombosis is the formation of a clot, or thrombus, inside a blood vessel. Thrombus formation that occurs in the arteries leading to the heart or brain can lead to serious thrombotic diseases including myocardial infarction, acute coronary syndrome and stroke. One of the initial events in thrombus formation is the activation of platelets, which then aggregate and adhere to one another as they release certain factors, including high concentrations of serotonin. Serotonin promotes further platelet aggregation and also causes constriction, or narrowing, of the blood vessels. Elevated serotonin levels have been associated with increased cardiovascular risk. The prothrombotic effects of serotonin on platelets and blood vessels are mediated by the serotonin 2A receptor, and inverse agonists of the serotonin 2A receptor have the potential to inhibit this activity.

As described below, temanogrel has completed single- and multiple-ascending dose Phase 1 trials in healthy volunteers. Under our Co-Development and License Agreement, Ildong will be responsible for funding and conducting the next two planned clinical trials in this program: an additional Phase 1 trial in healthy volunteers and a Phase 2a proof-of-concept trial in patients. We expect Ildong to initiate a Phase 1 trial in the first quarter of 2014 to evaluate the safety of co-administration of temanogrel with aspirin and clopidogrel.

### ***Temanogrel Development***

In July 2007, we initiated a randomized, double-blind, placebo-controlled, single-ascending dose Phase 1a clinical trial evaluating temanogrel 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 this trial, a maximum tolerated dose could not be defined despite achieving high concentrations in blood. Temanogrel 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 temanogrel and establishing initial clinical validation for temanogrel's novel mechanism of action.

The Phase 1b clinical 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 temanogrel over a period of one week. Total daily doses ranged from 15 mg to 80 mg. Temanogrel 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 temanogrel 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 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.

### ***Ildong Temanogrel Collaboration***

In November 2012, we entered into a Co-Development and License Agreement with Ildong for temanogrel. Under the agreement, we granted Ildong exclusive rights to commercialize temanogrel in South Korea for myocardial infarction, acute coronary syndrome, stroke, peripheral artery disease and other cardiovascular diseases, subject to further development and regulatory approval of temanogrel. Initially, Ildong will be responsible for funding and conducting, under the direction of a joint steering committee, the next two planned clinical trials in this program: an additional Phase 1 trial in healthy volunteers and a Phase 2a proof-of-concept trial in patients.

## **Table of Contents**

We will maintain ownership of temanogrel outside of South Korea, and have the rights to use data generated by Ildong for the development and potential commercialization of temanogrel outside of South Korea by us or other Arena licensees. In addition, Ildong has agreed to pay us a \$2.0 million development milestone if the planned additional Phase 1 and Phase 2a clinical trials conducted by Ildong support continued development and we or another Arena licensee initiates a Phase 2b clinical trial of temanogrel. We are also eligible to receive a royalty on net product sales of temanogrel in South Korea, while Ildong is eligible to receive a share of future payments received by us related to licensing transactions and sales of temanogrel in other territories.

Ildong will indemnify us for losses resulting from certain third-party claims, including for (a) Ildong's negligence, willful misconduct or violation of law, (b) Ildong's breach of the agreement, (c) certain uses or misuses of temanogrel (including any product liability claim and other claims relating to sales or development of temanogrel in South Korea), and (d) certain governmental investigations of Ildong related to temanogrel. We will indemnify Ildong for losses resulting from certain third-party claims, including for (i) our negligence, willful misconduct or violation of law, and (ii) our breach of the agreement.

Unless terminated earlier or extended, the agreement will continue in effect until the later of the expiration of all issued patents relating to temanogrel in South Korea and 10 years after the first commercial sale of temanogrel in South Korea. Either party has the right to terminate the agreement early in certain circumstances, including (a) if the other party is in material breach, (b) for certain commercialization concerns, and (c) for certain intellectual property concerns.

### *Temanogrel Intellectual Property*

As of February 17, 2014, we owned issued patents that cover compositions of matter for temanogrel and related compounds and methods of treatment utilizing temanogrel and related compounds in 83 jurisdictions, including the United States, Japan, Germany, France, China, Canada, Italy, Spain, the United Kingdom, Russia, Australia, and South Korea, and had applications pending in 17 other jurisdictions, of which the largest pharmaceutical markets were Brazil and India. Based on sales statistics provided by IMS Health, the jurisdictions where temanogrel patents have been issued accounted for more than 92% of global pharmaceutical sales in 2011, while other jurisdictions where temanogrel patents remain pending accounted for more than 6% of global pharmaceutical sales in that same year. The patent on temanogrel issued by the US Patent and Trademark Office has serial number US 7,884,101, while the corresponding patent granted by the European Patent Office has serial number EP 1 833 799 B1. Other of our temanogrel issued patents and patent applications, including those directed to the temanogrel HCl salt as well as its crystalline forms, synthetic routes and intermediates useful in the manufacturing of temanogrel, and the active metabolites of temanogrel have all been filed in a lesser number of commercially important jurisdictions. The earliest priority date for the patents on temanogrel is 2004. The terms of these patents are capable of continuing into 2025 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.

### *APD334 Program*

APD334, an orally available agonist of the S1P<sub>1</sub> receptor, is an internally discovered investigational drug candidate intended for the potential treatment of a number of conditions related to autoimmune diseases, including multiple sclerosis, psoriasis and rheumatoid arthritis. S1P<sub>1</sub> receptors have been demonstrated to be involved in the modulation of several biological responses, including lymphocyte trafficking from lymph nodes to the peripheral blood. By isolating lymphocytes in lymph nodes, fewer immune cells are available in the circulating blood to effect tissue damage. We have optimized APD334 as a potent and selective small molecule S1P<sub>1</sub> receptor agonist that reduces the severity of disease in preclinical autoimmune disease models. We have completed a Phase 1 single-ascending dose trial, as described below, and we plan to initiate a Phase 1 multiple-ascending dose trial of APD334 in 2014.

## **Table of Contents**

### *APD334 Development*

We have completed a Phase 1 single-ascending dose clinical trial of APD334. This randomized, double-blind and placebo-controlled trial evaluated the safety, tolerability and pharmacokinetics of single-ascending doses of APD334 in 40 healthy adult volunteers. In the trial, APD334 demonstrated favorable pharmacokinetic and pharmacodynamic effects, a dose-responsive reduction in blood lymphocyte count, and a slowing of heart rate (bradycardia) that appears comparable to other S1P<sub>1</sub> agonists. The terminal half-life was approximately 35 hours.

### *APD334 Intellectual Property*

As of February 17, 2014, we owned issued patents that cover compositions of matter for APD334 and related compounds, methods of treatment utilizing APD334 and related compounds, and various salts of APD334 and crystalline forms thereof in 5 jurisdictions, including the United States and Japan, and had applications pending in 11 other jurisdictions, of which the largest pharmaceutical markets were Europe, China, Canada, Brazil, Russia, Australia, India, and South Korea. Based on sales statistics provided by IMS Health, the jurisdictions where APD334 patents have been issued accounted for more than 50% of global pharmaceutical sales in 2011, while other jurisdictions where APD334 patents remain pending accounted for more than 44% of global pharmaceutical sales in that same year. The patent on APD334 issued by the US Patent and Trademark Office has serial number US 8,580,841. Other of our APD334 pending patent applications, including those directed to synthetic routes and intermediates useful in the manufacturing of APD334 have all been filed in a lesser number of commercially important jurisdictions. The earliest priority date for the patents on APD334 is 2008. The terms of any patents that may issue from these patent applications should be capable of continuing into 2029 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.

### *APD371 Program*

APD371, an orally available agonist of the CB2 receptor, is an internally discovered investigational drug candidate intended for the treatment of pain. Currently available CB receptor agonists have been limited in utility by the psychotropic effects associated with the activation of the CB1, but not CB2, receptor subtype. We have identified several novel, potent, CB2-selective, lead compounds that are intended to retain the analgesic activity of the 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.

In December 2013, we initiated dosing in a randomized, double-blind and placebo-controlled Phase 1 trial to evaluate the safety, tolerability and pharmacokinetics of single-ascending doses of APD371 in up to 56 healthy adult volunteers.

### *APD371 Intellectual Property*

As of February 17, 2014, we owned pending patent applications and patents covering compositions of matter for APD371 and related compounds and methods of treatment utilizing APD371 and related compounds, synthetic routes and intermediates useful in the manufacturing of APD371, and various solid state forms of APD371 filed in 23 jurisdictions, including the United States, Europe, Japan, China, Canada, Brazil, Russia, Australia, India, and South Korea. Based on sales statistics provided by IMS Health, the jurisdictions where APD371 patents have been filed accounted for more than 96% of global pharmaceutical sales in 2011. Other of our APD371 patent applications, including those directed methods useful in the manufacturing of APD371 and various solid state forms of APD371 have all been filed in a similar number of commercially important jurisdictions. The earliest priority date for the patents on APD371 is 2009. The terms of any patents that may issue from these patent applications should be capable of continuing into 2030 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 later filed patent applications.



## **Table of Contents**

### **Other Research and Development Programs**

We are continuing our efforts to discover and develop additional novel compounds that target GPCRs to address unmet medical needs, including programs that are in the early research stage. The extent we devote research and development efforts to these programs will depend on our available resources and prioritization decisions.

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

Our drug candidates have resulted from our validated 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: (a) eliminating the need to identify the native ligand for an orphan receptor; (b) enhancing the detection of, and allowing us to simultaneously identify, both receptor inhibitor and receptor activator drug leads; (c) allowing for the identification of drug leads that inhibit both ligand-independent and ligand-dependent activity; and (d) providing the ability to discover novel and improved therapeutics directed at known receptors.

### **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.

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. In addition, we regularly review our patent portfolio to identify patents and patent applications for potential abandonment that we deem to have relatively low value to our ongoing business operations. 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. 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. Because any marketing and 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, patent term extensions are available for certain delays in either patent office proceedings or marketing and regulatory approval processes. Under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, the term of a patent that covers an FDA-approved drug may also be eligible for patent term extension, or PTE. PTE permits patent term restoration of a US patent as

## **Table of Contents**

compensation for the patent term lost during product development and the FDA regulatory review process. The Hatch-Waxman Act permits a PTE of up to five years beyond the expiration of the patent. This period is generally one-half the time between the effective date of an Investigational New Drug, or IND (falling after issuance of the patent), and the submission date of a New Drug Application, or NDA, plus the time between the submission date of an NDA and the approval of that application, provided the sponsor acted with diligence. A PTE cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. The application for PTE is subject to approval by the US Patent and Trademark Office in conjunction with the FDA. We believe it currently takes about two years to obtain approval of the application for PTE.

Outside of the United States, similar provisions may be available in the European Union, Japan, South Korea and some other jurisdictions to extend the term of a patent that covers an approved drug. The length of any such extension would vary by country. Our European patents may be eligible for supplemental protection certificates of up to five years in one or more countries.

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 with drugs or drug candidates that do or may compete with BELVIQ or 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 and development 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 BELVIQ include Hoffmann-La Roche Inc., the US prescription drug unit of the Roche Group, which markets with Genentech USA, Inc., orlistat under the brand name Xenical, GlaxoSmithKline Consumer Healthcare which markets an over-the-counter low-dose version of orlistat in the United States under the brand name alli, and VIVUS Inc., which markets a combination of phentermine and topiramate under the brand name Qsymia. Another competitor is phentermine, which is a generic drug sold by a number of companies. Prescribers may also prescribe other drugs, including in combination or off label, that

## **Table of Contents**

would compete with BELVIQ. We also face competition from other approaches for weight loss, including behavior modification (such as diet and exercise), surgical approaches (such as gastric bypass surgery and gastric banding), and herbal or other supplements.

There are also potentially competing drug candidates and other approaches for weight loss being developed by various pharmaceutical and medical device companies and other entities. For example, Orexigen Therapeutics, Inc., announced that it submitted applications for EU and US regulatory approval of its drug candidate for a similar indication in October and December 2013, respectively. In addition, Novo Nordisk announced that it submitted applications in December 2013 for US and EU regulatory approval of its drug currently approval for patients with type 2 diabetes for the treatment of obesity. Some programs in discovery, preclinical or other stages of development may include serotonin 2C programs.

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 therapeutic products or drug discovery techniques, or to adapt more readily to technological advances than we can. Accordingly, our competitors may succeed in obtaining patent protection, receiving regulatory 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**

We and our collaborators are subject to significant governmental regulation. The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the preclinical and 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, tracking, recordkeeping, advertising, pricing and promotion of drug candidates and commercialized drugs. Failure to comply with applicable FDA or other regulatory requirements may result in inspectional notices of violation, warning letters, civil or criminal penalties, suspension or delays in clinical development, recall or seizure of products, partial or total suspension of production, withdrawal of a product from the market or other negative consequences.

*In the United States.* In the United States, the FDA regulates drug products under the Federal Food, Drug, and Cosmetic Act, or FD&C Act, 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;

## Table of Contents

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 adequate and well-controlled human clinical trials, generally accompanied by payment of a substantial user fee to the FDA;

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 cGMP, 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 may be subject to review and potential scheduling by the DEA.

In cases where a drug will not be approved based on the information provided in the NDA, the FDA will issue a CRL outlining the deficiencies in the application to which the sponsor must provide a complete response for the application to be further considered.

The development and approval process requires substantial expertise, 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.

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 IND to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA institutes a clinical hold within the 30-day time period because of 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 volunteers, 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.

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

*Phase 3 Clinical Trials.* These are commonly referred to as pivotal studies or adequate and well-controlled studies. When Phase 2 evaluations demonstrate that a dose range of the product is effective and has an

---

**Table of Contents**

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 chemistry, manufacturing and control, or CMC, information. An NDA is usually accompanied by a significant user fee. Once the submission has been accepted for filing, the FDA's goal is to review applications within 10 months from its acceptance of the filing or, if the application relates to an unmet medical need in a serious or life-threatening indication, 6 months from its acceptance of the filing. The review process can be significantly extended by FDA requests for additional information or clarification. The FDA may refer the application to a preestablished 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 Complete Response Letter, or 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 may limit the labeling, distribution or promotion of a drug 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 postmarketing programs or other information.

*Other US 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 inspections (which may be unannounced) by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including current Good Manufacturing Practice, or cGMPs, regulations, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Following such inspections, the FDA may issue notices on Form FDA 483 and warning letters that could cause us to modify certain activities. A Form FDA 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. 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 FDA 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 or criminal penalties.

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 their approved indications and in accordance with the provisions of the approved label. Further, modifications to the drug may require us to develop additional data or conduct additional preclinical studies and clinical trials and we may be required to submit and obtain FDA approval of a new or supplemental NDA,

## **Table of Contents**

including changes in indications, labeling, or manufacturing processes or facilities. Failure to comply with these requirements can subject a manufacturer to possible legal or regulatory action, such as warning letters, corrective advertising, suspension of manufacturing, seizure of product, injunctive action or 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, if in their professional medical judgment the physicians deem such use to be appropriate. Such off-label uses are common across certain medical specialties. 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.

To distribute products commercially, we or our collaborators, as applicable, must comply with state laws that require the registration of manufacturers and wholesale distributors of pharmaceutical products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution.

*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 based on an evaluation of its abuse potential, and scheduling by the DEA is a separate process that may delay the commercial launch of a drug even after FDA approval of the NDA. Companies with a scheduled drug are subject to periodic and ongoing inspections by the DEA and similar state drug enforcement authorities to assess 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.

*Outside of the United States.* Outside of the United States, the ability to market a product is contingent upon obtaining marketing authorization from the appropriate regulatory authorities. The requirements governing marketing authorization, pricing and reimbursement vary widely from country to country.

*Hatch-Waxman Exclusivity and Patent Term Extension.* Market exclusivity provisions of the Hatch-Waxman Act can delay the submission or approval of applications seeking to rely upon the FDA's findings of safety and effectiveness for a previously approved NDA. A new chemical entity subject to an NDA, such as BELVIQ, is entitled to a five-year period of non-patent marketing exclusivity in the United States. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, such an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement of patents listed with the FDA by the NDA holder. The Hatch-Waxman Act also provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA, if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active ingredient. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

## **Table of Contents**

*Drug Product Manufacturing.* 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 Heilmittelinспекtorat der Nordostschweiz, Basel, Switzerland), acting on behalf of Swissmedic, which issued GMP and production licenses to Arena GmbH for the production of drugs. The FDA conducted a PAI of this facility in July 2010, which resulted in No Actions Indicated, and classified this facility as acceptable. Consistent with FDA practice, we expect a routine FDA inspection in the 2014/2015 timeframe.

*Prescription Drug Reimbursement.* In the United States and markets in other countries, sales of prescription drug products depend in part on the availability of reimbursement from third-party payers. Third-party payers include government health administrative authorities, managed care organizations, private health insurers and other organizations. The process for determining whether a payer will provide coverage for a drug product may be separate from the process for setting the price or reimbursement rate that the payer will pay for the drug product. Third-party payers may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the FDA-approved drug products for a particular indication. Third-party payers are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies to demonstrate the cost-effectiveness of our products. A payer's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payers to reimburse all or part of the costs associated with their prescription drugs. Patients are less likely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Therefore, coverage and adequate reimbursement are important to new product acceptance.

If a drug is reimbursed by Medicare or Medicaid, pricing and rebate programs must comply with, as applicable, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 as well as the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veterans Health Care Act of 1992, or VHCA, each as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Under the VHCA, drug companies are required to offer certain drugs at a reduced price to a number of federal agencies including US Department of Veterans Affairs and US Department of Defense, the Public Health Service and certain private Public Health Service designated entities in order to participate in other federal funding programs including Medicare and Medicaid. Participation under the VHCA requires submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as well as the entry into government procurement contracts governed by the Federal Acquisition Regulations.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of drugs have been a focus in this effort. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on drug pricing. Coverage policies, third-party reimbursement rates and drug pricing regulation may change at any time. In particular, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively PPACA, was enacted in the United States in March 2010 and contains provisions that may reduce the profitability of drug products, including, for example, increased rebates for drugs sold to Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal healthcare programs. Even if favorable coverage and reimbursement status is attained for our products, less favorable coverage policies and reimbursement rates may be implemented in the future. In the case of BELVIQ, Medicare explicitly excludes coverage of drugs for weight loss.



## Table of Contents

In markets outside the United States, pricing of pharmaceutical products may be subject to governmental control. Evaluation criteria used by many government agencies for the purposes of pricing and reimbursement typically focus on a product's degree of innovation and its ability to meet a clinical need unfulfilled by currently available therapies. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular drug candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country. There can be no assurance that any country that has price controls or reimbursement limitations for drug products will allow favorable reimbursement and pricing arrangements for any of our products.

*Healthcare Fraud and Abuse.* Pharmaceutical companies are subject to various federal and state laws pertaining to healthcare fraud and abuse, including, but not limited to, anti-kickback and false claims laws. We have a commercial compliance program and have adopted the voluntary Code on Interactions with Healthcare Professionals, or PhRMA Code, promulgated by the Pharmaceutical Research and Manufacturers of America and revised in 2009. The PhRMA Code provides guidelines for interactions with respect to marketed products and related pre- and post-launch activities and reinforces the intention that industry interactions with healthcare professionals are professional exchanges designed to benefit patients and to enhance the practice of medicine.

The Federal Anti-Kickback Statute makes it illegal for any person or entity, including a prescription drug manufacturer, or a party acting on its behalf, to knowingly and willfully solicit, offer, receive or provide any remuneration, directly or indirectly, in exchange for, or to induce, the referral of business, including the purchase, order, lease of any good, facility, service or item, including the prescription of a particular drug, for which payment may be made under federal healthcare programs such as Medicare and Medicaid. Some of the state prohibitions are broader in scope and apply to referral of patients for healthcare services reimbursed by any source, not only the Medicare and Medicaid programs.

In the course of practicing medicine, physicians may legally prescribe FDA-approved drugs for an indication that has not been approved by the FDA and which, therefore, is not described in the product's approved labeling, so-called off-label use, if deemed appropriate in the physician's professional medical judgment. The FDA does not ordinarily regulate the behavior of physicians in their choice of treatments. The FDA and other government agencies do, however, restrict communications on the subject of off-label use by a manufacturer or those acting on behalf of a manufacturer. Companies may not promote FDA-approved drugs for off-label uses. The FDA and other governmental agencies do permit a manufacturer (and those acting on its behalf) to engage in some limited, non-misleading, non-promotional exchanges of scientific information regarding unapproved indications.

There are numerous federal false claims laws and civil monetary penalty laws that forbid, among other things, anyone from knowingly presenting, or causing to be presented for payment to third-party payers (including Medicare and Medicaid) claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed or claims for medically unnecessary items or services.

Violations of fraud and abuse laws may be punishable by criminal, civil and/or administrative sanctions, including individual imprisonment, disgorgement, criminal fines and civil monetary penalties, as well as possible exclusion from federal healthcare programs (including Medicare and Medicaid). In addition, under certain healthcare fraud and abuse laws, there is an ability for private individuals to bring similar actions. Additionally, many states have analogous fraud and abuse laws, some of which may be broader in scope. Further, there are an increasing number of state laws that require pharmaceutical companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, or register their sales representatives, as well as prohibiting certain other sales and marketing practices. Beginning August 1, 2013, a federal disclosure requirement will require certain

## **Table of Contents**

manufacturers (which are known as applicable manufacturers ) to track and report to the federal government information about certain payments made to US-licensed physicians and teaching hospitals. If applicable to a manufacturer, the law may affect operational activities by imposing administrative and compliance burdens to track and report certain payments. Additionally, recent federal legislation imposes additional obligations on certain pharmaceutical manufacturers, among others, regarding drug product tracking and tracing.

Our activities are also potentially subject to federal and state consumer protection and unfair competition laws. We are also subject to the US Foreign Corrupt Practices Act, or the FCPA, which prohibits companies and individuals from engaging in specified activities to obtain or retain business or to influence a person working in an official capacity. Under the FCPA, it is illegal to pay, offer to pay, or authorize the payment of anything of value to any foreign government official, governmental staff members, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity.

*Healthcare Privacy and Security Laws.* Federal and state laws protect the confidentiality of certain health information, in particular, individually identifiable information, and restrict the use and disclosure of that information. At the federal level, the Department of Health and Human Services promulgated health information privacy and security rules under the Health Insurance Portability and Accountability Act of 1996, or HIPAA. In addition, many state laws apply to the use and disclosure of health information. We may be subject to, or our or our collaborators marketing activities may be limited by, HIPAA, and its implementing regulations, which established uniform standards for certain covered entities (healthcare providers, health plans and healthcare clearinghouses) governing the conduct of certain electronic healthcare transactions and protecting the security and privacy of protected health information. The American Recovery and Reinvestment Act of 2009, commonly referred to as the economic stimulus package, included sweeping expansion of HIPAA's privacy and security standards called the Health Information Technology for Economic and Clinical Health Act, or HITECH, which became effective on February 17, 2010. Among other things, the law makes HIPAA's privacy and security standards directly applicable to business associates, which are independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions.

## **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. We are using this facility to manufacture and package BELVIQ as well as certain drug products for Siegfried. From time to time, we may also use this facility to manufacture and package tablets and capsules for other of our programs.

All of our manufacturing services revenues are attributable to Siegfried, which is our only customer for such services. Our revenues of \$81.4 million for the year ended December 31, 2013, included \$2.7 million, or 3.3% of our total revenues, from Siegfried. Our revenues of \$27.6 million for the year ended December 31, 2012, included \$3.8 million, or 13.8%, of our total revenues, from Siegfried. Our revenues of \$12.7 million for the year ended December 31, 2011, included \$5.3 million, or 41.9%, of our total revenues, from Siegfried.

We purchase raw materials, starting materials, intermediates, API, excipients and other materials from commercial sources. To decrease the risk of an interruption to our supply, when we believe it is reasonable 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 commercial production, project timelines or inventory of supplies for our studies or clinical trials. However, currently we have only one or a limited number of suppliers for some of these materials for BELVIQ and for other of our programs. The loss of a primary source of supply

---

## **Table of Contents**

would potentially delay our production of BELVIQ or our development projects and potentially those of current or future collaborators. We intend to maintain a safety stock of certain of these materials to help avoid delays in production, but we do not know whether such stock will be sufficient. Our facility in Zofingen is the only manufacturer of finished drug product for BELVIQ. We intend to have a second source of supply for finished drug product of BELVIQ, but we believe that it could take two years or longer to secure another source.

Eisai is our only customer for commercial sales of BELVIQ. Eisai purchases BELVIQ from Arena GmbH, and is the exclusive distributor of BELVIQ in the United States, which is the only jurisdiction for which BELVIQ has received regulatory approval for marketing. Our revenues of \$81.4 million for the year ended December 31, 2013, included \$78.1 million, or 96.0% of our total revenues, from Eisai. Our revenues of \$27.6 million for the year ended December 31, 2012, included \$23.6 million, or 85.6%, of our total revenues, from Eisai. Our revenues of \$12.7 million for the year ended December 31, 2011, included \$6.8 million, or 53.2%, of our total revenues, from Eisai.

## **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, US Environmental Protection Agency, California Environmental Protection Agency, the Toxic Substances Control Act, the Resource Conservation and Recovery Act, the CSA 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, 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.

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.

---

## **Table of Contents**

### **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 for non-commercial products. Such expenses totaled \$66.5 million for the year ended December 31, 2013, \$54.1 million for the year ended December 31, 2012, and \$58.7 million for the year ended December 31, 2011. We include research and development sponsored by collaborators in our total research and development expenses. We estimate that such expenses totaled \$2.0 million, \$27,000 and \$3.3 million in 2013, 2012 and 2011, respectively.

### **Employees**

As of February 24, 2014, we had a total of 310 employees, including 254 in research, development and manufacturing and 56 in administration, which includes finance, legal, facilities, information technology and other general support areas.

### **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.**

#### **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.*

*BELVIQ® (pronounced BEL-VEEK ) is the trade name for the finished drug product containing the active pharmaceutical ingredient lorcaserin hydrochloride, or lorcaserin, that is marketed for chronic weight management in the United States. Lorcaserin may in the future be marketed in the United States or in other countries under a different trade name for chronic weight management. Lorcaserin may also be marketed under a different trade name for a different indication, in a different formulation or in combination with another drug. In this report, we use BELVIQ to refer to the finished drug product containing lorcaserin and/or, depending on the context, the active pharmaceutical ingredient lorcaserin, and without regard to the current or potential indication, formulation or combination.*

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

**Our prospects are highly dependent on the success of BELVIQ, our first and only FDA-approved drug. To the extent BELVIQ is not commercially successful, our business, financial condition and results of operations may be materially adversely affected and the price of our common stock may decline.**

Our prospects are highly dependent on the success of BELVIQ, which was approved for chronic weight management by the US Food and Drug Administration, or FDA, and is our first and only drug approved by any regulatory agency. We believe our prospects are highly dependent on, and a significant portion of the value of our company relates to, the successful commercialization of BELVIQ in the United States and potentially in additional territories. The marketing approval and successful commercialization of BELVIQ is subject to many

---

**Table of Contents**

risks, including the risks identified in other risk factors. As we have granted rights to commercialize BELVIQ to collaborators for most of the territories in the world, we are highly dependent on collaborators for obtaining marketing approval and commercializing BELVIQ. We do not know whether or when BELVIQ will be approved for sale or commercialized in any territories outside of the United States, and BELVIQ may not receive marketing approval from any other regulatory agency or be commercialized in any other territories. If the results or timing of regulatory filings, the regulatory process, regulatory developments, commercialization, clinical trials or preclinical studies, or other activities, actions or decisions related to BELVIQ do not meet our, your, analysts' or others' expectations, the market price of our common stock could decline significantly.

BELVIQ became available in June 2013 to patients in the United States by prescription, and is being marketed in the United States by Eisai under a marketing and supply agreement, among our wholly owned subsidiary, Arena Pharmaceuticals GmbH, or Arena GmbH, Eisai Inc., and Eisai Inc.'s parent company, Eisai Co., Ltd. (collectively with Eisai Inc., Eisai). The FDA approval of BELVIQ includes the following limitations of use: (i) the safety and efficacy of coadministration of BELVIQ with other products intended for weight loss including prescription drugs (e.g., phentermine), over-the-counter drugs, and herbal preparations have not been established, and (ii) the effect of BELVIQ on cardiovascular morbidity and mortality has not been established.

Under the marketing and supply agreement with Eisai, Arena GmbH also granted Eisai exclusive rights to market and distribute BELVIQ in all of other the countries in the world, except for South Korea, Taiwan, Australia, New Zealand and Israel. In addition, Arena GmbH has entered into marketing and supply agreements with Ildong Pharmaceutical Co., or Ildong, for South Korea and with CY Biotech Company Limited, or CYB, for Taiwan, granting them exclusive rights to market and distribute BELVIQ in the respective territories for weight loss or weight management in obese and overweight patients, subject to applicable regulatory approval. We refer collectively to all of these marketing and supply agreements as the BELVIQ Agreements.

We expect that revenues under the marketing and supply agreement with Eisai (and, to a lesser extent, the marketing and supply agreements with Ildong and CYB) will constitute the majority of our revenues over the next several years, and future payments to us under the BELVIQ Agreements will substantially depend on BELVIQ product sales and the achievement of milestones, and potentially on other BELVIQ products, if any. Each of the BELVIQ Agreements may be terminated early in certain circumstances, in which case we may not receive additional milestone or other payments under the terminated agreement. We cannot guarantee future BELVIQ product sales or achievement of any other milestones under the BELVIQ Agreements.

We and our collaborators have pending applications for regulatory approval for BELVIQ outside of the United States, and we expect our collaborators will seek regulatory approval for BELVIQ in additional territories in the future. There is no assurance that any pending or future regulatory applications will be approved. For example, we withdrew our Marketing Authorization Application, or MAA, for BELVIQ in the European Union, and we were notified that our MAA for BELVIQ in Switzerland would not be approved. We also plan to enter into marketing and supply agreements or similar arrangements with one or more pharmaceutical companies to commercialize BELVIQ in the territories not already under collaboration, but there is no assurance that we will be able to do so at all or on terms that you or others view as favorable.

In the United States, the degree of market acceptance and commercial success of BELVIQ, and our revenues, will depend on a number of factors, including the following, as well as risks identified in other risk factors:

the successful commercial introduction (or launch) of BELVIQ and growth of commercial sales;

the number of patients with the potential to use BELVIQ, the number of patients receiving BELVIQ treatment and the results achieved by such patients;

market acceptance of BELVIQ, which may depend on the public's view of BELVIQ, the timing and impact of current or new competition and BELVIQ's perceived advantages or disadvantages over alternative treatments (including relative convenience, ease of administration, and prevalence and severity of any adverse events, including any unexpected adverse events);

**Table of Contents**

the actual and perceived safety and efficacy of BELVIQ on both a short- and long-term basis among actual or potential patients, healthcare providers and others in the medical community, regulatory agencies and insurers and other payers, including related decisions by any such entity or individual;

incidence and severity of any side effects, including as a result of off-label use or in combination with one or more drugs;

new data relating to BELVIQ, including as a result of additional studies, trials or analyses of BELVIQ or related drugs or drug candidates (such as BELVIQ in combination with another drug or using another formulation);

physicians may not prescribe, and patients may not take, BELVIQ until at least results from our required postmarketing studies are available or other long-term efficacy and safety data exists;

the claims, limitations, warnings and other information in BELVIQ's current or future labeling;

the current or future scheduling designation for BELVIQ by the US Drug Enforcement Administration, or DEA;

Eisai's maintenance of an effective sales force, marketing team and strategy and medical affairs group and related functions, and its sales, marketing and other representatives accurately describing BELVIQ consistent with its approved labeling;

BELVIQ's commercial price (including discounting or other promotions) and perceived cost-effectiveness;

the placement of BELVIQ on third-party payer formularies, and the ability of patients and physicians and other providers to obtain and maintain adequate reimbursement, if any, by third-party payers, including government payers;

the ability and desire of group purchasing organizations, or GPOs, including distributors and other network providers, to sell BELVIQ to their constituencies;

introduction of counterfeit or unauthorized versions of BELVIQ;

the development of the market for weight-management medications;

to the extent BELVIQ is approved and marketed in a jurisdiction with a significantly lower price than in another jurisdiction, the impact of the lower pricing in the higher-priced territory, including on the pricing of reimbursement, if available, and by the diversion of lower-priced BELVIQ into the higher-priced territory; and

the establishment and maintenance of adequate commercial manufacturing capabilities ourselves or through third-party manufacturers, our ability to meet commercial demand for BELVIQ, and supply chain issues.

If BELVIQ is approved in territories outside the United States, the degree of market acceptance and commercial success of BELVIQ in these territories, and our revenues, will depend on similar factors as in the United States, as well as territory-specific risks.

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

We cannot predict with certainty the extent to which BELVIQ will be accepted or utilized by patients, physicians, healthcare insurers, maintenance organizations or the medical community in general. The potential population of patients eligible for treatment with BELVIQ may be reduced, including due to the limitations for use in the product label, which may be more restrictive in different territories. Efforts to educate the medical community and third-party payers regarding the benefits of BELVIQ will require significant resources and may not be successful in achieving the objectives. If BELVIQ does not achieve sufficient market acceptance in the United States, and ultimately in other territories, the revenues we generate from sales will be limited and we may not be profitable.

---

**Table of Contents**

**BELVIQ or any of our future drugs may not be commercially successful if not widely covered and adequately reimbursed by third-party payers, and we may depend on others to obtain and maintain third-party payer access; 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.**

Our and our collaborators' ability to commercialize any of our drugs that have been or 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 March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, PPACA (also referred to as "Obamacare"), was passed, which has the potential to 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 enhance remedies against healthcare fraud and abuse, add new transparency requirements, impose a new annual nondeductible fee on certain branded drugs based on market share in government healthcare programs, increases in rebates for government programs such as Medicaid, expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs, established the Medicare Part D coverage gap discount program by requiring manufacturers to provide a 50% point-of-sale discount off the negotiated price of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D, 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. In addition, many countries outside of the United States have nationalized healthcare systems in which the government pays for all such products and services and must approve product pricing.

The ability to successfully commercialize any drug depends, in part, on the extent to which coverage and reimbursement for the drug is available from government and health administration authorities, private health insurers, managed care programs and other third-party payers. It is increasingly difficult to obtain coverage and adequate reimbursement levels from third-party payers, and significant uncertainty exists as to the coverage and reimbursement of newly approved prescription drug products. We or our collaborators also face competition in negotiating for coverage from pharmaceutical companies and others with competitive drugs or other treatment, and such competitors may have significantly more negotiating leverage or success with respect to the individual payers than we or our collaborators may have.

With respect to BELVIQ, we depend on Eisai and our other collaborators for the achievement of third-party payer coverage and acceptable reimbursement and negotiating with individual payers. In the United States, even if a third-party payer ultimately elects to cover and reimburse for BELVIQ, most payers will not reimburse 100% of the cost, but rather require patients to pay a portion of the cost through a co-payment. Thus, even if reimbursement is available, the percentage of drug cost required to be borne by the patients may make use of BELVIQ financially difficult or impossible for certain patients, which would have a negative impact on sales of BELVIQ. For example, payers may approve coverage for BELVIQ in tiers requiring unacceptably high patient co-payments or only as a second- or later-line treatment. Since launch, several third-party payers have approved coverage for BELVIQ with limitations, including co-pays that may be unacceptably high for certain patients regardless of the availability of any coupon, voucher or other discount program. Failure to improve coverage or the reduction or loss of coverage could materially harm the ability to successfully market BELVIQ. Achieving coverage and acceptable reimbursement levels typically involves negotiating with individual payers and is a time-consuming and costly process. In addition, Medicare explicitly excludes coverage for drugs for weight loss. While new legislation may in the future remove this exclusion, there is no assurance any such legislation will be approved, and Medicare may continue to exclude drugs for weight loss from its coverage.

Given the continuing discussion regarding the cost of healthcare, managed care, universal healthcare coverage and other healthcare reform measures proposed or yet to be proposed, we cannot predict with certainty



## **Table of Contents**

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 and demand for our drugs.

We expect that the PPACA, as well as other federal and state healthcare reform measures that have and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any approved product, and could seriously decrease our future revenues. Any reduction in reimbursement from Medicare, Medicaid or other government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, commercialize our products or establish and maintain collaborations.

The full impact of these new laws, as well as laws and other reform measures that may be proposed and adopted in the future, remains uncertain, but may continue the downward pressure on pharmaceutical pricing, and may also increase our regulatory burdens and operating costs, which could have a material adverse effect on our business operations.

### **Forecasting of BELVIQ sales will be difficult, and if BELVIQ projections are inaccurate, our business may be harmed and our stock price may be adversely affected.**

Our business planning requires us to forecast demand and revenues for BELVIQ despite numerous uncertainties, which may be increased because we rely to a large extent on our collaborators, particularly Eisai, conducting commercial activities and providing us with accurate and timely information. Actual results may deviate materially from projected results for various reasons, including the following, as well as risks identified in other risk factors:

the rate of adoption in the United States;

pricing (including discounting or other promotions), reimbursement, product returns or recalls, competition, labeling, DEA scheduling, adverse events and others items that impact commercialization;

lack of patient and physician familiarity with BELVIQ;

lack of patient use and physician prescribing history;

lack of commercialization experience with BELVIQ, in particular, and weight loss or management drugs, in general;

actual sales to patients may significantly differ from expectations based on sales to wholesalers;

our collaborators under the BELVIQ Agreements control the commercialization of BELVIQ in all of the countries in the world, except for Australia, New Zealand and Israel, including related strategy and their allocation of resources, and we expect that any future collaborators for BELVIQ will similarly control the commercialization in the applicable territory; and

uncertainty relating to when BELVIQ may become commercially available to patients and rate of adoption in other territories.

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

The extent to which any of these or other factors individually or in the aggregate may impact sales of BELVIQ is uncertain and difficult to predict. This may lead to lower than expected revenue, increased difficulty

---

**Table of Contents**

in operational planning and higher than desired expenditures. Revenue shortfalls would have a negative impact on our cash flow and on our business in general. We expect that our revenues from BELVIQ will continue to be based in part on estimates, judgment and accounting policies, and incorrect estimates or regulators' or others' disagreement regarding such estimates or accounting policies may result in changes to guidance or previously reported results. For example, with respect to the commercialization of BELVIQ in the United States, our revenues are based on information we receive from Eisai, including their estimates of deductions for certain items, such as taxes, credits, allowances, discounts, rebates, chargebacks and returns, which are subject to significant judgment. We expect to continue to recognize revenues upon Eisai's sales to wholesalers. As BELVIQ is sold through to patients, if the actual level of deductions differ materially from Eisai's estimates, this could have a material impact on our revenues. In addition, expected and actual product sales and quarterly and other results may greatly fluctuate, including in the near-term, and such fluctuations can adversely affect the market price of our common stock, perceptions of our ability to forecast demand and revenues, and our ability to maintain and fund our operations.

**Data generated or analyzed with respect to product use in the market or required postmarketing or other studies may result in decreased demand, lower sales, product recall or regulatory action.**

A New Drug Application, or NDA, holder is responsible for assessing and monitoring the safety of a drug that has been approved for marketing. Eisai is the NDA holder of BELVIQ, and we expect that Eisai and other of our collaborators will hold the BELVIQ regulatory approvals, if any, in territories outside of the United States. Eisai, we and others will assess and monitor the safety of BELVIQ in the marketplace, and will receive reports of adverse safety events. In addition, as a condition to obtaining FDA approval of BELVIQ, the FDA required the conduct of postmarketing studies, including evaluation of the effect of long-term treatment with BELVIQ on the incidence of major adverse cardiovascular events in overweight and obese subjects with cardiovascular disease or multiple cardiovascular risk factors. The FDA required portion of the trial is designed to evaluate BELVIQ's effect on the incidence of major adverse cardiovascular events, or MACE, (non-fatal myocardial infarction, non-fatal stroke and cardiovascular death) compared to placebo, with a non-inferiority margin for the hazard ratio of 1.4. The trial will also include FDA-required echocardiographic assessments. Along with the FDA-required portion of the trial, we expect that the trial will include the non-FDA required evaluation of whether lorcaserin reduces the incidence of conversion to type 2 diabetes in patients without type 2 diabetes at baseline and the incidence of MACE+ (MACE or hospitalization for unstable angina or heart failure, or any coronary revascularization), both as compared to placebo. We expect that the trial (including the non-FDA required portion) will run approximately five years. In addition, we expect that, from time to time, we or others will conduct additional studies, clinical trials or analyses of BELVIQ, including in connection with seeking regulatory approval of BELVIQ outside of the United States, in combination with other drugs, for other indications or using different formulations.

New data relating to BELVIQ, including from adverse event reports, required postmarketing and other studies and trials in the United States, and registration and other studies and trials in territories outside the United States, may result in label changes, may adversely affect sales or result in withdrawal of BELVIQ from the market and may adversely affect prospects of developing or commercializing BELVIQ in combination with other drugs, for other indications or using different formulations. Foreign regulatory agencies may also consider the new data in reviewing BELVIQ marketing applications in their territories or impose post-approval requirements that require significant additional expenditures. Furthermore, the discovery of significant problems with a product or class of products similar to BELVIQ could have an adverse effect on the BELVIQ program, including commercialization.

In addition, new data or other information, including information about product misuse, may lead government agencies, professional societies, practice management groups or organizations involved in various diseases to publish guidelines or recommendations related to the use of BELVIQ or place greater restrictions on sales. Such guidelines or recommendations may lead to lower sales of BELVIQ.

## **Table of Contents**

**We will need to further collaborate or obtain additional funds to conduct our planned research, development and commercialization efforts; we may not be able to further collaborate or obtain adequate funds, your ownership may be substantially diluted if we do obtain additional funds, and you may not agree with the manner in which we allocate our available resources; and we may not be 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 for at least the short term.

Cash we may generate in the future from sales of BELVIQ or otherwise is uncertain and difficult to predict. All of our other programs are in the research or early development stage, and we may not have adequate funds to develop our compounds into marketed drugs. We intend to explore BELVIQ's therapeutic potential for other indications, in combination with other drugs or using different formulations, and from time to time we expect to collaborate with Eisai or others, or, possibly, to work independently, on related studies and trials. We also intend to advance other of our drug candidates and preclinical compounds in our pipeline. It takes many years and potentially hundreds of millions of dollars to successfully develop a drug candidate or preclinical compound into a marketed drug, and our efforts may not result in marketed drugs.

We cannot assure you that any additional payments we may receive under the BELVIQ Agreements will be sufficient to fund our planned research and development and other activities. We expect to enter into marketing and supply agreements or other arrangements with one or more pharmaceutical companies to commercialize BELVIQ in territories not already under collaboration and to research, develop and commercialize other drug candidates in our pipeline. We may not be able to enter into any such agreement on terms that we or third parties, including investors or analysts, view as favorable, if at all.

Our ability to enter into new collaborations for BELVIQ or any of our drug candidates may depend on the outcomes of regulatory applications for marketing approval or additional preclinical and clinical testing. We do not control these outcomes.

For example, if we experience a significant setback or delay, particularly any relating to BELVIQ, we may seek to obtain additional funding from the capital markets or we may eliminate, scale back or delay some or all of our research or development programs. Any such reductions or failure to apply our resources effectively may narrow, slow or otherwise adversely impact the development and commercialization of our pipeline, which we believe would reduce our opportunities for success and have a material adverse effect on our business and prospects.

We may allocate our resources in ways that do not improve our results of operations or enhance the value of our assets, and our stockholders and others may also not agree with the manner in which we choose to allocate our resources or obtain additional funding. Any failure to apply our resources effectively, how we obtain additional funding and the related views of stockholders or others could have a material adverse effect on our business or the development of our drug candidates and cause the market price of our common stock to decline. In addition, we cannot assure you that we will be profitable or, if we are profitable for any particular time period, that we will be profitable in the future.

**If BELVIQ is not approved for marketing outside the United States, or if any such approval is significantly delayed or limited, our results of operations and business may be materially adversely affected and our stock price may decline.**

We or our collaborators have pending applications for regulatory approval of BELVIQ outside of the United States, and we expect that our current or future collaborators or we will seek regulatory approval for the marketing of BELVIQ in additional territories. The FDA's approval of a drug does not assure or predict with any certainty that

## Table of Contents

any other regulatory authority will grant marketing approval for such drug. For example, as described below, we withdrew our MAA for BELVIQ in the European Union. As another example, VIVUS, Inc., announced in October 2012 that, despite the FDA's approval of its drug candidate for the treatment of obesity, the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or EMA, recommended against approval of its MAA for such drug candidate. We cannot assure or predict with any certainty that BELVIQ will be approved in any additional territories or the expected timeframe of any such approval. The review and potential approval of BELVIQ carries many risks and uncertainties, and our or others' BELVIQ regulatory submissions may not be satisfactory to the applicable regulatory authorities, including with regard to demonstrating adequate safety and efficacy for regulatory approval. We have made, and expect to make in the future, assumptions, estimations, calculations and decisions as part of our analyses of data and regulatory submissions, and the applicable regulatory authorities may not accept or agree with our assumptions, estimations, calculations, decisions or analyses or may interpret or weigh the importance of data differently.

Furthermore, as was the case with FDA approval, other regulatory approvals, even if obtained, may be limited to specific indications, limit the type of patients in which the drug may be used, or otherwise require specific warning or labeling language, any of which might reduce the commercial potential of BELVIQ. As with the FDA's approval of BELVIQ, regulatory authorities in other territories may condition BELVIQ marketing approval on the conduct of specific postmarketing studies to further evaluate safety and efficacy, in either particular or general patient populations or both. The results of these studies, discovery of previously unknown issues involving safety or efficacy or failure to comply with post-approval regulatory requirements, including requirements with respect to manufacturing practices, reporting of adverse effects, advertising, promotion and marketing, may result in restrictions on the marketing of BELVIQ or the withdrawal of BELVIQ from the market.

With respect to the European Union, in 2013, the EMA's CHMP identified major objections related to nonclinical and clinical issues, including tumors in rats, valvulopathy and psychiatric events, and the CHMP requested that we further justify BELVIQ's overall benefit-risk balance taking these issues into consideration. The major objections needed to be addressed before the CHMP could have recommended BELVIQ for marketing approval in the European Union. We did not believe we could resolve the major objections related to the results of nonclinical studies prior to the time we expected the CHMP to issue its final opinion, and, therefore, we withdrew the BELVIQ MAA for the European Union. We expect Eisai to potentially submit for regulatory approval in Europe at a later date, but BELVIQ may not be submitted for regulatory approval in Europe when expected or ever.

With respect to Switzerland, Swissmedic provided feedback to our MAA in the form of a list of questions with major objections, which include objections that are similar to those identified with respect to our MAA for the European Union. We responded to the list of questions in writing, and we subsequently received a determination from Swissmedic that those concerns have not yet been satisfied and that our application would not be approved. While we expect to continue to work with Eisai to pursue regulatory approval in Switzerland, BELVIQ may not be approved for marketing in Switzerland when expected or ever.

We cannot assure you that our collaborator's or our past or any future responses or submissions will be sufficient to the applicable regulatory authority or others, that the applicable regulatory authority or others will consider our BELVIQ program or data, including with regard to BELVIQ's efficacy or safety, as sufficient, or that any other regulatory authority will ever approve BELVIQ.

### **Our commercialization and continuing development of BELVIQ may be adversely impacted by cardiovascular side effects associated with drugs used for the treatment of obesity.**

We developed BELVIQ 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

---

**Table of Contents**

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, BELVIQ 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 BELVIQ's selectivity profile may not be adequate to avoid these side effects. BELVIQ's selectivity profile and the potential relationship between the activity of BELVIQ and the activity of fenfluramine and dexfenfluramine may result in increased FDA or other regulatory scrutiny of the safety of BELVIQ, may raise potential adverse publicity and may affect enrollment of any future clinical trials or product sales. In addition, we cannot guarantee that any other regulatory authority will find our safety data to be sufficient to approve BELVIQ for marketing outside of the United States.

As a condition to obtaining FDA approval of BELVIQ, the FDA required the conduct of postmarketing studies to, among other things, evaluate the effect of long-term treatment with BELVIQ on the incidence of major adverse cardiovascular events in overweight and obese subjects with cardiovascular disease or multiple cardiovascular risk factors. As described above, this trial will include echocardiographic assessments in a subset of the patients as well as non-FDA required evaluations. The results of such trial and assessments may be unfavorable. Unfavorable results from these studies or other studies we or others conduct, including for related development programs, could negatively impact the commercialization of BELVIQ, limit the revenues we generate from sales, result in BELVIQ's withdrawal from the market, and preclude us from being profitable.

**We are dependent on marketing and supply agreements for BELVIQ and the failure to maintain such agreements, or poor performance under such agreements, could negatively impact our business.**

Eisai has primary responsibility for the marketing and distribution of BELVIQ in all of the countries in the world, except for South Korea, Taiwan, Australia, New Zealand and Israel, and Ildong and CYB have primary responsibility for the regulatory approval and, ultimately, marketing and distribution of BELVIQ in South Korea and Taiwan, respectively. We have limited or no control over the amount and timing of resources that any of these collaborators will dedicate to such activities. In addition, they are responsible for compliance with certain regulatory requirements.

We are subject to a number of other risks associated with our dependence on the BELVIQ Agreements, including:

our collaborators may not comply with applicable regulatory guidelines with respect to BELVIQ, which could adversely impact the commercialization or development of BELVIQ;

there could be disagreements regarding the agreements or the study or development of BELVIQ that delay or terminate the commercialization, research, study or development of BELVIQ, delay or eliminate potential payments under the agreements or increase our costs under or outside of the agreements;

our collaborators may not allocate adequate resources or otherwise support BELVIQ or may have limited experience in a particular territory; and

our collaborators may not perform as expected, including with regard to making any required payments, and the agreements may not provide adequate protection or may not be effectively enforced.

We and our collaborators have the right to terminate the BELVIQ Agreements in certain circumstances. We could also agree with a collaborator to amend the terms of our agreement, and we or others, including investors



---

## **Table of Contents**

and analysts, may not view any amendments as favorable. If any of the BELVIQ Agreements is terminated early, we may not be able to find another company to further develop and commercialize BELVIQ in the covered territory on acceptable terms, if at all, and even if we elected to pursue further development or commercialization of BELVIQ 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 BELVIQ or one or more of our drug candidates, and may be similarly dependent on the performance of third parties with similar and potentially company-specific risks.

**We are responsible for supplying BELVIQ under the BELVIQ Agreements, including for commercial sale. We rely to an extent on other companies, including third-party manufacturers and sole-source suppliers, and we or such other companies may encounter failures or difficulties or not receive or provide adequate supply, which could adversely affect the commercial production of BELVIQ or the clinical development or regulatory approval of our drug candidates.**

Under each of the BELVIQ Agreements, we are the exclusive supplier of BELVIQ. Our Swiss subsidiary owns and operates a drug product manufacturing facility in Switzerland that will produce finished drug product of BELVIQ and potentially of one or more of our drug candidates. Such facility is currently our only source for finished drug product of BELVIQ. Accordingly, we must either rely on third-party manufacturers for such production or develop or acquire such facilities, which, in either case, would require substantial time and funds. With respect to BELVIQ, we estimate that it could take two years or longer and a substantial amount of financial and other resources to secure another source for finished drug product.

In addition, we do not own or operate manufacturing facilities that can produce active pharmaceutical ingredient, or API, intermediates and other material required to make BELVIQ and our drug candidates, or finished drug product for all of our drug candidates. Instead, we currently contract with other companies to supply API, intermediates and other materials. Certain of these materials are available from only one or a small number of suppliers, and using a new supplier, if available, for finished drug product, API and certain of the other materials could result in substantial delay and greater cost. We expect Siegfried AG, or Siegfried, will be the only source of BELVIQ API for at least the short term. Our dependence on one source of finished drug product and API, as well as our dependence on other third parties in the supply chain, may adversely affect our ability to develop and deliver drug products on a timely and competitive basis, or at all.

Any performance failure on the part of us or a third-party manufacturer could delay or otherwise adversely affect the sales of BELVIQ or the clinical development or regulatory approval of BELVIQ or one or more 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 BELVIQ, as well as one or more of our drug candidates, could be delayed, limited or denied if the applicable regulatory authority does not approve our processes or facilities or those of a third-party manufacturer. Moreover, the ability to adequately and timely manufacture and supply drug product 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;

having the ability to adjust to changes in actual or anticipated use of the facility, including with respect to having sufficient capacity and a sufficient number of qualified personnel;

facility contamination by microorganisms or viruses or cross contamination;

compliance with regulatory requirements, including inspectional notices of violation and warning letters;





---

**Table of Contents**

maintenance and renewal of any required licenses or certifications;

changes in actual or forecasted demand;

timing and number of production runs;

production success rates and bulk drug yields; and

timing and outcome of product quality testing.

In addition, we or our third-party manufacturers may encounter delays and problems in manufacturing our drug candidates or drugs for a variety of reasons, including accidents during operation, failure of equipment, delays in receiving materials, natural or other disasters, political or governmental unrest or changes, social unrest, intentional misconduct or other factors inherent in operating complex manufacturing facilities. Supply chain management is complex, and involves sourcing from a number of different companies and foreign countries. Commercially available starting materials, reagents and excipients may be or 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 or maintain agreements for the manufacture of BELVIQ or one or more of our drug candidates with manufacturers whose facilities and procedures comply with applicable law. Manufacturers are subject to ongoing periodic inspection (which may be unannounced) by the FDA, the DEA, corresponding state and foreign authorities and other regulatory authorities to ensure strict compliance with Current Good Manufacturing Practices, or cGMPs, regulations 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, we have contracted with Siegfried to provide to us certain business and technical services, including safety, health and environmental services. We are, therefore, relying at least in part on Siegfried's judgment, experience and expertise. We intend to reduce or eliminate our dependence on Siegfried for such business and technical services, and any changes may result in increased cost, additional risk or otherwise negatively impact our operations. If we or one of our manufacturers fail to maintain compliance or otherwise experience setbacks, we or they could be subject to civil or criminal penalties, the production of BELVIQ or one or more 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.

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

Negative conditions in the US or global economy, including financial markets, may adversely affect our business and the business of our current and prospective collaborators, distributors and licensees, which we sometimes refer to generally as our collaborators, and others with which we do or may conduct business. The duration and severity of these conditions is uncertain. If negative economic conditions persist or worsen, we may be unable to secure 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. Such negative conditions could also impact commercialization of BELVIQ or any other drugs we develop as well as our financial condition.

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,

## **Table of Contents**

such agencies may reduce the credit quality of our individual holdings, which could adversely affect their value. Lower credit quality and other market events, such as changes in interest rates and further deterioration in the credit markets, may have an adverse effect on the fair value of our investment holdings and cash position.

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

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

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

### **Our stock price could decline significantly based on the results and timing of clinical trials and preclinical studies of, and decisions affecting, BELVIQ or one or more of our drug candidates.**

The results and timing of clinical trials and preclinical studies, as well as related decisions, 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 BELVIQ or one or more of our drug candidates (including development programs related to BELVIQ) 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 decisions regarding the focus and prioritization of our research and development efforts, how we design individual studies, trials and development programs of BELVIQ as well as for any of our drug candidates, and regulatory decisions (including by us or regulatory authorities) affecting our 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 or product 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.

## **Table of Contents**

As a condition to obtaining FDA approval of BELVIQ, the FDA required the conduct of postmarketing studies to assess the safety and efficacy of BELVIQ for weight management in obese pediatric patients, as well as to evaluate the effect of long-term treatment with BELVIQ on the incidence of major adverse cardiovascular events in overweight and obese patients with cardiovascular disease or multiple cardiovascular risk factors. As described above, this trial will include echocardiographic assessments in a subset of the patients as well as non-FDA required evaluations. In addition, we may decide or need to conduct additional studies, clinical trials or analyses of BELVIQ, including in connection with seeking regulatory approval of BELVIQ outside of the United States. Unfavorable results from these studies, trials or analyses could negatively impact market acceptance of BELVIQ, limit the revenues we generate from sales, result in BELVIQ's withdrawal from the market, and preclude us from being profitable.

We may not be successful in initiating or completing our studies or trials or advancing our programs on our projected timetable, if at all. Any failure to initiate or delays in our studies, trials or development programs, or unfavorable results or decisions or negative perceptions regarding any of our programs, could cause our stock price to decline significantly. This is particularly the case with respect to BELVIQ (including related development programs).

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

**If we do not seek regulatory approval or commercialize BELVIQ with one or more collaborators, our lack of corporate experience and resources may negatively impact our ability to commercialize BELVIQ independently.**

Subject to applicable regulatory approval, we expect our collaborators to commercialize BELVIQ under the BELVIQ Agreements. We may not be able to maintain the BELVIQ Agreements or enter into new agreements in the few territories outside of such agreements on acceptable terms, if at all. If we are unable to maintain or enter into agreements to commercialize BELVIQ and we develop or acquire our own capabilities to commercialize BELVIQ in any territory independently, we may require additional capital to develop such capabilities, and the marketing and sale of BELVIQ in such territory may be delayed or otherwise impeded by our lack of resources. We may not be successful in developing the requisite capabilities to commercialize BELVIQ without a collaborator. Even if we were able to do so, we have not previously commercialized a drug, and our limited experience may make us less effective at commercial planning, marketing and selling than a more experienced pharmaceutical company. Our lack of corporate experience and adequate resources may impede our efforts to successfully commercialize BELVIQ independently.

If our competitors are able to establish commercialization arrangements with companies who have substantially greater resources than we have (or, with respect to commercializing BELVIQ in a territory under an existing marketing and supply agreement, than our collaborator has), our competitors may be more successful in marketing and selling their drugs, and our ability to successfully commercialize BELVIQ 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 and clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, marketing and distribution, and other possible activities relating to BELVIQ and our drug candidates are, and any other resulting drugs will be, subject to extensive regulation by the FDA and

---

**Table of Contents**

other regulatory agencies. We are subject to periodic inspections (which may be unannounced) by the FDA, the DEA and other regulatory agencies, including inspections at Arena GmbH by the FDA and other regulatory agencies. Failure to comply with applicable regulatory requirements may, either before or after product approval, subject us to administrative or judicially imposed sanctions that may negatively impact the commercialization of BELVIQ or approval of one or more of our drug candidates or otherwise negatively impact our business. Regulatory agencies have in the past inspected certain aspects of our business in the United States and Switzerland, and we were provided with observations of objectionable conditions or practices with respect to our business in the United States. We believe we satisfactorily addressed such observations, but there is no assurance that regulatory agencies will not provide us with observations in future inspections or that we satisfactorily addressed observations provided to us in past inspections.

Neither collaborators nor we are permitted to market a drug candidate in the United States until the particular drug candidate is approved for marketing by the FDA. Specific preclinical data, chemistry, manufacturing and controls data, a proposed clinical trial protocol and other information must be submitted to the FDA as part of an investigational new drug, or IND, application, and clinical trials may commence only after the IND application becomes effective. To market a new drug in the United States, we must submit to the FDA and obtain FDA approval of an NDA. An NDA must be supported by extensive clinical and preclinical data, as well as extensive information regarding chemistry, manufacturing and controls to demonstrate the safety and effectiveness of the drug candidate. Following its review of an NDA or a response to a Complete Response Letter, or CRL, the FDA may approve the NDA or issue a CRL.

Obtaining approval of an NDA can be a lengthy, expensive and uncertain process. As part of the Prescription Drug User Fee Act, or PDUFA, the FDA has a goal to review and act on a percentage of all submissions in a given time frame. The FDA's review goals are subject to change, and it is unknown whether any particular FDA review will be completed within the FDA's review goals or will be delayed. Moreover, the duration of the FDA's review may depend on the number and types of other submissions with the FDA around the same time period.

As with BELVIQ, any drug that acts on the CNS has the potential to be scheduled as a controlled substance by the DEA. DEA scheduling is a separate process that can delay when a drug may become available to patients beyond an NDA approval date, and the timing and outcome of such DEA process is uncertain. For example, the FDA approved the NDA for BELVIQ in June 2012, subject to the final scheduling of BELVIQ by the DEA. The DEA's final rule placing BELVIQ into Schedule IV of the Controlled Substances Act was not effective until June 2013. The scheduling designation can also change after it has been finalized. DEA scheduling ranges from I to V, with I being the most tightly controlled category. If BELVIQ were to be rescheduled into a different category, such scheduling could negatively impact the ability or willingness to prescribe or dispense BELVIQ, the likelihood that patients will use it and other aspects of our and Eisai's ability to commercialize it.

Regulatory approval of an NDA 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;

## Table of Contents

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. 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.

With the exception of our regulatory submissions for BELVIQ, we have not previously submitted an application for marketing approval in the United States or any other jurisdiction. This lack of corporate experience may impede our ability to obtain regulatory approval in a timely manner, if at all, for BELVIQ in territories in which regulatory approval is our responsibility or for any of our drug candidates. Our preclinical and clinical data, other information and procedures relating to a drug candidate 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. 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 our 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. With respect to our BELVIQ collaborations, our collaborators are responsible for regulatory filings, and we will depend on their capabilities, plans and diligence in obtaining regulatory approval.

With respect to our previously filed MAA for BELVIQ in the European Union, we did not believe we could resolve the major objections identified by the CHMP prior to the time we expected the CHMP to issue its final opinion, and, therefore, we withdrew the MAA. We expect Eisai to potentially submit for regulatory approval of BELVIQ in Europe at a later date. If such an application is submitted, the regulatory authority could determine that the application and data from our BELVIQ studies and trials is not sufficient for approval in such territory. The approval requirements in the European Union are different than in the United States. For example, the 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. Such EMA guidelines also provide primary and alternative primary efficacy criteria for weight loss drug candidates. We believe BELVIQ will satisfy the EMA's alternative primary efficacy criterion, which is the proportion of responders achieving more than 10% weight loss at the end of a 12-month period. However, we do not believe BELVIQ meets the more stringent EMA primary efficacy criterion, which requires demonstrating weight loss of at least 10% of baseline weight that is also at least 5% greater than that associated with placebo. Also, with respect our previously filed MAA for BELVIQ in the European Union, the EMA raised questions regarding the dropout rate in our clinical trials and how this affects the analysis of efficacy in those trials.

We also submitted an MAA with Swissmedic for the marketing approval of BELVIQ in Switzerland. In February 2013, Swissmedic provided feedback to our MAA in the form of a list of questions with major objections, which include objections that are similar to those identified with respect to the MAA we previously submitted for the European Union. We responded to the list of questions in writing, and we subsequently received a determination from Swissmedic that those concerns have not yet been satisfied and that our application would not be approved. While we expect to continue to work with Eisai to pursue regulatory approval in Switzerland, BELVIQ may not be

## **Table of Contents**

approved for marketing in Switzerland when expected or ever. In addition, Eisai filed regulatory applications for marketing approval of BELVIQ in Mexico, Canada and Brazil, and Ildong filed a regulatory application for marketing approval in South Korea. We expect that we or our collaborators will submit applications for regulatory approval of BELVIQ in additional territories in the future, but there is no guarantee that we or any of our collaborators will submit any additional regulatory applications.

We cannot assure you that our collaborator s or our past or any future responses or submissions will be sufficient to the applicable regulatory authority or others, that the applicable regulatory authority or others will consider our BELVIQ program or data, including with regard to BELVIQ s efficacy or safety, as sufficient, or that any other regulatory authority will ever approve BELVIQ.

Regulatory approval of a drug in one territory does not ensure additional regulatory approval in such territory (such as approval of the drug in combination with other drugs, for other indications or using different formulations) or regulatory approval in another territory, but a failure or delay in obtaining regulatory approval may negatively impact other regulatory processes. Failure to obtain regulatory approval in a territory, any delay or setback in obtaining such approval, or our regulatory strategy or decisions could adversely affect the regulatory approval or commercialization of our drug candidates in other territories, including that our drug candidates may not be approved for all indications requested, that such approval may be subject to limitations on the indicated uses for which the drug may be marketed, and with regard to the pricing or reimbursement of any approved drugs.

### **Our drugs will still be subject to extensive postmarketing regulation if approved.**

Following regulatory approval of any of our drug candidates, 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. As with BELVIQ, there may also be additional postmarketing obligations imposed by the FDA or other regulatory agencies. These obligations may result in significant expense and limit the ability to commercialize such drugs.

The FDA or other regulatory agencies may also require that the sponsor of the NDA or foreign equivalent, as applicable, conduct additional clinical trials to further assess approved drugs after approval under a post-approval commitment. Such additional studies may be costly and may impact the commercialization of the drug. For example, as part of the approval of BELVIQ, the FDA required the conduct of postmarketing studies to assess the safety and efficacy of BELVIQ for weight management in obese pediatric patients, as well as to evaluate the effect of long-term treatment with BELVIQ on the incidence of major adverse cardiovascular events in overweight and obese subjects with cardiovascular disease or multiple cardiovascular risk factors. As described above, this trial will include echocardiographic assessments in a subset of the patients and other FDA-required as well as non-FDA required evaluations. Along with being costly and time consuming, unfavorable results from these trials could negatively impact market acceptance of BELVIQ; limit the revenues we generate from sales; result in BELVIQ s withdrawal from the market; negatively impact the potential approval of BELVIQ in other territories for weight management, for other indications, in combination with other drugs or using different formulations; and preclude us from being profitable.

The FDA or other regulatory agencies may also impose significant restrictions on the indicated uses for which a drug may be marketed. Additionally, the FDA may require a REMS, including in connection with a drug s approval, to help ensure that the benefits of the drug outweigh its risks. A REMS may be required to include various elements, such as a medication guide or patient package insert, a communication plan to educate healthcare providers of the drug s risks, limitations on who may prescribe or dispense the drug, requirements that patients enroll in a registry or undergo certain health evaluations or other measures that the FDA deems necessary to ensure the safe use of the drug.

With regard to BELVIQ and any of our drug candidates that receive regulatory approval, 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 cGMP

## **Table of Contents**

regulations, which include requirements relating to quality control and quality assurance, as well as the corresponding maintenance of records and documentation. Further, regulatory agencies must approve these manufacturing facilities before they can be used to manufacture our products, and these facilities are subject to ongoing regulatory inspections. In addition, regulatory agencies subject a drug, its manufacturer and the manufacturer's facilities to continual review and inspections. The subsequent discovery of previously unknown problems with a drug, including adverse events of unanticipated severity or frequency, or problems with the facility where the drug is manufactured, may result in restrictions on the marketing of that drug, up to and including withdrawal of the drug from the market. In the United States, the DEA and comparable state-level agencies also heavily regulate the manufacturing, holding, processing, security, recordkeeping and distribution of drugs that are considered controlled substances.

The DEA has placed BELVIQ into Schedule IV of the Controlled Substances Act, which subjects us to the DEA's regulations. The scheduling designation can change after finalization. If BELVIQ were to be rescheduled into a different category, such scheduling could negatively impact the ability or willingness to prescribe or dispense BELVIQ, 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 us to administrative or judicially imposed sanctions, including:

issuance of inspectional notices of violation or warning letters by any regulatory agency;

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 any regulatory agency to approve pending applications or supplements to approved applications filed by us or collaborators;

refusals to permit drugs or related materials to be imported into or exported from the United States or other countries;

restrictions on operations, including costly new manufacturing requirements; and

product recalls or seizures.



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

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.

## **Table of Contents**

**Our ability to generate revenues from BELVIQ or any of our drug candidates that receive regulatory approval will be subject to a variety of risks, many of which are out of our control.**

BELVIQ or any of our drug candidates that may be approved for marketing may not gain market acceptance among patients, healthcare providers, 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 and alternative treatments;

actual and perceived efficacy and safety of our drug candidates;

incidence and severity of any side effects;

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

strength of sales, marketing and distribution support;

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

the general marketplace for the particular drug;

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 fail to achieve market acceptance, we may not be able to generate significant revenues to be profitable.

**Drug development programs 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. In addition, the FDA or other regulatory authority may require us to, or we or others may decide to, conduct additional research and development of any of our approved drugs. For example, the FDA is requiring the conduct of postmarketing studies of BELVIQ, and we or others may from time to time conduct additional studies or trials of BELVIQ alone or in combination with other drugs. 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:

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

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 approval or agreement from the applicable regulatory authority to commence a clinical trial or approval of a study protocol;

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

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

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

**Table of Contents**

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 and cost more than expected to complete. In addition, the FDA, other regulatory authorities, collaborators, or we may suspend, delay or terminate our development programs at any time for various reasons, including:

lack of effectiveness of any drug candidate during clinical trials;

side effects experienced by study participants or other safety issues;

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

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

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 or 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 or 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 expect to experience additional setbacks from time to time in the future. If we or our collaborators abandon or are delayed in our development efforts related to BELVIQ or any drug candidate, we may not be able to generate sufficient revenues to continue our operations at the current level or be 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 may decrease significantly.

## **Table of Contents**

### **The results of preclinical studies and completed clinical trials are not necessarily predictive of future results, and our current drug candidates or any approved drugs 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 or drugs 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 program. Preclinical and clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals or commercialization. Negative or inconclusive results or adverse medical events during a clinical trial could cause a clinical trial to be delayed, repeated or terminated; a program to be abandoned; or negatively impact a related marketed drug.

### **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, present significant distractions to our management and be viewed as unfavorable.**

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, such as 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 transaction may be viewed as unfavorable by our stockholders or others and may require us to incur non-recurring or other charges, may create potential liabilities, 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.

---

## **Table of Contents**

**Drug discovery and development is intensely competitive in the therapeutic areas on which we focus. If our competitors increase or they develop treatments that are approved faster, marketed better, less expensive or demonstrated to be more effective or safer than our drugs or 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 the United States and other territories. In addition, many companies are pursuing the development of new drugs that target the same diseases and conditions that we target.

For example, with regard to BELVIQ, VIVUS announced the US market availability of its drug for chronic weight management in September 2012. We also face competition from other drugs that may be indicated or used off label or otherwise for weight loss and from other approaches for weight loss, including behavior modification (such as diet and exercise), surgical approaches (such as gastric bypass surgery and gastric banding), and herbal or other supplements. With respect to future weight-loss treatments, we expect that companies and others may allocate resources to discover and develop additional drugs, additional drug candidates may be approved and competition may increase. For example, in December 2013, Orexigen Therapeutics, Inc., announced that it resubmitted with the FDA an NDA for its drug candidate for a similar indication, and it has also filed an MAA for the approval of such drug candidate in the European Union; and, in December 2013, Novo Nordisk announced that it has filed submissions for regulatory approval in the United States and Europe of its drug candidate for the treatment of obesity that is currently approved for the treatment of type 2 diabetes.

Our competitors, particularly large pharmaceutical companies, may 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 marketing exclusivity rights. In addition, our competitors' drugs may have fewer side effects, more desirable characteristics (such as efficacy, route of administration or frequency of dosing), or be viewed more favorably by patients, healthcare providers, healthcare payers, the medical community, the media or others than our drug candidates or drugs, if any, for the same indication. Our competitors may also market generic or other drugs that compete with our drugs at a lower price than our drugs, which may negatively impact our drug sales, if any. Any results from our research and development efforts, or from our joint efforts with our existing or any future collaborators, may not compete successfully with existing or newly discovered products or therapies.

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

We may have conflicts with our prospective, current or past collaborators, such as conflicts concerning rights and obligations under our agreements, the interpretation of preclinical or clinical data, the achievement of milestone or other payments, the ownership of intellectual property, or research and development, regulatory, commercialization or other strategy. Collaborators may stop supporting our drug candidates or drugs, including if they no longer view the program as in their best financial or other interests or they develop or obtain rights to competing drug candidates or drugs. In addition, collaborators may fail to effectively develop, obtain approval for or commercialize our drugs, which may result in us not realizing their full commercial potential. If any conflicts arise with any of our current, past or prospective collaborators, the other party 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 or drugs, and in turn prevent us from generating revenues:

unwillingness on the part of a collaborator to pay for studies or other research, milestones, 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;

## Table of Contents

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

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

litigation or arbitration.

### **Setbacks and consolidation in the pharmaceutical and biotechnology industries 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, including by making it more difficult to enter into agreements with pharmaceutical companies to collaborate or commercialize our drugs and diminishing our revenues. 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.

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

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

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

Our success depends on the continued contributions of our principal management, development and scientific personnel, and the ability to hire and retain key and other personnel. We face competition for such personnel, and we believe that risks and uncertainties related to our business, including the timing and risk



---

## **Table of Contents**

associated with research, development and commercialization, the regulatory process, our available and anticipated cash resources, pending and possible future litigation involving us, and the volatility of our 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., D.Sc., our Executive Vice President and Chief Scientific Officer, or a combination of different key employees, could adversely impact our operations and ability to generate or 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.

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

We develop, test, manufacture and expect to commercialize drugs for use by humans. We face an inherent risk of product liability exposure related to the testing of our drug candidates in clinical trials, and face an even greater risk with the commercialization of BELVIQ as well as any other drug that may be approved for marketing. In addition, under the marketing and supply agreement with Eisai, Arena GmbH and Eisai will, in general, share equally in losses resulting from third-party product liability claims, with certain limited exceptions.

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 drugs or drug candidates 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;

increased difficulty to attract, or 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 will have limited product liability insurance that covers our clinical trials and products. We may not be able to maintain or obtain 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 results of operations and financial condition.

We expect that Arena GmbH will manufacture BELVIQ for commercialization and, from time to time, for clinical trials or other studies. Arena GmbH also manufactures certain generic drug products for Siegfried. Arena GmbH is subject to liability for non-performance, product recalls and breaches of the agreements with Siegfried and our collaborators under the BELVIQ Agreements.

### **We have significant contractual obligations, which may adversely affect our cash flow, cash position and stock price.**

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

We have long-term leases on real properties and other contractual obligations. If we are unable to generate cash from operations sufficient to meet financial obligations, we will need to obtain additional funds from other

---

**Table of Contents**

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 our contractual obligations, or we need to use existing cash to fund our contractual 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 on terms that you or others may view as unfavorable. Our contractual obligations 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.

**We may be subject, directly or indirectly, to federal and state healthcare laws, including but not limited to fraud and abuse and false claims laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties and prosecution.**

In the United States, drug manufacturers and marketers are subject to various state and federal fraud and abuse laws, including, without limitation, the Federal Anti-Kickback Statute and Federal False Claims Act. There are similar laws in other countries. These laws may impact, among other things, the research, manufacturing, sales, marketing and education programs for our drugs.

The Federal Anti-Kickback Statute prohibits persons and entities from knowingly and willingly soliciting, offering, receiving or providing any remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the purchase, lease, order or the furnishing or arranging for, a good, item, facility or service, for which payment may be made, in whole or in part, 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 statutory exceptions and regulatory safe harbors, prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Moreover, the PPACA, among other things, amended the intent requirement of the Federal Anti-Kickback Statute and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them. The PPACA also provides that the government may assert that a claim including items or services resulting from a violation of the Federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. 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, among other things, persons or entities from knowingly presenting, or causing to be presented, 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 can be brought by any individual on behalf of the government, known as qui tam actions, 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, in addition to other penalties that may apply. Various states have also enacted laws modeled after the Federal False Claims Act, some of which are broader in scope and may apply regardless of payer.

## **Table of Contents**

The Federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payers, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Additionally, the civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

The Federal Physician Payment Sunshine Act, created under the PPACA, and its implementing regulations requires certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services, or HHS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

We may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their respective implementing regulations, impose specified requirements relating to the privacy, security and transmission of individually identifiable health information. Additionally, other legislative changes have been proposed and adopted since the PPACA was enacted. For example, the Drug Supply Chain Security Act imposes new obligations on manufacturers of pharmaceutical products, among others, related to product tracking and tracing. Among the requirements of this new legislation, manufacturers will be required to provide certain information regarding the drug product to individuals and entities to which product ownership is transferred, label drug product with a product identifier, and keep certain records regarding the drug product. The transfer of information to subsequent product owners by manufacturers will eventually be required to be done electronically. Manufacturers will also be required to verify that purchasers of the manufacturers' products are appropriately licensed. Further, under this new legislation, manufacturers will have drug product investigation, quarantine, disposition, and notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

We are unable to predict whether we could be subject to actions under any of these fraud and abuse or other 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, criminal and/or administrative penalties, damages, fines, individual imprisonment, disgorgement, possible 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 aspects of the supply chain, regulatory compliance, distribution of finished products, alliance management, and strategic planning and development. There are significant risks associated with foreign operations, including, but not limited to, compliance with local laws and regulations, the protection of our intellectual property, the ability to integrate our corporate culture with local customs and

## **Table of Contents**

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, 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, development or manufacturing efforts;

injury to our employees and others;

environmental damage resulting in costly clean up; and

liabilities under domestic or foreign 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 business and operations might be adversely affected by business disruptions and security breaches, including any cybersecurity incidents.**

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 manufacturing facility in Zofingen, Switzerland, and we expect that, at least for the near-term, this facility will be the sole location for the manufacturing of BELVIQ 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, disruption in transportation networks or delivery services, 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.

We depend on the efficient and uninterrupted operation of our computer and communications systems, which we use for, among other things, sensitive company data, including our intellectual property and proprietary business information. We maintain our information technology, or IT, infrastructure for our San Diego campus, and, at least for the near term, we have contracted with Siegfried to use their IT infrastructure for our manufacturing facility in Switzerland. We are in the process of building our own IT infrastructure for such manufacturing facility, but the timing and outcome of such process is uncertain.

While certain of our operations have business continuity and disaster recovery plans and other security measures intended to prevent and minimize the impact of IT-related interruptions, our IT infrastructure and the IT infrastructure of our current and any future collaborators, contractors and vendors are vulnerable to damage from cyberattacks, computer viruses, unauthorized access, electrical failures and natural disasters or other catastrophic events. Siegfried or we could experience failures in our information systems and computer servers, which could result in an interruption of our normal business operations and require substantial expenditure of financial and administrative resources to remedy. System failures, accidents or security breaches can cause



## **Table of Contents**

interruptions in our operations and can result in a material disruption of our research and development programs, manufacturing or commercialization activities and other business operations. The loss of data from completed or future studies or clinical trials could result in delays in our research, development or regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Similarly, we rely on third parties to supply materials for the manufacture of BELVIQ and our drug candidates, conduct studies and clinical trials of our drug candidates and warehouse, market and distribute BELVIQ, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the development of any of our other drug candidates and the commercialization of BELVIQ could be delayed or otherwise adversely affected.

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 SEC Rule 10b5-1.

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

We primarily spend and generate cash in US dollars, and present our consolidated financial statements in US dollars. However, a portion of our expected and potential payments and receipts under our agreements are in foreign currencies, including Swiss francs. For example, payments and receipts under our agreements 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 in the future enter into hedging transactions to try to reduce our foreign currency exposure, 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 directors' and officers' 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.

## **Table of Contents**

### ***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 BELVIQ and our drug candidates 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 marketing, licensing or financing transaction.

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

We also rely on confidentiality agreements and trade secrets to protect our technologies. However, such information is difficult to protect. We require our employees to contractually agree not to improperly use our confidential information or disclose it to others, but we may be unable to determine if our employees have conformed or will conform to their legal obligations under these agreements. We also enter into confidentiality agreements with prospective collaborators, collaborators, service providers and consultants, but we may not be able to adequately protect our trade secrets or other proprietary information in the event of any unauthorized use or disclosure or the lawful development by others of this information. Many of our employees and consultants were, and many of them may currently be, parties to confidentiality agreements with other pharmaceutical and biotechnology companies, and the use of our technologies could violate these agreements. In addition, third parties may independently discover our trade secrets or proprietary information.

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

We believe that the United States is by far the largest single market for pharmaceuticals in the world. Because of the critical nature of patent rights to our industry, changes in US patent laws could have a profound effect on our future profits, if any. It is unknown which, if any, patent laws will change, how changes to the patent laws will ultimately be enforced by the courts and the impact on our business. For example, in September



---

## **Table of Contents**

2011 the America Invents Act was signed into US law, which changes include, among others, the awarding of a patent to the first inventor to file a patent as opposed to the first inventor to make an invention and the creation of new administrative procedures for challenging US patents. It may be several years before the impact of the America Invents Act on patent law is understood, and we cannot predict with certainty whether or to what extent the changes may impair our business.

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

Our commercial success depends upon our ability to develop and manufacture our drugs and drug candidates, market and sell drugs, 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 drugs, drug candidates, technologies or activities infringe the intellectual property rights of others. Numerous US and foreign issued patents and pending patent applications owned by others exist in the area of G protein-coupled receptors, or GPCRs, including some which purport to allow the patent holder to control the use of all drugs that modulate a particular drug target or GPCR, regardless of whether the infringing drug bears any structural resemblance to a chemical compound known to the patent holder at the time of patent filing. Numerous US and foreign issued patents and pending patent applications owned by others also exist in the therapeutic areas in, and for the therapeutic targets for, which we are developing drugs. There are also numerous issued patents and patent applications to chemical compounds or synthetic processes that may be necessary or useful to use in our research, development, manufacturing or commercialization activities. These could materially affect our ability to develop our drug candidates or manufacture, import or sell drugs, and our activities, or those of our licensors or collaborators, could be determined to infringe these patents. Because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our drugs, drug candidates or technologies may infringe. There also may be existing patents, of which we are not aware, that our drug candidates or technologies may infringe. Further, there may be issued patents or pending patent applications in fields relevant to our business, of which we are or may become aware, that we believe (i) are invalid or we do not infringe; (ii) relate to immaterial portions of our overall drug discovery, development, manufacturing and commercialization efforts; or (iii) in the case of pending patent applications, the resulting patent would not be granted or, if granted, would not likely be enforced in a manner that would materially impact such efforts. We cannot assure you that others holding any of these patents or patent applications will not assert infringement claims against us for damages or seek to enjoin our activities. We also cannot assure you that, in the event of litigation, we will be able to successfully assert any belief we may have as to non-infringement, invalidity or immateriality, or that any infringement claims will be resolved in our favor.

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

There could 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;

---

**Table of Contents**

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. For example, a third party has communicated that it believes its issued US patents includes patent claims that cover BELVIQ or its use. We do not believe such patent claims are valid or, even if they were held valid, that they cover BELVIQ or its use. If we fail to obtain any required licenses or make any necessary changes to our technologies, we may become involved in expensive and time-consuming litigation or we may be unable to develop or commercialize some or all of our drugs or drug candidates.

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

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

***Risks Relating to Our Securities***

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

Our stock price has fluctuated historically. From January 1, 2012, to February 24, 2014, the market price of our stock was as low as \$1.51 per share and as high as \$13.50 per share.

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

regulatory actions or decisions or legislation affecting BELVIQ, including decisions of regulatory authorities relating to BELVIQ, or other drugs or drug candidates, including those of our competitors;

the commercial availability and success or failure of BELVIQ (including perceptions of prescription trends or other information) or any of our drug candidates;

**Table of Contents**

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

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

fluctuation in prescriptions, sales or financial results (including with respect to revenue recognition) or inaccurate sales or cash forecasting;

accounting restatements and changes;

supply chain or manufacturing issues;

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

results or decisions affecting the development or commercialization of BELVIQ or any of our drug candidates, including the results of studies, trials and other analyses;

the development and implementation of our continuing development and research plans, including outcome studies and other research and development for BELVIQ (including related development programs);

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

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 drugs or drug candidates;

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; and

capital market conditions.

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

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

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

As of February 24, 2014, we had outstanding a seven-year warrant issued in August 2008 to purchase 1,965,418 shares of our common stock at an exercise price of \$4.34 per share. Such warrant was adjusted as a result of certain equity sales following its issuance to decrease the exercise price and increase the number of shares issuable upon exercise of the warrant. Certain future equity issuances below the pre-defined warrant adjustment price may result in additional adjustments to such warrant to the extent then outstanding.

Along with our outstanding warrant, as of February 24, 2014, there were (i) options to purchase 14,305,116 shares of our common stock outstanding under our equity incentive plans at a weighted-average exercise price of \$4.99 per share, (ii) 434,846 restricted stock unit awards outstanding under our equity incentive plans, (iii) performance restricted

---

**Table of Contents**

stock unit awards outstanding under our 2012 Long-Term Incentive Plan, targeted at 780,000 shares (however, the actual number of shares that may be awarded ranges from 0% to 200% of such amount), (iv) 25,770,147 additional shares of common stock remaining issuable under our 2013 Long-Term Incentive Plan, (v) 900,659 shares of common stock remaining issuable under our 2009 Employee Stock Purchase Plan, as amended, and (vi) 79,169 shares of common stock remaining issuable under our Deferred Compensation Plan.

Once issued, the shares described above 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. As of February 24, 2014, there were 219,259,995 shares of our common stock outstanding.

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

We have been opportunistic in our efforts to obtain cash, and we expect to continue to evaluate various funding alternatives from time to time. We have primarily financed our operations, and we may continue to finance our operations, by issuing and selling our common stock or securities convertible into or exercisable for shares of our common stock. 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.

**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 stockholders may hold or acquire a significant amount of our outstanding stock. From time to time, there is a large short interest in our stock. These holders of such stock or positions may seek control of us, support transactions that we or you do not believe are favorable, and have interests that are different from yours. In addition, sales of a large number of shares of our stock by these large stockholders or other stockholders within a short period of time could adversely affect our stock price.

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

**Certain of our agreements, provisions in our charter documents, possible future agreements and Delaware law could delay or prevent a change in management or a takeover attempt that you may consider to be in your best interests.**

There is a standstill provision in our marketing and supply agreement with Eisai, and we may enter into agreements with similar provisions. In addition, we may in the future adopt a stockholders' rights agreement, which would cause substantial dilution to any person who attempts to acquire us in a manner or on terms not approved by our board of directors. These provisions or agreements, 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 interests. For example, our charter provisions:

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

limit who can call a special meeting of stockholders;

**Table of Contents**

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.

**Item 2. Properties.**

As set forth in the table below, we own or lease approximately 356,000 square feet of research, development, warehouse and office space located at various addresses in the same business park in San Diego, California and approximately 85,000 square feet of laboratory, manufacturing, warehouse and office space located in the same business park in Zofingen, Switzerland.

Location	Own/ Lease	Description
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 commenced cGMP operations in this facility in 2004.
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.
6122-6124-6126 Nancy Ridge Drive	Lease with option to purchase	This facility of approximately 68,000 square feet consists of approximately 28,500 square feet of laboratory space, 28,500 square feet of office space, 9,000 square feet of unoccupied space and 2,000 square feet of warehouse space.
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.
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.
6162 Nancy Ridge Drive	Own	This facility includes approximately 20,000 square feet of warehouse and office space, all of which is presently unoccupied.
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 18,000 square feet, consisting of approximately 7,000 square feet of warehouse space, 8,000 square feet of office space and 3,000 square feet of laboratory space, in various facilities.

## **Table of Contents**

We expect these facilities to be sufficient for our needs for at least the near term. We have significantly more space in San Diego than we expect to need for the foreseeable future, and are exploring subleasing some of our space and other options to reduce our expenses.

### **Item 3. Legal Proceedings.**

Beginning on September 20, 2010, a number of complaints were filed in the US District Court for the Southern District of California against us and certain of our current and former employees and directors on behalf of certain purchasers of our common stock. The complaints have been brought as purported stockholder class actions, and, in general, include allegations that we and certain of our current and former employees and directors violated federal securities laws by making materially false and misleading statements regarding our BELVIQ program, thereby artificially inflating the price of our common stock. The plaintiffs are seeking unspecified monetary damages and other relief. On November 19, 2010, eight prospective lead plaintiffs filed motions to consolidate, appoint a lead plaintiff, and appoint lead counsel. The Court took the motions to consolidate under submission on January 14, 2011. On August 8, 2011, the Court consolidated the actions and appointed a lead plaintiff and lead counsel. On November 1, 2011, the lead plaintiff filed a consolidated amended complaint. On December 30, 2011, we filed a motion to dismiss the consolidated amended complaint. On March 28, 2013, the Court granted our motion to dismiss the consolidated amended complaint without prejudice. On May 13, 2013, the lead plaintiff filed a new consolidated amended complaint. On June 14, 2013, we filed a motion to dismiss the new consolidated amended complaint. On July 15, 2013, the lead plaintiff filed an opposition to our motion to dismiss. On July 29, 2013, we filed our reply. On October 25, 2013, the Court heard oral argument on the motion to dismiss. On November 5, 2013, the Court granted our motion to dismiss the new consolidated amended complaint without prejudice as to all parties except for Robert E. Hoffman, who was dismissed from the action with prejudice. On November 27, 2013, the lead plaintiff filed a motion for leave to amend the now-dismissed new consolidated amended complaint. On December 20, 2013, we filed an opposition to the motion for leave to amend. On December 27, 2013, the lead plaintiff filed his reply. On December 30, 2013, the Court took the motion under submission without a hearing.

In addition to the class actions, a complaint involving similar legal and factual issues has been brought by at least one individual stockholder and is pending in federal court. On December 30, 2011, we filed a motion to dismiss the individual stockholder's complaint. On March 29, 2013, the Court granted our motion to dismiss, in part without prejudice. On May 13, 2013, the individual stockholder filed a new amended complaint. On June 14, 2013, we filed a motion to dismiss the new amended complaint. On July 10, 2013, the individual stockholder filed an opposition to our motion to dismiss. On July 29, 2013, we filed our reply. On October 22, 2013, the Court took the motion under submission without a hearing.

Due to the stage of these proceedings, we are not able to predict or reasonably estimate the ultimate outcome or possible losses relating to these claims.

### **Item 4. Mine Safety Disclosures.**

Not applicable.

**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.

	High	Low
Year ended December 31, 2012		
First Quarter	\$ 3.47	\$ 1.51
Second Quarter	\$ 13.50	\$ 2.00
Third Quarter	\$ 12.07	\$ 6.95
Fourth Quarter	\$ 10.05	\$ 7.09

	High	Low
Year ended December 31, 2013		
First Quarter	\$ 11.00	\$ 7.39
Second Quarter	\$ 9.25	\$ 7.35
Third Quarter	\$ 7.87	\$ 5.06
Fourth Quarter	\$ 6.71	\$ 4.05

 **Holders**

As of February 24, 2014, there were approximately 110 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. 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.

 **Securities authorized for issuance under equity compensation plans**

Information on securities authorized for issuance under our equity compensation plans is set forth in Item 12 of Part III of this Annual Report on Form 10-K.



**Table of Contents**

**Performance graph**

The graph below compares the cumulative five-year total return on our common stock from December 31, 2008, through December 31, 2013, to the cumulative total return over such period for (i) the NASDAQ Composite Index and (ii) the NASDAQ Biotechnology Index. The graph assumes the investment of \$100 on December 31, 2008, with the reinvestment of dividends, although dividends have not been declared on our common stock, and is calculated according to the Securities and Exchange Commission's methodology. We caution that the stock price performance shown in the graph may not be indicative of future stock price performance. The graph, including each of the graph lines, was provided by Research Data Group, Inc.

*This information, including the graph below, is not deemed to be soliciting material or to be filed with the Securities and Exchange Commission, or subject to the Securities and Exchange Commission's proxy rules, other than as provided in such rules, or to the liabilities of Section 18 of the Securities Exchange Act of 1934, and shall not be deemed incorporated by reference into any prior or subsequent filing by us under the Securities Act of 1933 or the Securities Exchange Act of 1934, except to the extent that we specifically incorporate it by reference into any such filing.*

**COMPARISON OF FIVE-YEAR CUMULATIVE TOTAL RETURN**

Among Arena Pharmaceuticals, Inc., the NASDAQ Composite Index and the NASDAQ Biotechnology Index

**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,				
	2013	2012	2011	2010	2009
	(In thousands, except share and per share data)				
<b>Revenues</b>					
Net product sales	\$ 5,702	\$ 0	\$ 0	\$ 0	\$ 0
Eisai collaborative revenue	72,416	23,617	6,770	1,923	0
Manufacturing services	2,690	3,817	5,338	7,057	6,579
Other collaborative revenue	586	153	611	7,633	3,808
<b>Total revenues</b>	<b>81,394</b>	<b>27,587</b>	<b>12,719</b>	<b>16,613</b>	<b>10,387</b>
<b>Operating Costs and Expenses</b>					
Cost of product sales	1,803	0	0	0	0
Cost of manufacturing services	4,377	3,671	8,100	7,414	6,536
Research and development	66,468	54,112	58,706	75,459	110,159
General and administrative	31,681	26,226	24,248	27,936	25,247
Restructuring charges	0	0	3,467	0	3,324
Amortization of intangibles	0	691	997	2,159	3,508
<b>Total operating costs and expenses</b>	<b>104,329</b>	<b>84,700</b>	<b>95,518</b>	<b>112,968</b>	<b>148,774</b>
Interest and other income (expense), net	3,500	(28,364)	(26,425)	(28,179)	(14,817)
<b>Net loss</b>	<b>(19,435)</b>	<b>(85,477)</b>	<b>(109,224)</b>	<b>(124,534)</b>	<b>(153,204)</b>
Deemed dividends related to beneficial conversion feature of convertible preferred stock	0	(2,824)	(2,260)	0	0
<b>Net loss allocable to common stockholders</b>	<b>\$ (19,435)</b>	<b>\$ (88,301)</b>	<b>\$ (111,484)</b>	<b>\$ (124,534)</b>	<b>\$ (153,204)</b>
<b>Net loss per share allocable to common stockholders, basic and diluted</b>	<b>\$ (0.09)</b>	<b>\$ (0.45)</b>	<b>\$ (0.80)</b>	<b>\$ (1.14)</b>	<b>\$ (1.82)</b>
Shares used in calculating net loss per share allocable to common stockholders, basic and diluted	218,104,323	196,523,708	139,170,725	109,573,177	84,341,362

	As of December 31,				
	2013	2012	2011	2010	2009
	(In thousands)				
<b>Balance Sheet Data:</b>					
Cash and cash equivalents	\$ 221,878	\$ 156,091	\$ 57,632	\$ 150,669	\$ 94,733
Short-term investments, available-for-sale	0	0	0	0	20,716
<b>Total assets</b>	<b>339,807</b>	<b>261,206</b>	<b>157,129</b>	<b>266,362</b>	<b>236,278</b>
Total deferred revenues	139,190	62,735	44,682	48,077	4,086
Total lease financing obligations	72,794	74,458	75,771	76,769	77,486
Total derivative liabilities	4,892	15,042	1,617	2,271	6,642
Total notes payable	0	0	14,698	48,138	57,049
<b>Accumulated deficit</b>	<b>(1,207,733)</b>	<b>(1,188,298)</b>	<b>(1,079,751)</b>	<b>(970,527)</b>	<b>(845,993)</b>

Edgar Filing: ARENA PHARMACEUTICALS INC - Form 10-K

Total stockholders' equity	91,857	98,639	10,562	80,015	74,567
----------------------------	--------	--------	--------	--------	--------

---

## **Table of Contents**

### **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.

BELVIQ® (pronounced BEL-VEEK) is the trade name for the finished drug product containing the active pharmaceutical ingredient lorcaserin hydrochloride, or lorcaserin, that is marketed for chronic weight management in the United States. Lorcaserin may in the future be marketed in the United States or in other countries under a different trade name for chronic weight management. Lorcaserin may also be marketed under a different trade name for a different indication, in a different formulation or in combination with another drug. In this report, we use BELVIQ to refer to the finished drug product containing lorcaserin and/or, depending on the context, the active pharmaceutical ingredient lorcaserin, and without regard to the current or potential indication, formulation or combination.

## **OVERVIEW AND RECENT DEVELOPMENTS**

We have incurred net losses of \$1.2 billion from our inception in April 1997 through December 31, 2013, and may incur substantial net losses in the future as we manufacture BELVIQ for commercial sale and studies, advance our research and development programs and continue our efforts to discover additional drug candidates.

BELVIQ, our internally discovered drug for chronic weight management, is approved for marketing in the United States and was made available by prescription in June 2013 to adults who are overweight with a comorbidity or obese. Eisai is responsible for marketing and distributing BELVIQ in the United States under the Second Amended and Restated Marketing and Supply Agreement, or Eisai Agreement, which is among our wholly owned subsidiary, Arena Pharmaceuticals GmbH, or Arena GmbH, Eisai Inc., and Eisai Inc.'s parent company, Eisai Co., Ltd., which we refer to collectively with Eisai Inc. as Eisai. Eisai recently doubled its BELVIQ sales force to approximately 400 representatives, which will enable Eisai to reach approximately 65,000 physicians in the United States, while reimbursement coverage for BELVIQ has also increased since BELVIQ's launch.

Under the Eisai Agreement, Arena GmbH also granted Eisai exclusive commercialization rights for BELVIQ in all of the other countries in the world, except for South Korea, Taiwan, Australia, New Zealand and Israel. Arena GmbH also has marketing and supply agreements with Ildong Pharmaceutical Co., Ltd., or Ildong, for BELVIQ in South Korea, which we refer to as the Ildong BELVIQ Agreement, and with CY Biotech Company Limited, or CYB, in Taiwan, which we refer to as the CYB Agreement. We intend to enter into additional collaborative agreements for the potential regulatory approval and commercialization of BELVIQ in Australia, New Zealand and Israel.

The marketing of BELVIQ is subject to applicable regulatory approval. BELVIQ has been approved for marketing in the United States, but currently not in any other country.

Our collaborators are responsible for regulatory activities related to obtaining marketing approval of BELVIQ in the territories covered under the respective agreement. Eisai filed applications for regulatory approval of BELVIQ in Mexico and Canada in March and June of 2013, respectively, and in Brazil in February 2014. In addition, Ildong submitted an application for regulatory approval of BELVIQ in South Korea in

---

**Table of Contents**

November 2013. We previously filed applications for marketing approval of BELVIQ with the regulatory authorities for the European Union and Switzerland, and these regulatory authorities notified us that we had not yet satisfactorily addressed their concerns and that our applications would not be approved. We expect to continue to work with Eisai in pursuing regulatory approvals for BELVIQ in Europe and other territories outside the United States. In addition, CYB intends to file an application for regulatory approval of BELVIQ in Taiwan.

In November 2013, we received from Eisai an upfront payment of \$60.0 million in connection with expanding the territories under the Eisai Agreement. This upfront payment is in addition to the \$50.0 million and \$5.0 million we received in connection with entering into the original marketing and supply agreement and the first amended agreement, respectively. In addition to the upfront payments, through December 31, 2013, we have received from Eisai a total of \$66.0 million in milestones payments, and have recognized \$5.7 million in net product sales of BELVIQ. In 2014, we also expect to receive from Eisai additional payments for purchases of BELVIQ product supply and a milestone payment of \$0.5 million in connection with the recent filing of an application for regulatory approval of BELVIQ in Brazil.

In addition to commercializing BELVIQ as a monotherapy for chronic weight management, we intend to explore, with our collaborators or independently, BELVIQ's therapeutic potential in combination with other drugs, for other indications, and using different formulations. Under the Eisai Agreement, we and Eisai have initially prioritized the development areas of smoking cessation, a once-daily formulation, and co-administration with phentermine, as well as exploring BELVIQ's effect on conversion to type 2 diabetes and improvements in cardiovascular outcomes. We plan to initiate a Phase 2 clinical trial in the first half of 2014 to evaluate the potential of lorcaserin as a drug candidate for smoking cessation, for which we and Eisai will share equally the expenses. We have completed an initial study to evaluate the safety, tolerability and pharmacokinetic properties of different formulations of lorcaserin 20 mg extended release tablets, and selected a once-daily formulation for further development. We and Eisai will share equally the expenses related to the once-daily formulation. In November 2013, Eisai initiated dosing in a pilot study of 12-week duration to preliminarily assess as the primary outcome the short-term safety and tolerability of lorcaserin and phentermine when co-administered, for which Eisai is responsible for 100% of the expenses.

In January 2014, Eisai initiated enrollment in the cardiovascular outcomes trial, or CVOT, required by the US Food and Drug Administration, or FDA, as a postmarketing commitment. The CVOT is also referred to as CAMELLIA (Cardiovascular And Metabolic Effects of Lorcaserin In Overweight And Obese Patients). We and Eisai will be responsible for 10% and 90%, respectively, of the expenses for the FDA-required portion of such trial. In addition, CAMELLIA will also evaluate whether lorcaserin reduces the incidence of conversion to type 2 diabetes in patients without type 2 diabetes at baseline and the incidence of MACE+ (MACE or hospitalization for unstable angina or heart failure, or any coronary revascularization), both as compared to placebo. We and Eisai will share equally the expenses for this non-FDA required portion of the trial up to \$40.0 million each, and Eisai will be responsible for 100% of such expenses thereafter. CAMELLIA is expected to run approximately five years.

We also intend to utilize our discovery and development approach focused on G protein-coupled receptors, or GPCRs, to advance other of our internally discovered drug candidates, which include the following clinical-stage, orally available candidates:

APD811, an agonist of the prostacyclin receptor intended for the treatment of pulmonary arterial hypertension, has completed single- and multiple-ascending dose Phase 1 trials and is expected to begin a Phase 2 trial in the first half of 2014.

Temanogrel, an inverse agonist of the serotonin 2A receptor intended for the treatment of thrombotic diseases, has completed single- and multiple-ascending dose Phase 1 trials. Under our Co-Development and License Agreement with Ildong, which we refer to as the Ildong Temanogrel Agreement, we expect Ildong to fund and complete an additional Phase 1 trial in healthy volunteers and potentially a Phase 2a proof-of-concept trial in patients. We expect Ildong to initiate the Phase 1 trial in the first quarter of 2014 to evaluate the safety of co-administration of temanogrel with aspirin and clopidogrel.

**Table of Contents**

APD334, an agonist of the sphingosine 1-phosphate subtype 1, or S1P<sub>1</sub>, receptor intended for the treatment of a number of conditions related to autoimmune diseases, which has completed a Phase 1 single-ascending dose trial. We plan to initiate a Phase 1 multiple-ascending dose trial in 2014.

APD371, an agonist of the cannabinoid-2 receptor intended for the treatment of pain, for which we have initiated a Phase 1 single-ascending dose trial.

Developing marketed drugs is a long, uncertain and expensive process, and our ability to achieve our goals, including furthering our collaborators' commercialization of BELVIQ, and obtaining regulatory approval of, and commercializing, BELVIQ in additional territories, conducting required postmarketing and other studies of BELVIQ, and advancing our drug candidates, depends on numerous factors, many of which we do not control. We will continue to seek to balance the high costs of research, development and manufacturing against the need to maintain our operations long enough to achieve sustained profitability.

We will require substantial cash to achieve our goals. To date, we have generated limited revenues from sales of BELVIQ, which is our first and only drug approved by any regulatory authority. We may continue to incur substantial losses, and do not expect to generate consistent positive operating cash flows for at least the short term. Accordingly, we will need to receive additional funds under our existing collaborative agreements, under future collaborative agreements for BELVIQ or one or more of our drug candidates or programs, or by raising additional funds through equity, debt or other financing transactions.

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, 2013, we have generated \$1.8 billion in cash from these sources, of which \$1.2 billion was through sales of equity, \$425.0 million was through payments from collaborators, \$96.9 million was through the issuance of debt and related financial instruments to certain Deerfield entities and \$77.1 million was from sale and leaseback transactions. At December 31, 2013, we had \$221.9 million in cash and cash equivalents.

See the above Business section for a more complete discussion of our business.

**RESULTS OF OPERATIONS**

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

**Revenues**

Source of revenue	Years ended December 31,			% change from 2012 to 2013	% change from 2011 to 2012
	2013	2012	2011		
Milestone payments from Eisai	\$ 66.0	\$ 20.0	\$ 0.0	230.0%	100.0%
Net product sales	5.7	0.0	0.0		
Amortization of upfront payments from Eisai	4.0	3.5	3.4	15.2%	2.0%
Manufacturing services agreement with Siegfried	2.7	3.8	5.3	(29.5)%	(28.5)%
Reimbursements of development and patent expenses from Eisai	2.4	0.1	3.3	1998.0%	(96.6)%
Other collaborative agreements	0.6	0.2	0.7	281.6%	(74.9)%
<b>Total revenues</b>	<b>\$ 81.4</b>	<b>\$ 27.6</b>	<b>\$ 12.7</b>	<b>195.0%</b>	<b>116.9%</b>

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

Type of expense	Years ended December 31,			% change from 2012 to 2013	% change from 2011 to 2012
	2013	2012	2011		
Salary and other personnel costs (excluding non-cash share-based compensation)	\$ 27.7	\$ 23.7	\$ 24.9	17.1%	(4.7)%
Facility and equipment costs	10.0	11.0	12.0	(8.4)%	(9.0)%
External clinical and preclinical study fees and internal non-commercial manufacturing costs	16.4	12.1	13.8	35.5%	(12.1)%
Research supply costs	5.6	3.3	3.5	68.5%	(5.0)%
Non-cash share-based compensation	4.3	1.8	1.9	135.8%	(7.4)%
Other	2.5	2.2	2.6	9.6%	(13.6)%
<b>Total research and development expenses</b>	<b>\$ 66.5</b>	<b>\$ 54.1</b>	<b>\$ 58.7</b>	<b>22.8%</b>	<b>(7.8)%</b>

**General and administrative expenses**

Type of expense	Years ended December 31,			% change from 2012 to 2013	% change from 2011 to 2012
	2013	2012	2011		
Salary and other personnel costs (excluding non-cash share-based compensation)	\$ 11.4	\$ 9.8	\$ 9.1	16.8%	8.1%
Legal, accounting and other professional fees	7.3	6.7	7.6	9.1%	(12.3)%
Facility and equipment costs	5.1	4.4	4.2	13.9%	4.2%
Non-cash share-based compensation	4.7	3.2	1.7	44.1%	91.7%
Other	3.2	2.1	1.6	55.8%	27.2%
<b>Total general and administrative expenses</b>	<b>\$ 31.7</b>	<b>\$ 26.2</b>	<b>\$ 24.2</b>	<b>20.8%</b>	<b>8.2%</b>

**YEAR ENDED DECEMBER 31, 2013, COMPARED TO YEAR ENDED DECEMBER 31, 2012**

**Revenues.** We recognized revenues of \$81.4 million for the year ended December 31, 2013, compared to \$27.6 million for the year ended December 31, 2012. This increase was primarily due to (i) \$65.0 million of non-refundable milestone payments from Eisai that we earned in connection with the final scheduling designation for BELVIQ by the US Drug Enforcement Administration, or DEA, (ii) \$5.7 million from net product sales of BELVIQ, (iii) a \$2.3 million increase in reimbursements from Eisai for development and patent expenses and (iv) two non-refundable milestone payments of \$0.5 million each that we earned in connection with Eisai filing applications for regulatory approval of BELVIQ in Mexico and Canada. Of the \$5.7 million of BELVIQ net product sales recognized in the year ended December 31, 2013, \$5.3 million represented 31.5% of Eisai's net product sales and \$0.4 million related to redemptions of vouchers. The revenue recognized for the year ended December 31, 2012, included a \$20.0 million non-refundable milestone payment from Eisai that we earned in connection with FDA approval of BELVIQ.

When collaborators pay us before revenues are earned, we record such payments as deferred revenues. As of December 31, 2013, we had a total of \$139.2 million in deferred revenues. Of such amount, \$102.1 million is attributable to upfront payments we received under our collaboration with Eisai, \$30.3 million is attributable to the BELVIQ product supply, \$4.6 million is attributable to the upfront payment we received under the Ildong BELVIQ Agreement and \$2.2 million is attributable to the upfront payment we received under the CYB Agreement.

Absent any new collaborations, we expect our 2014 revenues will primarily consist of (i) revenues from sales of BELVIQ, (ii) amortization of the upfront payments we have received from Eisai and (iii) reimbursements from Eisai for development expenses.

## Table of Contents

Revenues from sales of BELVIQ and for milestones that may be achieved in the future are difficult to predict, and our revenues will likely vary significantly from quarter to quarter and year to year. We expect that this will particularly be the case in the short term as we transition from a research and development company to a company with a marketed drug.

With respect to the United States, we expect that Eisai's sales of BELVIQ will increase, but, due to the early stage of commercialization, it is difficult to predict the amount or timing of such sales or the related revenues we will generate. Future sales of BELVIQ will depend on, among other factors, the availability and use of BELVIQ, the effectiveness of Eisai's marketing program, competition and reimbursement coverage. Revenues we generate from Eisai's sales of BELVIQ depend on Eisai's net product sales of BELVIQ, which are the gross invoiced sales less certain deductions described in the Eisai Agreement. Deductions from gross sales to net product sales may vary from period to period, particularly in the near term, depending on the amount and extent of such deductions, which include deductions for vouchers, savings cards or other promotions for free or discounted product. Eisai has reported that a majority of all BELVIQ prescriptions utilized vouchers or savings cards.

In addition to revenues from Eisai's commercialization of BELVIQ in the United States, we expect that any significant revenues in the short term will depend on whether and when (i) BELVIQ receives regulatory approval, and is commercialized, outside of the United States, (ii) we enter into any additional agreements to commercialize BELVIQ and (iii) we enter into any agreements to collaborate on or license any of our drug candidates or programs.

**Cost of product sales.** Cost of product sales consists primarily of direct and indirect costs related to manufacturing BELVIQ, including, among other costs, salaries, share-based compensation and other personnel costs, machinery depreciation costs and amortization expense related to our manufacturing facility production licenses. Upon receiving approval of BELVIQ by the FDA in June 2012 (which approval was subject to the DEA's final scheduling designation), we began to capitalize inventory costs for BELVIQ, which is subsequently recognized as cost of product sales when the related inventory is sold. We recognized cost of product sales of \$1.8 million for the year ended December 31, 2013, and none for the year ended December 31, 2012, which was prior to when BELVIQ was made available to patients.

**Cost of manufacturing services.** Cost of manufacturing services consists primarily of direct and indirect costs associated with manufacturing drug products for Siegfried AG, or Siegfried, under our amended manufacturing services agreement, including related salaries, other personnel costs, machinery depreciation costs and amortization expense related to our manufacturing facility production licenses. Cost of manufacturing services increased by \$0.7 million to \$4.4 million for the year ended December 31, 2013, from \$3.7 million for the year ended December 31, 2012, primarily due to our contract loss provision for these services, which is the result of providing the services at sales prices that are less than our costs, as well as the reduced volume of manufacturing services performed.

**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 as they are incurred when these expenditures have no alternative future uses. We generally do not track our earlier-stage, internal research and development expenses by project; rather, we track such expenses by the type of cost incurred.

Research and development expenses increased by \$12.4 million to \$66.5 million for the year ended December 31, 2013, from \$54.1 million for the year ended December 31, 2012. This was primarily due to increases of (i) \$4.3 million in external clinical and preclinical study fees and internal non-commercial manufacturing costs, primarily related to manufacturing costs for non-commercial products and the BELVIQ



---

**Table of Contents**

cardiovascular outcomes trial, (ii) \$4.0 million in salary and other personnel costs, primarily as a result of an increase in headcount, (iii) \$2.5 million in non-cash share-based compensation expense and (iv) \$2.3 million in research supply costs. We expect to continue to incur substantial research and development expenses in 2014, which we expect will be substantially higher than 2013. Such expenses will include costs for FDA-required and non-FDA required development work relating to BELVIQ, including studies for smoking cessation and using a once-daily formulation, as well as our other research and development programs.

Included in the \$16.4 million total external clinical and preclinical study fees and internal non-commercial manufacturing costs for the year ended December 31, 2013, was \$7.2 million of non-commercial manufacturing and other development costs related to BELVIQ, \$4.5 million related to BELVIQ, \$1.9 million related to APD811, \$1.2 million related to APD334 and \$1.1 million related to APD371. Included in the \$12.1 million total external clinical and preclinical study fees and internal non-commercial manufacturing costs for the year ended December 31, 2012, was \$4.4 million related to BELVIQ, \$4.2 million of non-commercial manufacturing and other development costs related to BELVIQ, \$2.2 million related to APD811 and \$1.0 million related to APD371.

Cumulatively through December 31, 2013, we have recognized external clinical and preclinical study fees and internal non-commercial manufacturing costs of \$267.3 million for BELVIQ, \$43.7 million for nelotanserin (an inverse agonist of the serotonin 2A receptor, which we previously studied in Phase 2 for the treatment of insomnia), \$33.0 million of non-commercial manufacturing and other development costs related to BELVIQ, \$8.5 million for APD811, \$7.3 million for temanogrel, \$3.0 million for APD334 and \$2.2 million for APD371. As described above, Ildong will be responsible for funding and conducting the next two planned clinical trials of temanogrel under the Ildong Temanogrel Agreement.

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 with one or more collaborators or independently. As a 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 BELVIQ or 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 potential therapeutic indication;

the number of patients who participate in the trials;

the number and location 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 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 \$5.5 million to \$31.7 million for the year ended December 31, 2013, from \$26.2 million for the year ended December 31, 2012. This was primarily due to increases of (i) \$1.6 million in salary and other personnel costs, (ii) \$1.5 million in non-cash share-based compensation and (iii) \$1.1 million in consultants and contractors. We

expect that our 2014 general and administrative expenses will be higher than in 2013.

**Amortization of intangibles.** We recognized \$0.7 million for amortization of intangibles related to our manufacturing facility production licenses for the year ended December 31, 2012, and none for the year ended December 31, 2013. In June 2012 when we received FDA approval for BELVIQ, we began to capitalize into inventory amortization expense related to the manufacturing of BELVIQ. Such amortization will subsequently be recognized as cost of product sales when the related inventory is sold.

---

**Table of Contents**

**Interest and other income (expense), net.** Interest and other income (expense), net, increased to income of \$3.5 million for the year ended December 31, 2013, from an expense of \$28.4 million for the year ended December 31, 2012. This \$31.9 million increase was primarily due to (i) a \$10.2 million non-cash gain from revaluation of our derivative liabilities for the year ended December 31, 2013, compared to a \$13.4 million loss for the year ended December 31, 2012, (ii) a \$6.3 million non-cash loss on extinguishment of debt recognized for the year ended December 31, 2012, and (iii) a \$2.0 million decrease in interest expense due to the May 2012 payoff of our then-outstanding loan from certain Deerfield entities. Although our total interest expense decreased due to the payoff of the Deerfield loan, we expect that it will continue to be substantial due to payments on our lease financing obligations.

**YEAR ENDED DECEMBER 31, 2012, COMPARED TO YEAR ENDED DECEMBER 31, 2011**

**Revenues.** We recognized revenues of \$27.6 million for the year ended December 31, 2012, compared to \$12.7 million for the year ended December 31, 2011. This increase was primarily due to the \$20.0 million non-refundable milestone payment we earned in connection with the FDA approval of BELVIQ, which was partially offset by (i) a \$3.3 million decrease in reimbursements we received from Eisai related to additional BELVIQ development work and (ii) a \$1.5 million decrease in manufacturing services revenue under our manufacturing services agreement with Siegfried. The decrease in manufacturing services revenues was primarily the result of decreased volume and, to a lesser extent, decreases in certain sales prices under the manufacturing services agreement with Siegfried.

**Cost of manufacturing services.** We recognized cost of manufacturing services of \$3.7 million and \$8.1 million for the years ended December 31, 2012, and 2011, respectively. This decrease was primarily related to our contract loss provision for these services, as well as the reduced volume of manufacturing services performed.

**Research and development expenses.** Research and development expenses decreased by \$4.6 million to \$54.1 million for the year ended December 31, 2012, from \$58.7 million for the year ended December 31, 2011. This was primarily due to decreases of (i) \$1.7 million in external clinical and preclinical study fees and internal non-commercial manufacturing costs, (ii) \$1.2 million in salary and personnel costs and (iii) \$1.0 million in facility and equipment costs, primarily depreciation expense. We previously recorded BELVIQ manufacturing costs as research and development expenses.

Included in the \$12.1 million total external clinical and preclinical study fees and internal non-commercial manufacturing costs for the year ended December 31, 2012, was \$4.4 million related to BELVIQ, \$4.2 million of non-commercial manufacturing and other development costs related to BELVIQ, \$2.2 million related to APD811 and \$1.0 million related to APD371. Included in the \$13.8 million total external clinical and preclinical study fees and internal non-commercial manufacturing costs for the year ended December 31, 2011, was \$7.2 million of non-commercial manufacturing and other development costs related to BELVIQ, \$3.6 million related to BELVIQ, \$1.7 million related to APD811 and \$0.7 million related to APD334.

**General and administrative expenses.** General and administrative expenses increased by \$2.0 million to \$26.2 million for the year ended December 31, 2012, from \$24.2 million for the year ended December 31, 2011. This was primarily due to increases of (i) \$1.5 million in non-cash share-based compensation and (ii) \$0.7 million in salary and other personnel costs. These increases were partially offset by a \$1.1 million decrease in patent fees.

**Amortization of intangibles.** We recognized \$0.7 million for amortization of intangibles for the year ended December 31, 2012, compared to \$1.0 million for the year ended December 31, 2011. This decrease was primarily due to reaching the end of the 10-year estimated useful life of our Melanophore screening technology in the first quarter of 2011. The remaining amortization expense related to the manufacturing facility production licenses we acquired in connection with our Swiss manufacturing facility.

---

## **Table of Contents**

**Interest and other expense, net.** Interest and other expense, net, increased by \$2.0 million to \$28.4 million for the year ended December 31, 2012, from \$26.4 million for the year ended December 31, 2011. This was primarily due to a \$13.4 million non-cash loss from revaluation of our derivative liabilities, primarily resulting from the increase in the price of our common stock in 2012, which is an input into our Black-Scholes option pricing model. This increased expense was partially offset by (i) a \$5.2 million decrease in interest expense primarily related to the May 2012 payoff of our former loan from certain Deerfield entities and (ii) a \$4.2 million decrease in the non-cash loss on extinguishment of debt.

**Deemed dividend related to beneficial conversion feature of convertible preferred stock.** We recorded a deemed dividend of \$2.8 million in the year ended December 31, 2012, upon the issuance of our formerly outstanding Series D Convertible Preferred Stock and, in the year ended December 31, 2011, we recorded a deemed dividend of \$2.3 million upon the issuance of our formerly outstanding Series C Convertible Preferred Stock. The fair value of the common stock into which both series of preferred stock was convertible on the respective dates of issuance of the preferred stock exceeded the allocated proceeds on a relative fair value basis, resulting in the beneficial conversion feature.

## **LIQUIDITY AND CAPITAL RESOURCES**

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. In June 2013, BELVIQ was made available to patients by prescription in the United States by our collaborator, Eisai. It is difficult to predict the payments we will receive from commercialization of BELVIQ in the United States or in any other territory in which BELVIQ may be approved for marketing. We may incur substantial losses for at least the short term as a result of manufacturing BELVIQ for commercial sale and studies, conducting required postmarketing and other studies of BELVIQ, including other indications and formulations, and advancing our research and development programs.

### *Short term*

As of December 31, 2013, we had \$221.9 million in cash and cash equivalents. We believe our cash and cash equivalents will be sufficient to fund our operations for at least the next 12 months. We expect that our short-term operating expenses will be substantial as we continue to fund BELVIQ-related activities, and, at the same time, advance certain of our research and development programs.

In addition to payments expected from Eisai for purchases of BELVIQ product supply, other potential sources of liquidity in the short term include (i) payments from Eisai upon achievement of additional milestones, (ii) entering into new collaborative, licensing or commercial agreements for BELVIQ in additional territories or for one or more of our drug candidates or programs, (iii) milestone and other payments from collaborators other than Eisai and (iv) the sale or lease of facilities or other assets we own.

Due to impairment charges, our investment in TaiGen Biotechnology Co., Ltd., or TaiGen, has had a cost basis of zero since December 31, 2011. On January 17, 2014, TaiGen completed an initial public offering on the GreTai Securities Listed Market, valuing our investment at a fair value of \$49.1 million. In accordance with generally accepted accounting principles, on January 17, 2014, we will record our investment in TaiGen at such fair value, with the unrealized gain recorded as a component of accumulated other comprehensive income (loss) in the stockholders' equity section of our consolidated balance sheets. Our investment in TaiGen will continue to be recorded at fair value based on the trading price of TaiGen's common stock, with any unrealized gains or losses being recorded in accumulated other comprehensive income (loss) until realized.

Eisai is commercializing BELVIQ in the United States, and, subject to applicable regulatory approval, we expect Eisai to commercialize BELVIQ in additional territories under the Eisai Agreement. Eisai and we have

**Table of Contents**

regulatory applications for approval of BELVIQ under review. We also expect that Eisai will file additional regulatory applications for approval of BELVIQ in additional territories under the Eisai Agreement, but there is no assurance of whether, where or when Eisai may file any additional applications. There is also no assurance of whether, where or when BELVIQ will be approved for marketing outside of the United States, and, therefore, we expect that all or most of the revenues for BELVIQ sales in the short term will be from Eisai's commercialization of BELVIQ in the United States.

We manufacture BELVIQ at our facility in Switzerland, and sell BELVIQ to Eisai for Eisai's commercialization in the United States and, subject to applicable regulatory approval, in the other territories under the Eisai Agreement (other than Europe, China and Japan) for a purchase price starting at 31.5% and 30.75%, respectively (and starting at 27.5% in Europe, China and Japan), of Eisai's aggregate annual net product sales (which are the gross invoiced sales less certain deductions described in the Eisai Agreement), or the Product Purchase Price, in the respective territory. The Product Purchase Price will increase on a tiered basis in the United States and the other territories (other than Europe, China and Japan) to as high as 36.5% and 35.75%, respectively, on the portion of Eisai's annual aggregate net product sales exceeding \$750.0 million in all territories other than Europe, China and Japan. The Product Purchase Price will increase to 35% in Europe, China and Japan on the portion of Eisai's annual aggregate net product sales exceeding \$500.0 million in such territories. The Product Purchase Price is subject to reduction (for sales in a particular country), including in the event of generic competition in the applicable country. The revenue we recognize for BELVIQ product revenue related to redemption of vouchers is based on our cost of goods sold. Under the Eisai Agreement, we are eligible to receive up to an aggregate of \$176.5 million in additional regulatory and development milestone payments. We do not expect to receive the majority (or potentially any) of such payments in the short term.

As part of the US approval of BELVIQ, the FDA is requiring the evaluation of the effect of long-term treatment with BELVIQ on the incidence of major adverse cardiovascular events, or MACE, in overweight and obese patients with cardiovascular disease or multiple cardiovascular risk factors, as well as the conduct of postmarketing studies to assess the safety and efficacy of BELVIQ for weight management in obese pediatric patients. With respect to such studies, which we expect will take several years to complete, Eisai and we will be responsible for 90% and 10%, respectively, of the expenses for the FDA-required portion of the cardiovascular outcomes trial, and we will share equally with Eisai the expenses of certain pediatric studies.

Eisai is responsible for regulatory activities related to the BELVIQ New Drug Application, or NDA, and for the regulatory activities for obtaining marketing approval in any country in the additional territories under the Eisai Agreement. If the regulatory authority for a country in the additional territories requires development work before or following approval of BELVIQ in such country, we and Eisai will share expenses for such work. In addition, Ildong and CYB are responsible for the regulatory approval and, ultimately, marketing and distribution of BELVIQ in South Korea and Taiwan, respectively, including related development costs and other expenses.

We expect to incur additional expenses for the development of lorcaserin products that are in addition to BELVIQ for weight management. We expect Eisai to share such expenses, but, nevertheless, that such expenses will be significant. Under the Eisai Agreement, we and Eisai have initially prioritized the development areas of smoking cessation, a once-daily formulation and co-administration with phentermine, as well as exploring, including as part of CAMELLIA, BELVIQ's effect on conversion to type 2 diabetes and improvements in cardiovascular outcomes.

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

---

**Table of Contents**

*Long term*

We will need substantial cash to achieve our objectives of discovering, developing and commercializing drugs, and this process typically takes many years and potentially several hundreds of millions of dollars for an individual drug. We may not have adequate available cash, or assets that could be readily turned into cash, to meet these objectives in the long term. We will need to obtain significant funds under our existing collaborations, under new collaborative, licensing or other commercial agreements for BELVIQ or one or more of our drug candidates and programs or patent portfolios, or from other potential sources of liquidity, which may include the public and private financial markets.

We expect to continue to incur substantial costs for BELVIQ, including costs related to manufacturing and required postmarketing and other studies. As described above under short term, we will be responsible for a portion of the expenses for BELVIQ development work required by regulatory agencies. In addition, with respect to any development work not required by the FDA that we may conduct relating to BELVIQ, we would expect to incur additional expenses, which may be significant regardless of whether we share the expenses with Eisai. Expenses for the portion of CAMELLIA not required by the FDA (most of which we do not expect will be incurred for several years, if ever) will be shared equally by Eisai and us up to an aggregate of \$40.0 million each, and, thereafter, Eisai will be responsible for 100% of such expenses.

Subject to applicable regulatory approval, we expect Eisai to commercialize BELVIQ in additional territories under the Eisai Agreement. Under such agreement, in addition to payments for purchases of BELVIQ, we are eligible to receive up to an aggregate of \$1.56 billion in one-time purchase price adjustment payments and other payments. These payments include up to an aggregate of \$1.19 billion that are based on Eisai's annual net product sales of BELVIQ in all of the territories under the Eisai Agreement on an aggregate basis, with the first and last amounts payable with annual net product sales of \$250.0 million and \$2.5 billion, respectively. Of these payments, Eisai will pay us a total of \$330.0 million for annual net product sales of up to \$1.0 billion. The \$1.56 billion also includes \$370.0 million in one-time purchase price adjustment payments we are eligible to receive based on annual net product sales in the non-US territories, comprised of \$185.0 million based on Eisai's annual net product sales in the non-US territories in North and South America and \$185.0 million based on Eisai's annual net product sales in the territories outside of North and South America. The first and last amounts are payable upon first achievement of annual net product sales of \$100.0 million and \$1.0 billion, respectively, with respect to each of the following areas: (i) the non-US territories in North and South America and (ii) the territories outside of North and South America. In addition, we are also eligible to receive certain payments by Eisai if certain annual minimum sales requirements in Mexico, Canada and Brazil are not met during the first ten years after initial commercial sale in such territories.

Under the Ildong BELVIQ Agreement and CYB Agreement, we are eligible to receive additional payments upon regulatory approval, as well as payments from net product sales of BELVIQ. We will manufacture BELVIQ at our facility in Switzerland, and sell BELVIQ to Ildong for marketing and distribution in South Korea for a purchase price starting at 35% of Ildong's annual net product sales (which are the gross invoiced sales less certain deductions described in the Ildong BELVIQ Agreement). The purchase price will increase on a tiered basis up to 45% on the portion of annual net product sales exceeding \$15.0 million. If certain annual net product sales amounts are not met, we can convert Ildong's right to commercialize BELVIQ in South Korea to be non-exclusive. Additionally, we will manufacture and sell BELVIQ to CYB for a purchase price starting at 45% of CYB's annual net product sales (which are the gross invoiced sales less certain deductions described in the CYB Agreement). With respect to commercializing BELVIQ in countries that are not currently under collaboration (Australia, New Zealand and Israel), we will need additional funds or a collaborative or other agreement with one or more pharmaceutical companies.

In addition to potential payments from Eisai and other current collaborators, as well as funds from public and private financial markets, potential sources of liquidity in the long term include (i) upfront, milestone, royalty and other payments from any future collaborators or licensees and (ii) 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

---

**Table of Contents**

borrowings will sustain our operations will be based on, among other things, the rate of adoption and commercial success of BELVIQ, regulatory decisions, 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 and nonclinical studies, our research, development, manufacturing and commercialization costs (including personnel costs), our progress in any programs under collaborations, costs associated with intellectual property, our capital expenditures, and costs associated with securing any in-licensing opportunities. Any significant shortfall in funding may result in us 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.

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 acquisition or license or we use our cash to finance the acquisition or license.

*Sources and Uses of Our Cash*

Net cash of \$72.8 million was provided by operating activities in 2013, compared to net cash of \$44.0 million that was used in operating activities in 2012. This change was primarily the result of the \$66.0 million of milestone payments we received from Eisai in 2013, and a \$23.6 million change from a \$13.4 million loss from the revaluation of our derivative liabilities in 2012 to a \$10.2 million gain in 2013. Net cash used in operating activities in 2012 decreased by \$34.2 million to \$44.0 million. This was primarily due to a lower net loss in 2012, as well as changes in our operating assets and liabilities. Net cash used in operating activities in 2011 increased by \$26.0 million to \$78.3 million. This was primarily due to changes in our operating assets and liabilities.

Net cash used in investing activities increased by \$6.5 million to \$8.7 million in 2013. This increase was primarily the result of purchases of equipment and improvements to our facilities, primarily for our manufacturing facility in Switzerland. Net cash used in investing activities was \$2.2 million in 2012 and \$0.7 million in 2011, primarily for purchases of equipment and improvements to our facilities. We expect that our 2014 capital expenditures will increase over the 2013 amount due to deferrals of capital spending in previous years and purchases of equipment for our manufacturing facility in Switzerland.

Net cash of \$1.6 million was provided by financing activities in 2013, primarily due to net proceeds of \$3.3 million from stock option exercises and purchases under our employee stock purchase plan, which were partially offset by \$1.7 million for payments on our lease financing obligations. Net cash of \$144.1 million was provided by financing activities in 2012, primarily due to net proceeds of (i) \$65.7 million from a public offering of 12,650,000 shares of our common stock at \$5.50 per share, (ii) \$32.5 million from the portion of Deerfield's formerly outstanding warrants to purchase a total of 23,000,000 shares of our common stock that were cash exercised, (iii) \$27.9 million, after prepayment of \$5.0 million of loan principal, from the sale to Deerfield of 9,953,250 shares of our common stock and 9,953 shares of our preferred stock (subsequently converted in full into 9,953,250 shares of our common stock) and (iv) \$24.7 million from the sale of 14,414,370 shares of common stock under an equity line of credit agreement we had with Azimuth Opportunity, L.P. These proceeds were partially offset by principal repayments to Deerfield totaling \$22.3 million. Net cash of \$14.2 million was used in financing activities in 2011, primarily due to principal repayments to Deerfield totaling \$37.7 million and \$11.1 million paid to Siegfried in 2011. These repayments were partially offset by net proceeds of \$35.3 million from the sale of 12,150,000 shares of common stock and 12,150 shares of subsequently converted Series C Preferred to Deerfield in March 2011.

**Table of Contents****CONTRACTUAL OBLIGATIONS**

The following table summarizes our contractual obligations as of December 31, 2013, in thousands:

	Total	Payments due by period			
		Less than 1 year	1-3 years	3-5 years	More than 5 years
<b>Contractual Obligations</b>					
Financing obligations	\$ 119,994	\$ 8,090	\$ 18,298	\$ 19,225	\$ 74,381
Purchase obligations	2,575	2,502	73	0	0
Operating leases	12,947	873	1,704	1,790	8,580
Total	\$ 135,516	\$ 11,465	\$ 20,075	\$ 21,015	\$ 82,961

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 (subsequently exercised) to purchase a fourth property for total consideration of \$50.1 million. Our options to repurchase these properties in the future are considered continued involvement under the applicable accounting guidance 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, 2013, we expect interest expense over the term of these leases to total \$57.2 million. With the exception of the fourth property, which created an operating lease obligation and is included under operating leases above, we have included the lease obligations related to these properties in the above table as financing obligations.

*Off-Balance Sheet Arrangements*

Except for operating leases, we do not have, and did not have as of December 31, 2013, 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**

In November 2013, Arena GmbH and Eisai entered into the Eisai Agreement, which amended and restated the previous agreement and expanded Eisai's exclusive commercialization rights for BELVIQ to all of the countries in the world, except for South Korea, Taiwan, Australia, New Zealand and Israel. Eisai's commercialization rights are subject to applicable regulatory approval. In addition to providing commercialization rights, we provide services related to development and regulatory activities, and we manufacture and sell BELVIQ to Eisai. Under the Eisai Agreement, we are entitled to receive upfront payments, milestone payments based on the achievement of regulatory filings and approvals, one-time purchase price adjustment payments and other payments, and payments from sales of BELVIQ.

Arena GmbH and Eisai Inc. entered into the original marketing and supply agreement in July 2010, under which we granted Eisai Inc. exclusive commercialization rights for BELVIQ solely in the United States and its territories and possessions. In May 2012, Arena GmbH and Eisai Inc. amended and restated such agreement by entering into the first amended agreement, which expanded Eisai Inc.'s exclusive commercialization rights to include most of North and South America.



**Table of Contents**

The following table summarizes the revenues we have recognized under our collaboration with Eisai for the periods presented, in thousands:

	December 31,			From
	2013	2012	2011	Inception Through December 31, 2013
Milestone payments	\$ 66,000	\$ 20,000	\$ 0	\$ 86,000
Net product sales	5,702	0	0	5,702
Amortization of upfront payments	4,035	3,503	3,434	12,895
Reimbursement of research and development expenses	2,020	27	3,336	5,383
Reimbursement of patent expenses	361	87	0	448
Total	\$ 78,118	\$ 23,617	\$ 6,770	\$ 110,428

*Upfront and Milestone Payments*

In connection with entering into the Eisai Agreement, we received from Eisai an upfront payment of \$60.0 million. This payment is in addition to the \$50.0 million and \$5.0 million in upfront payments we received from Eisai in connection with entering into the original agreement and the first amended agreement, respectively. Revenues from these upfront payments have been deferred, as we determined that the exclusive rights did not have standalone value without our ongoing development and regulatory activities. Accordingly, these payments are recognized ratably as revenue over the periods in which we expect the services to be rendered, which are approximately 15, 16 and 15 years for the Eisai Agreement, original agreement and first amended agreement, respectively.

In addition to the upfront payments, we have received from Eisai a total of \$86.0 million in milestones payments, comprised of (i) \$65.0 million in 2013 earned upon the final scheduling designation for BELVIQ by the DEA, (ii) \$20.0 million earned in 2012 for the inclusion in the approved prescribing information of the FDA of the efficacy and safety data from the Phase 3 BLOOM-DM (Behavioral modification and Lorcaserin for Overweight and Obesity Management in Diabetes Mellitus) clinical trial in patients with type 2 diabetes, (iii) \$0.5 million earned in 2013 upon Eisai filing for regulatory approval of BELVIQ in Mexico and (iv) \$0.5 million earned in 2013 upon Eisai filing for regulatory approval of BELVIQ in Canada.

Under the Eisai Agreement, we are eligible to receive up to an aggregate of \$176.5 million in additional regulatory and development milestone payments.

*Product Purchase Price and Purchase Price Adjustment Payments*

We manufacture BELVIQ at our facility in Switzerland, and sell BELVIQ to Eisai for Eisai's commercialization in the United States and, subject to applicable regulatory approval, in the other territories under the Eisai Agreement (other than Europe, China and Japan) for a purchase price starting at 31.5% and 30.75%, respectively (and starting at 27.5% in Europe, China and Japan), of Eisai's aggregate annual net product sales (which are the gross invoiced sales less certain deductions described in the Eisai Agreement), or the Product Purchase Price, in the respective territory. The Product Purchase Price will increase on a tiered basis in the United States and the other territories (other than Europe, China and Japan) to as high as 36.5% and 35.75%, respectively, on the portion of Eisai's annual aggregate net product sales exceeding \$750.0 million in all territories other than Europe, China and Japan. The Product Purchase Price will increase to 35% in Europe, China and Japan on the portion of Eisai's annual aggregate net product sales exceeding \$500.0 million in such territories. The Product Purchase Price is subject to reduction (for sales in a particular country), including in the event of generic competition in the applicable country. The revenue we recognize for BELVIQ product revenue related to redemption of vouchers is based on our cost of goods sold.

## **Table of Contents**

In addition to payments for purchases of BELVIQ, we are eligible to receive up to an aggregate of \$1.56 billion in one-time purchase price adjustment payments and other payments. These payments include up to an aggregate of \$1.19 billion that are based on Eisai's annual net product sales of BELVIQ in all of the territories under the Eisai Agreement on an aggregate basis, with the first and last amounts payable with annual net product sales of \$250.0 million and \$2.5 billion, respectively. Of these payments, Eisai will pay us a total of \$330.0 million for annual net product sales of up to \$1.0 billion. The \$1.56 billion also includes \$370.0 million in one-time purchase price adjustment payments we are eligible to receive in the non-US territories, comprised of \$185.0 million based on Eisai's annual net product sales in the non-US territories in North and South America and \$185.0 million based on Eisai's annual net product sales in the territories outside of North and South America. The first and last amounts are payable upon first achievement of annual net product sales of \$100.0 million and \$1.0 billion, respectively, with respect to each of the following areas: (i) the non-US territories in North and South America and (ii) the territories outside of North and South America. In addition, we are also eligible to receive certain payments by Eisai if certain annual minimum sales requirements in Mexico, Canada and Brazil are not met during the first ten years after initial commercial sale in such territories.

The amount that Eisai pays us for BELVIQ product supply is based on Eisai's estimated price at the time the order is shipped, which is Eisai's estimate of the Product Purchase Price, and is subject to change on April 1 and October 1 of each year. Eisai's estimate of the Product Purchase Price was changed as of October 1, 2013. At the end of Eisai's fiscal year (March 31), the estimated price paid to us for product that Eisai sold to their distributors is compared to the Product Purchase Price of such product, and the difference is either refunded back to Eisai (for overpayments) or paid to us (for underpayments). On a monthly basis, Eisai provides us the total amount of net product sales for the month, details of the total deductions from gross sales to net product sales and the sales in units. We recognize our revenues monthly based on our percentage of Eisai's monthly net product sales figures. When the revenues we recognize differ from the estimated price that Eisai paid us for such product, the difference is reclassified from deferred revenues to a receivable or payable account, as appropriate. We also adjust the deferred revenues balance for the product supply held at Eisai based on the most current net product sales figures provided to us, with the difference reclassified from deferred revenues to a receivable or payable account.

### *Development Payments*

In connection with the US approval of BELVIQ, the FDA is requiring (i) an evaluation of the effect of long-term treatment with BELVIQ on the incidence of major adverse cardiovascular events, or MACE, in overweight and obese patients with cardiovascular disease or multiple cardiovascular risk factors and (ii) the conduct of postmarketing studies to assess the safety and efficacy of BELVIQ for weight management in obese pediatric patients. In addition to the FDA-required studies, we and Eisai are prioritizing the development areas of smoking cessation, a once-daily formulation, co-administration with phentermine, as well as exploring, including as part of the CVOT, BELVIQ's effect on conversion to type 2 diabetes and improvements in cardiovascular outcomes.

**Table of Contents**

The below chart summarizes the general agreement regarding cost sharing between Eisai and us for significant development activities under the Eisai Agreement. In addition, Eisai or we may from time to time conduct approved development of BELVIQ at such party's own expense. For example, Eisai is responsible for the expenses of the pilot study of 12-week duration to preliminarily assess BELVIQ and phentermine when co-administered.

**Eisai Second Amended and Restated Marketing and Supply Agreement: Cost Sharing for Development  
Rest of**

	<b>United States</b>	<b>North and South America General</b>	<b>Remaining Territories</b>
<b>BELVIQ for weight management - Pre-approval*</b>	Not Applicable	Eisai: 90%; Arena: 10%	Up to total of \$100.0 million - Eisai: 50%; Arena: 50%
		<b>Certain stability work</b>	Thereafter, Eisai: 100%
		Eisai: 50%; Arena: 50%	
<b>BELVIQ for weight management - Post-approval*</b>	<b>General - Eisai: 90%; Arena 10%</b>	<b>General</b>	Up to total of \$50.0 million - Eisai: 50%; Arena: 50%
	<b>Non-FDA required portion of CVOT</b>		
	Up to \$80.0 million - Eisai: 50%; Arena: 50%	<b>Certain stability work</b>	Thereafter, Eisai: 90%; Arena: 10%
	Thereafter, Eisai: 100%	Eisai: 50%; Arena: 50%	
	<b>Certain pediatric studies</b>		
	Eisai: 50%; Arena: 50%		
<b>Products other than BELVIQ for weight management - Pre-approval</b>	Up to total of \$250.0 million (as reduced by up to \$80.0 million for non-FDA required portion of CVOT) - Eisai: 50%; Arena: 50%		
<b>Products other than BELVIQ for weight management - Post-approval</b>	Up to a total of \$100.0 million in the aggregate across all additional products - Eisai: 50%; Arena: 50%		
	Thereafter, Eisai: 90%; Arena: 10%		

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

\* Development required by a regulatory authority, with the exception of the non-FDA required portion of the CVOT.

### *Certain Other Terms*

Eisai and we have agreed to limitations on the ability to commercialize outside of the Eisai Agreement any weight management product or addiction disorder product in the territories under the agreement. The agreement includes a stand-still provision limiting Eisai's ability to acquire our securities and assets.

Eisai may terminate the Eisai Agreement with respect to any country in the territory following the later of the expiration of all issued BELVIQ patents in such country and 12 years after the first commercial sale of BELVIQ in such country. Arena GmbH and Eisai each has the right to terminate the Eisai Agreement early in certain circumstances in its entirety or with respect to the applicable country or product, including (a) if the other party is in material breach, (b) for commercialization concerns, and (c) for certain intellectual property infringement. Eisai also has the right to terminate the Eisai Agreement early in its entirety or with respect to each country in certain circumstances, including (i) termination in a country if sales of generic equivalents of BELVIQ in such country exceed sales of BELVIQ in that country (based on volume), and (ii) if Eisai is acquired by a company that has a product that competes with BELVIQ. In addition, Arena GmbH can terminate the Eisai Agreement early in its entirety or with respect to each country in the non-US territories in North and South America in certain circumstances, including termination in each country if Eisai does not satisfy certain regulatory filing and commercialization diligence requirements in such country.

---

**Table of Contents**

Eisai will indemnify us for losses resulting from certain third-party claims, including for (a) Eisai's negligence, willful misconduct or violation of law, but excluding product liability claims, (b) Eisai's breach of the Eisai Agreement or related agreements, but excluding product liability claims, (c) certain uses or misuses of BELVIQ, (d) certain governmental investigations of Eisai related to BELVIQ, and (e) infringement relating to Eisai's use of certain trademarks, tag lines and logos related to BELVIQ. Arena GmbH will indemnify Eisai for losses resulting from certain third-party claims, including for (i) Arena GmbH's negligence, willful misconduct, failure to comply with law, breach of any agreement with a third party with respect to product development prior to the effective date of the original agreement with Eisai, but excluding product liability claims, (ii) Arena GmbH's negligence or willful misconduct with respect to certain uses or misuses of BELVIQ outside of the agreement, (iii) certain uses or misuses of BELVIQ after the term of the agreement, in any territory no longer under the agreement or with respect to any product after the termination of the agreement with respect to such product, (iv) Arena GmbH's negligence, willful misconduct or violation of law, but excluding product liability claims, (v) Arena GmbH's breach of the Eisai Agreement or related agreements, but excluding product liability claims, (vi) certain infringement of intellectual rights of a third party, and (vii) infringement relating to Eisai's use of certain trademarks related to BELVIQ. We are unable to predict the maximum potential amount of any indemnification claims. As of December 31, 2013, we have not incurred any losses under these indemnification provisions.

Arena GmbH and Eisai will, in general, share equally in losses resulting from third-party product liability claims, except where one party's acts or omissions did not contribute to the events or circumstances leading to such product liability claim and the other party's actual willful misconduct, violation of law or breach of its obligations under the Eisai Agreement or certain other agreements between Arena GmbH and Eisai were the sole and direct cause of the product liability claim. We are unable to predict the range of loss from future product liability claims.

**Ildong Pharmaceutical Co., Ltd.**

*BELVIQ*

In November 2012, Arena GmbH entered into the Ildong BELVIQ Agreement. Under this agreement, we granted Ildong exclusive rights to commercialize BELVIQ in South Korea for weight loss or weight management in obese and overweight patients, subject to regulatory approval of BELVIQ by the South Korean Ministry of Food and Drug Safety, or MFDS. We also provide certain services and will manufacture and sell BELVIQ to Ildong. Under the Ildong BELVIQ Agreement, in addition to the upfront payment received, we are entitled to receive a milestone payment based on regulatory approval as well as payments from sales of BELVIQ.

Under the agreement, we received from Ildong an upfront payment of \$5.0 million, less withholding taxes, and will receive an additional \$3.0 million if and when BELVIQ is approved by the MFDS. We recorded this upfront payment as deferred revenue and are recognizing it as revenue ratably over approximately 14 years, which is the period in which we expect to provide services under the arrangement. For the years ended December 31, 2013, and 2012, we recognized revenues of \$0.5 million and \$0.1 million, respectively, under this agreement.

Ildong is responsible for the regulatory approval and, ultimately, commercialization of BELVIQ in South Korea for weight loss or weight management in obese and overweight patients, including related development and other costs and expenses. We will manufacture BELVIQ at our facility in Switzerland, and sell BELVIQ to Ildong for a purchase price starting at 35% of Ildong's annual net product sales (which are the gross invoiced sales less certain deductions described in the Ildong BELVIQ Agreement). The purchase price will increase on a tiered basis up to 45% on the portion of annual net product sales exceeding \$15.0 million. If certain annual net product sales amounts are not met, we can convert Ildong's right to commercialize BELVIQ in South Korea to be non-exclusive.

Ildong has agreed not to conduct activities outside of our agreement related to the approval or commercialization of any other pharmaceutical product for weight loss, weight management or obesity in South Korea. We have agreed not to conduct activities outside of our agreement related to the commercialization in South Korea of any pharmaceutical product containing BELVIQ intended for end use in weight loss or weight management in obese and overweight patients.

---

**Table of Contents**

Ildong will indemnify us for losses resulting from certain third-party claims, including for (a) Ildong's negligence, willful misconduct or violation of law, (b) Ildong's breach of the marketing and supply agreement or related agreements, (c) certain uses or misuses of BELVIQ (including any product liability claim and other claims relating to sales or development of BELVIQ in South Korea), (d) certain governmental investigations of Ildong related to BELVIQ, and (e) infringement relating to Ildong's use of trademarks related to BELVIQ. Arena GmbH will indemnify Ildong for losses resulting from certain third-party claims, including for (i) Arena GmbH's negligence, willful misconduct or violation of law, and (ii) Arena GmbH's breach of the marketing and supply agreement or related agreements.

Unless terminated earlier, the agreement with Ildong will continue in effect until the later of the expiration of all issued patents relating to BELVIQ in South Korea and 12 years after the first commercial sale of BELVIQ in South Korea. Either party has the right to terminate the agreement early in certain circumstances, including (a) if the other party is in material breach, (b) for certain commercialization concerns, and (c) for certain intellectual property concerns. Ildong also has the right to terminate the agreement early in certain circumstances, including if we notify Ildong that Ildong's right to commercialize BELVIQ in South Korea will become non-exclusive.

*Temanogrel*

In November 2012, we entered into the Ildong Temanogrel Agreement for temanogrel, our internally discovered inverse agonist of the serotonin 2A receptor. Under such agreement, we granted Ildong exclusive rights to commercialize temanogrel in South Korea for myocardial infarction, acute coronary syndrome, stroke, peripheral artery disease, and other cardiovascular diseases, subject to further development and regulatory approval of temanogrel. Initially, Ildong will be responsible for funding and conducting, under the direction of a joint steering committee, the next two planned clinical trials in this program: an additional Phase 1 trial in healthy volunteers and a Phase 2a proof-of-concept trial in patients. To date, we have not recognized any revenue under this agreement.

We will maintain ownership of temanogrel outside of South Korea, and have the rights to use data generated by Ildong for the development and potential commercialization of temanogrel outside of South Korea by us or other Arena licensees. In addition, Ildong has agreed to pay us a \$2.0 million development milestone if the planned additional Phase 1 and Phase 2a clinical trials conducted by Ildong support continued development and we or another Arena licensee initiates a Phase 2b clinical trial of temanogrel. We are also eligible to receive a royalty on net product sales of temanogrel in South Korea, and Ildong is eligible to receive a share of future payments received by us related to licensing transactions and sales of temanogrel in other territories.

Ildong will indemnify us for losses resulting from certain third-party claims, including for (a) Ildong's negligence, willful misconduct or violation of law, (b) Ildong's breach of the agreement, (c) certain uses or misuses of temanogrel (including any product liability claim and other claims relating to sales or development of temanogrel in South Korea), and (d) certain governmental investigations of Ildong related to temanogrel. We will indemnify Ildong for losses resulting from certain third-party claims, including for (i) our negligence, willful misconduct or violation of law, and (ii) our breach of the agreement.

Unless terminated earlier or extended, the agreement will continue in effect until the later of the expiration of all issued patents relating to temanogrel in South Korea and 10 years after the first commercial sale of temanogrel in South Korea. Either party has the right to terminate the agreement early in certain circumstances, including (a) if the other party is in material breach, (b) for certain commercialization concerns, and (c) for certain intellectual property concerns.

**CY Biotech Company Limited**

In July 2013, Arena GmbH entered into the CYB Agreement. Under this agreement, we granted CYB exclusive rights to commercialize BELVIQ in Taiwan for weight loss or weight management in obese and overweight patients, subject to regulatory approval of BELVIQ by the Taiwan Food and Drug Administration, or

---

## **Table of Contents**

TFDA. We also provide certain services and will manufacture and sell BELVIQ to CYB. In addition to the upfront payment received, we will receive payments from sales of BELVIQ under the CYB Agreement, and are eligible to receive purchase price adjustment payments based on CYB's annual net product sales, as well as a milestone payment upon approval of the first additional indication for BELVIQ by the TFDA. We received from CYB an upfront payment of \$2.0 million, net of withholding taxes, which was recorded as deferred revenue and will be recognized as revenue ratably over approximately 14 years, which is the period in which we expect to provide services under the arrangement. For the year ended December 31, 2013, we recognized revenues of \$0.1 million under this agreement.

CYB is responsible for the regulatory approval and, ultimately, commercialization of BELVIQ in Taiwan for weight loss or weight management in obese and overweight patients, including related development and other costs and expenses. We will manufacture BELVIQ at our facility in Switzerland, and sell BELVIQ to CYB for a purchase price starting at 45% of CYB's annual net product sales (which are the gross invoiced sales less certain deductions described in the CYB Agreement).

CYB has agreed not to conduct outside of our agreement activities related to the approval or commercialization of any other pharmaceutical product for weight loss, weight management or obesity in Taiwan. We have agreed not to outside of our agreement commercialize in Taiwan any pharmaceutical product containing BELVIQ intended for end use in weight loss or weight management in obese and overweight patients.

CYB will indemnify us for losses resulting from certain third-party claims, including for (a) CYB's negligence, willful misconduct or violation of law, (b) CYB's breach of the marketing and supply agreement or related agreements, (c) certain uses or misuses of BELVIQ (including any product liability claim and other claims relating to sales or development of BELVIQ in Taiwan), (d) certain governmental investigations of CYB related to BELVIQ, and (e) infringement relating to CYB's use of trademarks related to BELVIQ. Arena GmbH will indemnify CYB for losses resulting from certain third-party claims, including for (i) Arena GmbH's negligence, willful misconduct or violation of law, and (ii) Arena GmbH's breach of the marketing and supply agreement or related agreements.

Unless terminated earlier, the agreement with CYB will continue in effect until the later of the expiration of all issued patents relating to BELVIQ in Taiwan and 12 years after the first commercial sale of BELVIQ in Taiwan. Either party has the right to terminate the agreement early in certain circumstances, including (a) if the other party is in material breach, (b) for certain commercialization concerns, and (c) for certain intellectual property concerns.

## **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.

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, to a lesser extent, a manufacturing services agreement. Our collaborative agreements may

## **Table of Contents**

contain multiple elements including commercialization rights, services (joint steering committee and research and development services) and manufactured products. Consideration we receive under these arrangements may include upfront payments, research and development funding, cost reimbursements, milestone payments and payments for net product sales. We recognize revenue when (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred and title has passed, (iii) the price is fixed or determinable and (iv) collectability is reasonably assured. Any advance payments we receive in excess of amounts earned are classified as deferred revenues on our consolidated balance sheets. We defer recognition of revenue at the time we sell BELVIQ to Eisai because we presently do not have the ability to estimate product that may be returned to us. Instead, we recognize revenues from net product sales when Eisai ships BELVIQ to their distributors.

We manufacture and sell BELVIQ to Eisai for Eisai's marketing and distribution in the United States and, subject to applicable regulatory approval, in most territories worldwide. The net product sales price Eisai pays us for product supply for commercialization in the United States starts at 31.5% of their gross invoiced sales, less certain deductions described in the Eisai Agreement. The amount we recognize for BELVIQ product revenue related to redemption of vouchers is based on our cost of goods sold.

We adopted revised guidance on accounting for revenue arrangements involving multiple elements on January 1, 2011, on a prospective basis, for agreements we entered into or materially modified after adoption. This updated guidance (i) relates to whether multiple deliverables exist, how the deliverables in a revenue arrangement should be separated and how the consideration should be allocated, (ii) requires companies to allocate revenues in an arrangement using estimated selling prices of deliverables if a vendor does not have vendor-specific objective evidence or third-party evidence of selling price and (iii) eliminates the use of the residual method and requires companies to allocate revenues using the relative selling price method.

Since adoption of this guidance, we evaluate deliverables in a multiple-element arrangement to determine whether each deliverable represents a separate unit of accounting. A deliverable constitutes a separate unit of accounting when it has standalone value to the customer. If the delivered element does not have standalone value without one of the undelivered elements in the arrangement, we combine such elements and account for them as a single unit of accounting. We allocate the consideration to each unit of accounting at the inception of the arrangement based on the relative selling price.

For agreements that we entered into prior to adoption of the revised multiple-element guidance, if fair value exists for all elements in the arrangement, 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 the delivered element does not have standalone value without one of the undelivered elements in the arrangement, or fair value does not exist for certain undelivered elements, we combine such delivered and undelivered elements and account for them as a single unit of accounting.

Non-refundable upfront payments received under our collaborative agreements for commercialization rights have been deferred as such rights have not been deemed to have standalone value without the ongoing services required under the agreement. Such amounts are recognized as revenue on a straight-line basis over the period in which we expect to perform the services. Amounts we receive as reimbursement for our research and development expenditures are recognized as revenue as the services are performed.

Under the milestone method, we recognize revenue that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. A milestone is an event (i) that can be achieved in whole or in part on either our performance or on the occurrence of a specific outcome resulting from our performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved and (iii) that would result in additional payments being due us. A milestone payment is considered substantive when the consideration payable to us for each milestone (a) is consistent with our performance necessary to achieve the milestone or the increase in value to the collaboration resulting from our



## **Table of Contents**

performance, (b) relates solely to our past performance and (c) is reasonable relative to all of the other deliverables and payments under the arrangement. In making this assessment, we consider all facts and circumstances relevant to the arrangement, including factors such as the scientific, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required to achieve the respective milestone and whether any portion of the milestone consideration is related to future performance or deliverables. Other contingent-based payments received are recognized when 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.

**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 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.

**Income taxes.** Significant judgment is required by management to determine our provision for income taxes, our deferred tax assets and liabilities, and the valuation allowance to record against our net deferred tax assets, which are based on complex and evolving tax regulations throughout the world. Our tax calculation is impacted by tax rates in the jurisdictions in which we are subject to tax and the relative amount of income earned in each jurisdiction. Our deferred tax assets and liabilities are determined using the enacted tax rates expected to be in effect for the years in which those tax assets are expected to be realized.

The effect of an uncertain income tax position is recognized at the largest amount that is more-likely-than-not to be sustained under audit by the taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained.

The realization of our deferred tax assets is dependent upon our ability to generate sufficient future taxable income. We establish a valuation allowance when it is more-likely-than-not that the future realization of all or some of the deferred tax assets will not be achieved. The evaluation of the need for a valuation allowance is performed on a jurisdiction-by-jurisdiction basis, and includes a review of all available evidence, both positive and negative. As of December 31, 2013, we concluded that it was more-likely-than-not that our deferred tax assets would not be realized.

*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 February 2013, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2013-04, Liabilities (Topic 405): Obligations Resulting from Joint and Several Liability Arrangements for Which the Total Amount of the Obligation Is Fixed at the Reporting Date. Under ASU No. 2013-04, companies are required to measure such obligations as the sum of the amount that the reporting entity agreed to pay on the basis of its arrangements with co-obligors, as well as any additional amount the reporting entity expects to pay on behalf of its co-obligors. ASU No. 2013-04 is effective for reporting periods beginning after December 15, 2013. We do not expect the adoption of ASU No. 2013-04 to have a material impact on our consolidated financial statements.

## **Table of Contents**

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

#### ***Foreign Currency Exchange Risk***

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 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 (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.

#### ***Equity Price Risk***

We received preferred stock in connection with our collaboration with TaiGen Biotechnology Co., Ltd., which has since converted into common stock. This investment had a cost basis of zero from December 31, 2011, through December 31, 2013.

On January 17, 2014, TaiGen (under the name TaiGen Biopharmaceuticals Holding Limited ) completed an initial public offering and its common stock began to trade on the GreTai Securities Listed Market. Such market is deemed to be comparable to a US over-the-counter market, and, as such, the fair value of our investment in TaiGen became readily determinable under generally accepted accounting principles. As a result, we began to record our investment in TaiGen on our financial statements based on the trading price of TaiGen's common stock. As of January 17, 2014, our investment in TaiGen was valued at approximately \$49.1 million. This investment will continue to be recorded at fair value based on the trading price of TaiGen's common stock, with any unrealized gains or losses being recorded in accumulated other comprehensive income (loss) in the stockholders' equity section of our consolidated balance sheets until realized.

Our investment in TaiGen is subject to market price volatility. Fluctuations in the market price of publicly traded securities may result from perceived changes in the underlying economic characteristics of the issuer, the relative price of alternative investments, general market conditions and other factors.

A 10% increase or decrease in the fair value of our investment in TaiGen would result in an increase or decrease to the fair value of the investment of approximately \$4.9 million, and a corresponding gain or loss in accumulated other comprehensive income (loss). Because the market price for this investment is subject to ongoing fluctuation, the amount we may eventually realize from a subsequent sale of the investment may differ significantly from the reported amount. This hypothetical increase or decrease will likely be different from what actually occurs in the future, and the impact may differ from that quantified herein.

**Table of Contents**

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

**ARENA PHARMACEUTICALS, INC.**

**INDEX TO FINANCIAL STATEMENTS**

<u>Report of Independent Registered Public Accounting Firm</u>	87
<u>Consolidated Balance Sheets</u>	88
<u>Consolidated Statements of Operations and Comprehensive Loss</u>	89
<u>Consolidated Statements of Stockholders' Equity</u>	90
<u>Consolidated Statements of Cash Flows</u>	92
<u>Notes to Consolidated Financial Statements</u>	93

**Table of Contents**

**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders

Arena Pharmaceuticals, Inc.:

We have audited the accompanying consolidated balance sheets of Arena Pharmaceuticals, Inc. and subsidiaries (the Company) as of December 31, 2013 and 2012, and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2013. 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 audits.

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 audits provide 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, 2013 and 2012, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2013, in conformity with U.S. generally accepted accounting principles.

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, 2013, based on criteria established in *Internal Control Integrated Framework (1992)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 3, 2014, expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ KPMG LLP

San Diego, California

March 3, 2014

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

	December 31,	
	2013	2012
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 221,878	\$ 156,091
Accounts receivable	10,602	5,556
Inventory	12,759	6,058
Prepaid expenses and other current assets	3,571	3,454
<b>Total current assets</b>	<b>248,810</b>	<b>171,159</b>
Land, property and equipment, net	77,388	75,417
Intangibles, net	10,182	10,611
Other non-current assets	3,427	4,019
<b>Total assets</b>	<b>\$ 339,807</b>	<b>\$ 261,206</b>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable and other accrued liabilities	\$ 7,317	\$ 7,123
Payable to Eisai	19,305	0
Accrued compensation	4,205	3,087
Current portion of deferred revenues	37,861	15,453
Current portion of derivative liabilities	0	2,587
Current portion of lease financing obligations	2,056	1,664
<b>Total current liabilities</b>	<b>70,744</b>	<b>29,914</b>
Deferred rent	247	122
Deferred revenues, less current portion	101,329	47,282
Derivative liabilities, less current portion	4,892	12,455
Lease financing obligations, less current portion		
	70,738	72,794
<b>Commitments and contingencies</b>		
Stockholders' equity:		
Preferred stock, \$.0001 par value: 7,500,000 shares authorized and 0 shares issued and outstanding at December 31, 2013, and 2012	0	0
Common stock, \$.0001 par value: 367,500,000 shares authorized at December 31, 2013, and 2012; 218,816,242 shares issued and outstanding at December 31, 2013; 217,476,458 shares issued and outstanding at December 31, 2012	22	22
Additional paid-in capital	1,293,840	1,281,426
Accumulated other comprehensive income	5,728	5,489
Accumulated deficit	(1,207,733)	(1,188,298)
<b>Total stockholders' equity</b>	<b>91,857</b>	<b>98,639</b>

Total liabilities and stockholders' equity	\$ 339,807	\$ 261,206
--	------------	------------

See accompanying notes to consolidated financial statements.

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

(In thousands, except share and per share data)

	2013	Years ended December 31, 2012	2011
<b>Revenues:</b>			
Net product sales	\$ 5,702	\$ 0	\$ 0
Eisai collaborative revenue	72,416	23,617	6,770
Manufacturing services	2,690	3,817	5,338
Other collaborative revenue	586	153	611
<b>Total revenues</b>	<b>81,394</b>	<b>27,587</b>	<b>12,719</b>
<b>Operating Costs and Expenses:</b>			
Cost of product sales	1,803	0	0
Cost of manufacturing services	4,377	3,671	8,100
Research and development	66,468	54,112	58,706
General and administrative	31,681	26,226	24,248
Restructuring charges	0	0	3,467
Amortization of intangibles	0	691	997
<b>Total operating costs and expenses</b>	<b>104,329</b>	<b>84,700</b>	<b>95,518</b>
Loss from operations	(22,935)	(57,113)	(82,799)
<b>Interest and Other Income (Expense):</b>			
Interest income	89	119	117
Interest expense	(7,091)	(9,120)	(14,309)
Gain (Loss) from valuation of derivative liabilities	10,150	(13,425)	47
Loss on extinguishment of debt	0	(6,338)	(10,514)
Other	352	400	(1,766)
<b>Total interest and other income (expense), net</b>	<b>3,500</b>	<b>(28,364)</b>	<b>(26,425)</b>
Net loss	(19,435)	(85,477)	(109,224)
Deemed dividend related to beneficial conversion feature of convertible preferred stock	0	(2,824)	(2,260)
<b>Net loss allocable to common stockholders</b>	<b>\$ (19,435)</b>	<b>\$ (88,301)</b>	<b>\$ (111,484)</b>
Net loss per share allocable to common stockholders:			
Basic	\$ (0.09)	\$ (0.45)	\$ (0.80)
Diluted	\$ (0.09)	\$ (0.45)	\$ (0.80)
Shares used in calculating net loss per share allocable to common stockholders:			
Basic	218,104,323	196,523,708	139,170,725
Diluted	218,104,323	196,523,708	139,170,725

**Comprehensive Loss:**

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

Net loss	\$	(19,435)	\$	(85,477)	\$	(109,224)
Foreign currency translation gain (loss)		239		746		(223)
Comprehensive loss	\$	(19,196)	\$	(84,731)	\$	(109,447)

See accompanying notes to consolidated financial statements.



**Table of Contents****ARENA PHARMACEUTICALS, INC.****Consolidated Statements of Stockholders' Equity**

(In thousands, except share data)

	Convertible Preferred Stock		Common Stock			Treasury Stock	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Additional Paid-In Capital				
<b>Balance at December 31, 2010</b>		<b>\$ 0</b>	<b>121,515,805</b>	<b>\$ 12</b>	<b>\$ 1,068,634</b>	<b>\$ (23,070)</b>	<b>\$ 4,966</b>	<b>\$ (970,527)</b>	<b>\$ 80,015</b>
Issuance of common stock under employee stock purchase plan			272,014	1	314				315
Issuance of common stock to Deerfield			12,150,000	1	15,412				15,413
Issuance of Series C preferred stock to Deerfield	12,150	1			15,412				15,413
Issuance of common stock to Deerfield upon conversion of Series C preferred stock	(12,150)	(1)	12,150,000	1					
Beneficial conversion feature of Series C preferred stock					2,260				2,260
Deemed dividend related to beneficial conversion feature of Series C preferred stock					(2,260)				(2,260)
Exchange of Deerfield warrants					5,105				5,105
Share-based compensation expense, net of forfeitures					3,748				3,748
Restricted shares released from deferred compensation plan			5,000						
Translation loss							(223)		(223)
Net loss								(109,224)	(109,224)
<b>Balance at December 31, 2011</b>		<b>0</b>	<b>146,092,819</b>	<b>15</b>	<b>1,108,625</b>	<b>(23,070)</b>	<b>4,743</b>	<b>(1,079,751)</b>	<b>10,562</b>
Issuance of common stock upon exercise of options			1,071,661		4,657				4,657
Issuance of common stock under employee stock purchase plan			341,108		470				470
Issuance of common stock under equity line of credit			14,414,370	1	24,726				24,727
Issuance of common stock in public offering, net of offering costs of \$3,875			12,650,000	1	65,699				65,700
Issuance of common stock to Deerfield			9,953,250	1	14,560				14,561
Issuance of Series D preferred stock to Deerfield	9,953				14,561				14,561
Issuance of common stock to Deerfield upon conversion of Series D preferred stock	(9,953)		9,953,250	1					1
Issuance of common stock upon exercise of Deerfield warrants			23,000,000	3	39,199				39,202
Exchange of Deerfield warrants					3,803				3,803
Beneficial conversion feature of Series D preferred stock					2,824				2,824
Deemed dividend related to beneficial conversion feature of Series D preferred stock					(2,824)				(2,824)



**Table of Contents**

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Treasury Stock	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders Equity
	Shares	Amount	Shares	Amount					
Share-based compensation expense, net of forfeitures					5,072				5,072
Share-based compensation expense capitalized					54				54
Retirement of treasury stock						23,070		(23,070)	
Translation gain							746		746
Net loss								(85,477)	(85,477)
<b>Balance at December 31, 2012</b>		<b>0</b>	<b>217,476,458</b>	<b>22</b>	<b>1,281,426</b>	<b>0</b>	<b>5,489</b>	<b>(1,188,298)</b>	<b>98,639</b>
Issuance of common stock upon exercise of options			954,174		2,375				2,375
Issuance of common stock under employee stock purchase plan			334,360		852				852
Issuance of common stock upon vesting of restricted stock unit awards			41,250						
Issuance of common stock upon exercise of Series B warrant			10,000		88				88
Share-based compensation expense, net of forfeitures					9,024				9,024
Share-based compensation expense capitalized					75				75
Translation gain							239		239
Net loss								(19,435)	(19,435)
<b>Balance at December 31, 2013</b>		<b>\$ 0</b>	<b>218,816,242</b>	<b>\$ 22</b>	<b>\$ 1,293,840</b>	<b>\$ 0</b>	<b>\$ 5,728</b>	<b>\$ (1,207,733)</b>	<b>\$ 91,857</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>2013</b>	<b>2012</b>	<b>2011</b>
<b>Operating Activities</b>			
Net loss	\$ (19,435)	\$ (85,477)	\$ (109,224)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	7,733	9,055	10,127
Amortization of intangibles	469	691	997
Share-based compensation	9,024	5,072	3,748
(Gain) Loss from valuation of derivative liabilities	(10,150)	13,425	(47)
Amortization of prepaid financing costs	136	292	438
Accretion of note payable to Deerfield	0	1,225	4,146
Accretion of note payable to Siegfried	0	0	345
Investment write-down	0	0	1,963
Loss on extinguishment of debt	0	6,338	10,514
(Gain) Loss on disposal or sale of equipment	49	(31)	18
Changes in assets and liabilities:			
Accounts receivable	(4,473)	(5,260)	2,878
Inventory	(6,065)	(5,875)	0
Prepaid expenses and other assets	(65)	(1,524)	539
Accounts payable, payable to Eisai and accrued liabilities	19,572	276	(1,117)
Deferred revenues	75,880	17,849	(3,395)
Deferred rent	125	(103)	(187)
Net cash provided by (used in) operating activities	72,800	(44,047)	(78,257)
<b>Investing Activities</b>			
Purchases of land, property and equipment	(9,164)	(1,777)	(619)
Proceeds from sale of equipment	60	31	33
Other non-current assets	439	(425)	(86)
Net cash used in investing activities	(8,665)	(2,171)	(672)
<b>Financing Activities</b>			
Principal payments on lease financing obligations	(1,664)	(1,313)	(998)
Principal payments on note payable to Deerfield	0	(22,261)	(37,739)
Payments on note payable to Siegfried	0	0	(11,060)
Proceeds from issuance of common stock	3,315	151,218	17,977
Proceeds from issuance of preferred stock	0	16,462	17,662
Net cash provided by (used in) financing activities	1,651	144,106	(14,158)
Effect of exchange rate changes on cash	1	571	50
Net increase (decrease) in cash and cash equivalents	65,787	98,459	(93,037)
Cash and cash equivalents at beginning of year	156,091	57,632	150,669
Cash and cash equivalents at end of year	\$ 221,878	\$ 156,091	\$ 57,632
<b>Supplemental Disclosure Of Cash Flow Information:</b>			
Interest paid	\$ 6,954	\$ 7,670	\$ 9,492

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

### Supplemental Disclosure Of Non-Cash Investing and Financing Information:

Conversion of preferred stock into common stock	\$	0	\$	14,561	\$	15,413
Deemed dividend related to beneficial conversion feature of convertible preferred stock	\$	0	\$	2,824	\$	2,260
Retirement of treasury stock	\$	0	\$	23,070	\$	0
Purchases of land, property and equipment included in accounts payable and accrued liabilities	\$	72	\$	110	\$	46

See accompanying notes to consolidated financial statements.

---

**Table of Contents**

**ARENA PHARMACEUTICALS, INC.**

**Notes to Consolidated Financial Statements**

*BELVIQ® (pronounced BEL-VEEK ) is the trade name for the finished drug product containing the active pharmaceutical ingredient lorcaserin hydrochloride, or lorcaserin, that is marketed for chronic weight management in the United States. Lorcaserin may in the future be marketed in the United States or in other countries under a different trade name for chronic weight management. Lorcaserin may also be marketed under a different trade name for a different indication, in a different formulation or in combination with another drug. In this report, we use BELVIQ to refer to the finished drug product containing lorcaserin and/or, depending on the context, the active pharmaceutical ingredient lorcaserin, and without regard to the current or potential indication, formulation or combination.*

**(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 biopharmaceutical company focused on discovering, developing and commercializing novel drugs that target G protein-coupled receptors, or GPCRs, to address unmet medical needs. We operate in one business segment. Our US operations are located in San Diego, California, and our operations outside of the United States, including our commercial manufacturing facility, are located in Zofingen, Switzerland.

BELVIQ, our internally discovered drug for chronic weight management in adults who are overweight with a comorbidity or obese, is our first and only drug approved for marketing by any regulatory agency. In June 2013, BELVIQ was made available to patients by prescription in the United States by Eisai. Our wholly owned subsidiary, Arena Pharmaceuticals GmbH, or Arena GmbH, granted Eisai Inc. and Eisai Inc.'s parent company, Eisai Co., Ltd. (collectively with Eisai Inc., Eisai) exclusive commercialization rights to market BELVIQ in the all of the countries in the world, except for South Korea, Taiwan, Australia, New Zealand and Israel. Arena GmbH also granted exclusive commercialization rights to market BELVIQ to Ildong Pharmaceutical Co., Ltd., or Ildong, for South Korea and to CY Biotech Company Limited, or CYB, for Taiwan. We also intend to enter into collaborations for the potential regulatory approval and commercialization of BELVIQ in Australia, New Zealand and Israel.

The marketing of BELVIQ is subject to applicable regulatory approval. BELVIQ has been approved for marketing in the United States, but currently not in any other country.

With our collaborators or independently, we intend to continue to explore BELVIQ's therapeutic potential for additional indications, using new formulations and in combination with other drugs. We also intend to continue our research and development efforts to advance our earlier-stage drug candidates and to discover and advance additional compounds.

BELVIQ and our earlier-stage drug candidates and compounds have resulted from our GPCR-focused drug discovery and development approach, specialized expertise and technologies.

**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.

**New Accounting Guidance**

In February 2013, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2013-04, Liabilities (Topic 405): Obligations Resulting from Joint and Several Liability

**Table of Contents**

Arrangements for Which the Total Amount of the Obligation Is Fixed at the Reporting Date. Under ASU No. 2013-04, companies are required to measure such obligations as the sum of the amount that the reporting entity agreed to pay on the basis of its arrangements with co-obligors, as well as any additional amount the reporting entity expects to pay on behalf of its co-obligors. ASU No. 2013-04 is effective for reporting periods beginning after December 15, 2013. We do not expect the adoption of ASU No. 2013-04 to have a material impact on our consolidated financial statements.

**Use of Estimates**

The preparation of financial statements in conformity with US generally accepted accounting principles, or GAAP, requires our management to make estimates and assumptions that affect the reported amounts (including assets, liabilities, revenues and expenses) and related disclosures. The amounts reported could differ under different estimates and assumptions.

**Reclassifications**

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

**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.

**Inventory**

Inventory is stated at the lower of cost or market. We determine cost, which includes amounts related to materials, labor and overhead, using a first-in, first-out basis. We evaluate our inventory each period to identify potential obsolete, excess or otherwise non-saleable items. If non-saleable items are observed and there are no alternate uses for the inventory, we will record a write-down to net realizable value in the period that the decline in value is first recognized.

**Concentration of Credit Risk and Major Customers**

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

Eisai is our only significant customer for BELVIQ. Eisai is the exclusive distributor of BELVIQ in the United States, which is the only jurisdiction for which BELVIQ has received regulatory approval for marketing. We also produce drug products for Siegfried AG, or Siegfried, under a manufacturing services agreement, and all of our manufacturing services revenues are attributable to Siegfried.

Percentages of our total revenues are as follows:

	Year Ended December 31,		
	2013	2012	2011
Eisai marketing and supply agreement (See Note 12)	96.0%	85.6%	53.2%
Manufacturing services agreement with Siegfried	3.3%	13.8%	41.9%
Other collaborative agreements	0.7%	0.6%	4.9%
Total percentage of revenues	100.0%	100.0%	100.0%

**Table of Contents**

Percentages of our total accounts receivable are as follows:

	At December 31,		
	2013	2012	2011
Eisai marketing and supply agreement (See Note 12)	94.5%	2.0%	91.3%
Manufacturing services agreement with Siegfried	4.3%	12.3%	8.0%
Ildong marketing and supply agreement (See Note 12)	1.0%	85.5%	0.0%
Other collaborative agreements	0.2%	0.2%	0.7%
<b>Total percentage of accounts receivable</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>

**Property and Equipment**

Property and equipment are stated at cost and depreciated over the estimated useful lives of the assets (generally 3 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.

**Intangibles**

Intangible assets consist of our manufacturing facility production licenses we acquired from Siegfried in January 2008 and are amortized using the straight-line method over its estimated useful life of 20 years.

**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 flows. 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 sheets and no further adjustments to their valuation are made. Warrants classified as derivative liabilities and other derivative financial instruments that require separate accounting as liabilities are recorded on our consolidated balance sheets at their fair value on the date of issuance and are revalued on each balance sheet date until such instruments are exercised or expire, with changes in the fair value between reporting periods recorded as other income or expense. We estimate the fair value of our warrants classified as derivative liabilities using the Black-Scholes option pricing model.

**Foreign Currency Translation**

The functional currency of our wholly owned subsidiary in Switzerland, Arena GmbH, 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



## **Table of Contents**

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**

Our share-based awards are measured at fair value and recognized over the requisite service or performance period. The fair value of each stock option is estimated on the date of grant using the Black-Scholes option pricing model, based on the market price of the underlying common stock, expected life, expected stock price volatility and expected risk-free interest rate. Expected volatility is computed using a combination of historical volatility for a period equal to the expected term and implied volatilities from traded options to buy our common stock, with historical volatility being weighted at 75% due to the historically low volume of traded options on our common stock. The expected life of options is determined based on historical experience of similar awards, giving consideration to the contractual terms of the share-based awards, vesting schedules and post-vesting terminations. The risk-free interest rates are based on the US Treasury yield curve, with a remaining term approximately equal to the expected term used in the option pricing model. The fair value of each restricted stock unit award is estimated based on the market price of the underlying common stock on the date of the grant. The fair value of restricted stock unit awards that include market-based performance conditions is estimated on the date of grant using a Monte Carlo simulation model, based on the market price of the underlying common stock, expected performance measurement period, expected stock price volatility and expected risk-free interest rate. We estimate forfeitures at the time of grant and revise our estimate in subsequent periods if actual forfeitures differ from those estimates.

### **Revenue Recognition**

Our revenues to date have been generated primarily through collaborative agreements and, to a lesser extent, a manufacturing services agreement. Our collaborative agreements may contain multiple elements including commercialization rights, services (joint steering committee and research and development services) and manufactured products. Consideration we receive under these arrangements may include upfront payments, research and development funding, cost reimbursements, milestone payments and payments for net product sales. We recognize revenue when (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred and title has passed, (iii) the price is fixed or determinable and (iv) collectability is reasonably assured. Any advance payments we receive in excess of amounts earned are classified as deferred revenues. We defer recognition of revenue at the time we sell BELVIQ to Eisai because we presently do not have the ability to estimate product that may be returned to us. Instead, we recognize revenues from net product sales when Eisai ships BELVIQ to their distributors. See Note 12.

We adopted revised guidance on accounting for revenue arrangements involving multiple elements on January 1, 2011, on a prospective basis, for agreements we entered into or materially modified after adoption. This updated guidance (i) relates to whether multiple deliverables exist, how the deliverables in a revenue arrangement should be separated and how the consideration should be allocated, (ii) requires companies to allocate revenues in an arrangement using estimated selling prices of deliverables if a vendor does not have vendor-specific objective evidence or third-party evidence of selling price and (iii) eliminates the use of the residual method and requires companies to allocate revenues using the relative selling price method.

Since adoption of this guidance, we evaluate deliverables in a multiple-element arrangement to determine whether each deliverable represents a separate unit of accounting. A deliverable constitutes a separate unit of accounting when it has standalone value to the customer. If the delivered element does not have standalone value without one of the undelivered elements in the arrangement, we combine such elements and account for them as a single unit of accounting. We allocate the consideration to each unit of accounting at the inception of the arrangement based on the relative selling price.

## **Table of Contents**

For agreements that we entered into prior to adoption of the revised multiple-element guidance, if fair value exists for all elements in the arrangement, 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 the delivered element does not have standalone value without one of the undelivered elements in the arrangement, or fair value does not exist for certain undelivered elements, we combine such delivered and undelivered elements and account for them as a single unit of accounting.

Non-refundable upfront payments received under our collaborative agreements for commercialization rights have been deferred as such rights have not been deemed to have standalone value without the ongoing services required under the agreement. Such amounts are recognized as revenue on a straight-line basis over the period in which we expect to perform the services. Amounts we receive as reimbursement for our research and development expenditures are recognized as revenue as the services are performed.

Under the milestone method, we recognize revenue that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. A milestone is an event (i) that can be achieved in whole or in part on either our performance or on the occurrence of a specific outcome resulting from our performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved and (iii) that would result in additional payments being due us. A milestone payment is considered substantive when the consideration payable to us for each milestone (a) is consistent with our performance necessary to achieve the milestone or the increase in value to the collaboration resulting from our performance, (b) relates solely to our past performance and (c) is reasonable relative to all of the other deliverables and payments under the arrangement. In making this assessment, we consider all facts and circumstances relevant to the arrangement, including factors such as the scientific, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required to achieve the respective milestone and whether any portion of the milestone consideration is related to future performance or deliverables. Other contingent-based payments received are recognized when 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.

## **Research and Development Expenses**

Research and development expenses, which consist primarily of salaries and other personnel costs, clinical trial costs and preclinical study fees, manufacturing costs for non-commercial products, and the development of earlier-stage programs and technologies, are expensed as incurred when these expenditures have no alternative future uses.

We accrue clinical trial expenses based on work performed. Payments made to reimburse collaborators for our share of their research and development activities are recorded as research and development expenses, and are recognized as the work is performed.

## **Comprehensive Loss**

We report components of comprehensive income (loss), consisting of foreign currency translation gain and loss, 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 calculate basic and diluted net loss per share allocable to common stockholders using the weighted-average number of shares of common stock outstanding during the period.

**Table of Contents**

Since we are in a net loss position, we have excluded from our calculation of diluted net loss per share all potentially dilutive (i) stock options, (ii) restricted stock unit awards, or RSUs, (iii) Total Stockholder Return, or TSR, performance restricted stock unit, or PRSU, awards, (iv) invested restricted stock in our deferred compensation plan and (v) warrants, and our diluted net loss per share is the same as our basic net loss per share. The table below presents the potentially dilutive securities that were excluded from our calculation of diluted net loss per share allocable to common stockholders at December 31, 2013, 2012, and 2011, in thousands.

	December 31,		
	2013	2012	2011
Stock options	5,158	4,261	0
Warrants	776	607	0
RSUs and unvested restricted stock	74	303	40
Total	6,008	5,171	40

Because the market condition for the PRSUs was not satisfied at December 31, 2013, such securities are excluded from the table above.

**Income Taxes**

We use the asset and liability method of accounting for income taxes. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Our deferred tax assets and liabilities are determined using the enacted tax rates expected to be in effect for the years in which those tax assets are expected to be realized.

The realization of our deferred tax assets is dependent upon our ability to generate sufficient future taxable income. We establish a valuation allowance when it is more-likely-than-not the future realization of all or some of the deferred tax assets will not be achieved. The evaluation of the need for a valuation allowance is performed on a jurisdiction-by-jurisdiction basis, and includes a review of all available evidence, both positive and negative.

The impact of an uncertain income tax position is recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained.

**(2) 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 Significant unobservable inputs based on our assumptions.

**Table of Contents**

The following tables present our valuation hierarchy for our financial assets and liabilities that are measured at fair value on a recurring basis, in thousands:

	Fair Value Measurements at December 31, 2013			
	Balance at December 31, 2013	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 <sup>1</sup>	\$ 208,833	\$ 208,833	\$ 0	\$ 0
<i>Liabilities:</i>				
Warrants	\$ 4,892	\$ 0	\$ 4,892	\$ 0
	Fair Value Measurements at December 31, 2012			
	Balance at December 31, 2012	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 <sup>1</sup>	\$ 143,747	\$ 143,747	\$ 0	\$ 0
<i>Liabilities:</i>				
Warrants	\$ 15,042	\$ 0	\$ 15,042	\$ 0

<sup>(1)</sup> Included in cash and cash equivalents on our consolidated balance sheets.

Due to impairment charges, our investment in TaiGen Biotechnology Co., Ltd., or TaiGen, has had a cost basis of zero since December 31, 2011. In September 2013, TaiGen's common shares began to trade on the GreTai Securities Emerging Market, which is a thinly traded, over-the-counter market for pre-IPO securities, under the name TaiGen Biopharmaceuticals Holding Limited. As this market is not deemed to be comparable to a US over-the-counter market, the prices of securities traded on this market do not reflect fair value pursuant to the accounting guidance over marketable securities. Accordingly, through December 31, 2013, we continued to account for our investment in TaiGen as a cost method investment with a cost basis of zero. On January 17, 2014, TaiGen completed an initial public offering and its common stock began to trade on the GreTai Securities Listed Market, which is deemed to be comparable to a US over-the-counter market such that the fair value of our investment in TaiGen became readily determinable under the accounting guidance. We will record our investment in TaiGen, valued at approximately \$49.1 million on January 17, 2014, with the unrealized gain recorded as a component of accumulated other comprehensive income (loss) in the stockholders' equity section of our consolidated balance sheets. Our investment in TaiGen will continue to be recorded at fair value based on the trading price of TaiGen's common stock, with any unrealized gains or losses being recorded in accumulated other comprehensive income (loss) until realized.

**Table of Contents****(3) Inventory**

In June 2012, we began to capitalize inventory costs for BELVIQ, which were recorded as research and development expenses prior to regulatory approval. Inventory consisted of the following, in thousands:

	December 31,	
	2013	2012
Raw materials	\$ 657	\$ 423
Work in process	4,104	4,184
Finished goods at Arena GmbH	0	0
Finished goods at Eisai	7,998	1,451
<b>Total inventory</b>	<b>\$ 12,759</b>	<b>\$ 6,058</b>

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

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

	December 31,	
	2013	2012
Land	\$ 10,854	\$ 10,854
Building and capital improvements	67,747	67,436
Leasehold improvements	17,854	19,253
Machinery and equipment	55,143	49,840
Computers and software	11,568	9,719
Furniture and office equipment	2,207	2,230
	165,373	159,332
Less accumulated depreciation and amortization	(87,985)	(83,915)
<b>Land, property and equipment, net</b>	<b>\$ 77,388</b>	<b>\$ 75,417</b>

**(5) Intangibles**

Intangibles consisted of the following, in thousands:

	December 31,	
	2013	2012
Acquired manufacturing production licenses gross	\$ 14,545	\$ 14,148
Acquired manufacturing production licenses accumulated amortization	(4,363)	(3,537)
<b>Intangibles, net</b>	<b>\$ 10,182</b>	<b>\$ 10,611</b>

In June 2012 when we received US Food and Drug Administration, or FDA, approval for BELVIQ, we began to capitalize into inventory amortization expense related to the manufacturing of BELVIQ. Such amortization will subsequently be recognized as cost of product sales when the related inventory is sold. Using the exchange rate in effect on December 31, 2013, we expect to record amortization of \$0.7 million per year through 2027 for our manufacturing facility production licenses.



**Table of Contents****(6) Accounts Payable and Other Accrued Liabilities**

Accounts payable and other accrued liabilities consisted of the following, in thousands:

	December 31,	
	2013	2012
Accounts payable	\$ 3,721	\$ 3,884
Accrued expenses	1,477	2,006
Accrued clinical and preclinical study fees	1,317	566
Loss provision (See Note 7)	567	482
Other accrued liabilities	235	185
 Total accounts payable and other accrued liabilities	 \$ 7,317	 \$ 7,123

**(7) Agreements with Siegfried**

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. These assets are being used to manufacture BELVIQ as well as certain drug products for Siegfried. The purchase price under the asset purchase agreement consisted of cash consideration of CHF 31.8 million and common stock valued at \$8.0 million. We paid CHF 21.8 million, or \$19.6 million, of the cash consideration in January 2008 and paid the remaining CHF 10.0 million, or \$11.1 million, in 2011.

In connection with this transaction, we also entered into a long-term supply agreement for the active pharmaceutical ingredient of BELVIQ, a manufacturing services agreement and a technical services agreement with Siegfried. The sales prices under the manufacturing services agreement, as amended in 2011, 2012 and 2013, are below our cost to provide such services. Accordingly, we record loss provisions, classified in costs of manufacturing services, reflecting our best estimate of the losses to be incurred during the remainder of the agreement. Losses are determined to be the amount by which the estimated direct and indirect costs of the services rendered exceed the estimated total manufacturing services revenues that will be generated under the manufacturing services agreement. The remaining loss provision of \$0.6 million as of December 31, 2013, is recorded in accounts payable and other accrued liabilities on our consolidated balance sheets. See Note 6.

During the years ended December 31, 2013, 2012, and 2011, we recognized expenses of \$2.8 million, \$2.6 million and \$3.0 million, respectively, for services incurred under the technical services agreement. The technical services agreement provides us with administrative and other services to operate the facility.

**(8) Transactions with Deerfield**

In July 2009, pursuant to a Facility Agreement we entered into in June 2009, or the Facility Agreement, 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. We received net proceeds of \$95.6 million from this loan and had the right, at any time, to prepay any or all of the outstanding principal at par. In connection with the funding of this loan, we issued Deerfield warrants to purchase an aggregate of 28,000,000 shares of our common stock, which were exercisable until June 17, 2013, at an exercise price of \$5.42 per share. As described below, the Deerfield loan has been repaid in full and none of Deerfield's former warrants remain outstanding.

As of the July 2009 funding of the loan, we separately valued the following four components under the Facility Agreement: (i) the formerly outstanding \$100.0 million loan was valued at \$47.9 million on a relative fair value basis and recorded as a liability, (ii) the formerly outstanding warrants to purchase 28,000,000 shares

---

**Table of Contents**

of our common stock were valued at \$39.1 million on a relative fair value basis and recorded as additional paid-in capital, (iii) Deerfield's former right to loan us up to an additional \$20.0 million under the Facility Agreement, which we refer to as the Deerfield Additional Loan Election, was valued at \$9.5 million and classified as a liability and (iv) Deerfield's former ability to accelerate principal payments under the loan under certain circumstances was valued at \$0.5 million and classified as a liability.

As part of our various transactions with Deerfield subsequent to the funding of the loan, we amended the terms of the Facility Agreement, repaid portions of the loan and exchanged all of the original warrants for a lesser number of warrants at lower exercise prices. We exchanged certain of the warrants as part of equity financings with Deerfield in June 2010, March 2011, and January 2012. Other than the exercise period, the exercise price and certain provisions related to cashless exercise and early termination of the warrants, all of the warrants issued in exchange contained substantially the same terms as the original warrants. In May 2012, we repaid the remaining portion of our note payable to Deerfield.

In addition to various transactions with Deerfield that included warrant exchanges, the following Deerfield transactions occurred in the years ended December 31, 2012 and 2011 as follows:

In January 2011, we prepaid \$20.0 million of the then-outstanding principal balance on the loan. In connection with this 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 \$2.5 million in 2011.

In March 2011, Deerfield purchased 12,150,000 shares of our common stock at \$1.46 per share and 12,150 shares of our Series C Convertible Preferred Stock, or Series C Preferred, at \$1,460.00 per share. In April 2011, Deerfield converted all of the Series C Preferred into a total of 12,150,000 shares of common stock. The fair value of the common stock into which the Series C Preferred was convertible on the date of issuance exceeded the proceeds allocated to the Series C Preferred on a relative fair value basis by \$2.3 million, resulting in a beneficial conversion feature that we recognized as a decrease to additional paid-in capital and a deemed dividend to the Series C Preferred stockholders in 2011. Net proceeds to us from this transaction, after prepayment of \$17.7 million of the then-outstanding principal balance on the loan, were \$17.6 million. In conjunction with this transaction, we agreed to exchange warrants to purchase 14,368,590 shares of our common stock at an exercise price of \$3.45 per share for new warrants to purchase a like number of shares of our common stock at an exercise price of \$1.68 per share. On a relative fair value basis, we determined that the incremental value of these new warrants was \$5.1 million, which was recorded as a component of the stock issuance and warrant exchange. With respect to the \$17.7 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 \$8.0 million, which, along with the January 2011 amount above, totaled \$10.5 million in 2011.

In January 2012, Deerfield purchased 9,953,250 shares of our common stock at \$1.65775 per share and approximately 9,953 shares of our Series D Convertible Preferred Stock, or Series D Preferred, at \$1,657.75 per share. In February 2012, Deerfield converted all of the Series D Preferred into a total of 9,953,250 shares of common stock. The fair value of the common stock into which the Series D Preferred was convertible on the date of issuance of the Series D Preferred exceeded the proceeds allocated to the Series D Preferred on a relative fair value basis by \$2.8 million, resulting in a beneficial conversion feature that we recognized as a decrease to additional paid-in capital and a deemed dividend to the Series D Preferred stockholders in 2012. Net proceeds to us from this transaction, after prepayment of \$5.0 million of the then-outstanding principal balance on the loan, were \$27.9 million. In conjunction with this transaction, we issued Deerfield warrants to purchase 8,631,410 shares of our common stock at an exercise price of \$1.745 per share in exchange for the cancellation of outstanding warrants to purchase 11,800,000 shares of our common stock at an exercise price of \$5.42 per share and outstanding warrants to purchase 1,831,410 shares of our common stock at an exercise price of \$3.45 per share. On a relative fair value basis, we determined that the incremental



**Table of Contents**

value of these new warrants was \$3.8 million, which was recorded as a component of the stock issuance and warrant exchange. With respect to the \$5.0 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 \$1.7 million in 2012.

In April and May 2012, Deerfield exercised certain of its warrants to purchase a total of 4,000,000 shares of our common stock, and elected to pay the exercise price by canceling \$6.7 million of the then-outstanding principal balance on its loan. In May 2012, we prepaid the remaining outstanding principal balance and unpaid interest on the Deerfield loan, and the Facility Agreement was terminated. In connection with these transactions, we retired the related debt discount and issuance costs and recognized a non-cash loss on extinguishment of debt of \$4.7 million, which, along with the January 2012 amount above, totaled \$6.4 million in 2012.

From June to August 2012, we received net proceeds totaling \$32.5 million from the cash exercise of Deerfield's remaining warrants to purchase a total of 19,000,000 shares of our common stock.

The following table summarizes the principal repayments made on the Deerfield loan from its inception through the date it was repaid in full, in thousands:

	<b>Loan Principal</b>
Original loan principal	\$ 100,000
July 2009 repayment	(10,000)
August 2010 repayment	(30,000)
January 2011 repayment	(20,000)
March 2011 repayment	(17,739)
January 2012 repayment	(5,000)
April and May 2012 cancellations as part of warrant exercises	(6,720)
May 2012 repayment	(10,541)
<b>Outstanding principal balance at December 31, 2012</b>	<b>\$ 0</b>

Total interest expense of \$1.9 million and \$6.6 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 in the years ended December 31, 2012, and 2011, respectively.

**(9) 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. As a result of the warrants anti-dilution provision and certain subsequent equity issuances at prices below the adjustment price of \$6.72 defined in the Series B Warrants, the number of shares issuable upon exercise of the warrants increased and the exercise price decreased. In June 2013, a portion of the June 2006 Series B Warrant was exercised to purchase 10,000 shares of our common stock, resulting in net proceeds to us of \$0.1 million, and the remaining portion of the June 2006 Series B Warrant to purchase 1,457,405 shares of common stock expired pursuant to its terms in June 2013. As of December 31, 2013, the number of shares issuable upon exercise of the outstanding August 2008 Series B Warrant was 1,965,418 at an exercise price of \$4.34 per share. The outstanding August 2008 Series B Warrant is recorded as a derivative liability on our consolidated balance sheets.

**Table of Contents**

Our derivative liabilities consisted of the following as of December 31, 2013, and 2012, in thousands:

	December 31	
	2013	2012
Series B Warrants current portion	\$ 0	\$ 2,587
Total current derivative liabilities	0	2,587
Series B Warrants, less current portion	4,892	12,455
Total long-term derivative liabilities	4,892	12,455
<b>Total derivative liabilities</b>	<b>\$ 4,892</b>	<b>\$ 15,042</b>

Our outstanding warrants are revalued on each balance sheet date, with changes in the fair value between reporting periods recorded as other income or expense. At December 31, 2013, and 2012, our outstanding warrants were valued using the Black-Scholes option pricing model and the following assumptions:

	December 31, 2013	December 31, 2012	
	August 2008 Series B Warrant	June 2006 Series B Warrant	August 2008 Series B Warrant
Risk-free interest rate	0.4%	0.1%	0.3%
Dividend yield	0%	0%	0%
Expected volatility	64%	66%	93%
Expected life (years)	1.62	0.50	2.62

The change in the fair value of our derivative liabilities between reporting periods is recorded in the interest and other income (expense) section of our consolidated statements of operations and comprehensive loss. We recognized the following gain (loss) in the years ended December 31, 2013, 2012, and 2011, in thousands:

	December 31,		
	2013	2012	2011
Series B Warrants	\$ 10,150	\$ (13,480)	\$ (328)
Former Deerfield acceleration right	0	55	375
<b>Total gain (loss) from valuation of derivative liabilities</b>	<b>\$ 10,150</b>	<b>\$ (13,425)</b>	<b>\$ 47</b>

The Deerfield acceleration right, which we separately valued at \$0.5 million as of the July 2009 issuance date and previously recorded as a derivative liability, related to a formerly outstanding right to require us to accelerate principal payments under our formerly outstanding loan from certain Deerfield entities. Until this right was terminated in connection with the repayment of the Deerfield loan in May 2012 (see Note 8), such right was revalued on each balance sheet date, with changes in the fair value between reporting periods recorded as other income or expense.

**(10) Commitments**

We occupy four US properties under sale and leaseback agreements that allow us the option to repurchase these properties at various dates between 2017 and 2027 and, in some cases, include renewal options. The terms of these leases stipulate annual increases in monthly rental payments of 2.5%. We accounted for our sale and leaseback transactions using the required financing method because our options to repurchase

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

these properties in the future are considered continued involvement. 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

**Table of Contents**

interest expense. We recorded interest expense of \$7.1 million, \$7.2 million and \$7.3 million in the years ended December 31, 2013, 2012, and 2011, respectively, related to these leases. We expect interest expense related to our facilities to total \$57.2 million from December 31, 2013, through the terms of the leases. As of December 31, 2013, the total financing obligation for these facilities was \$72.8 million. The aggregate residual value of the facilities at the end of the lease terms is \$10.0 million.

We lease an additional US property under an operating lease, which expires in May 2027 and stipulates annual increases in monthly rental payments of 2.5%. We also lease space in various facilities in Zofingen, Switzerland that can be terminated with 12 months written notice under an agreement that expires in 2032.

In accordance with the lease terms for certain of our US 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 and \$1.5 million were recorded in other non-current assets on our consolidated balance sheets as of December 31, 2013, and 2012, respectively, related to such leases.

We recognize rent expense on a straight-line basis over the term of each lease. Rent expense of \$1.1 million, \$1.7 million and \$1.2 million was recognized in the years ended December 31, 2013, 2012, and 2011, respectively.

Annual future obligations as of December 31, 2013, are as follows, in thousands:

Year ending December 31,	Financing Obligations	Operating Leases
2014	\$ 8,090	\$ 873
2015	9,036	841
2016	9,262	863
2017	9,494	884
2018	9,731	906
Thereafter	74,381	8,580
<b>Total minimum lease payments</b>	<b>119,994</b>	<b>\$ 12,947</b>
Less amounts representing interest	(57,190)	
Add amounts representing residual value	9,990	
Lease financing obligations	72,794	
Less current portion	(2,056)	
	<b>\$ 70,738</b>	

**(11) Stockholders Equity****Equity Compensation Plans**

On June 10, 2013, our stockholders approved our 2013 Long-Term Incentive Plan, or 2013 LTIP. Upon such approval, our 2012 Long-Term Incentive Plan, or 2012 LTIP, was terminated. However, notwithstanding such termination or the previous termination of our 2009 Long-Term Incentive Plan, 2006 Long-Term Incentive Plan, as amended, 2002 Equity Compensation Plan, Amended and Restated 2000 Equity Compensation Plan, and Amended and Restated 1998 Equity Compensation Plan (together with the 2012 LTIP, the Prior Plans), all outstanding awards under the Prior Plans will continue to be governed under the terms of the Prior Plans. The number of shares of common stock authorized for issuance under the 2013 LTIP may be increased by the number of shares subject to any stock awards under the Prior Plans that are forfeited, expire or otherwise terminate without the issuance of such shares and would otherwise be returned to the share reserve under the Prior Plans but for their termination and as otherwise provided in the 2013 LTIP.

**Table of Contents**

The 2013 LTIP provides for the grant of a total of 30 million shares of our common stock (subject to adjustment for certain corporate events), as (i) decreased for grants made under the Prior Plans between December 31, 2012, and the approval of the 2013 LTIP and (ii) increased by the number of shares subject to any stock awards under the Prior Plans that, between December 31, 2012, and the approval of the 2013 LTIP, are forfeited, expire or settled for cash and as otherwise provided in the 2013 LTIP.

Shares under the 2013 LTIP may be granted as incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards and performance awards. Subject to certain limited exceptions, stock options and stock appreciation rights granted under the 2013 LTIP reduce the available number of shares by one share for every share issued while awards other than stock options and stock appreciation rights granted under the 2013 LTIP reduce the available number of shares by 1.25 shares for every share issued. In addition, shares that are released from awards granted under the Prior Plans or the 2013 LTIP because the awards expire, are forfeited or are settled for cash will increase the number of shares available under the 2013 LTIP by one share for each share released from a stock option or stock appreciation right and by 1.25 shares for each share released from awards other than stock options and stock appreciation rights.

Stock options granted under the 2013 LTIP generally vest 25% a year for four years and are exercisable for up to seven years from the date of grant. The recipient of a restricted stock award has all rights of a stockholder at the date of grant, subject to certain restrictions on transferability and a risk of forfeiture. Restricted stock unit awards generally vest over one or four years from the date of grant. The minimum performance period under a performance award is 12 months. Neither the exercise price of an option nor the grant price of a stock appreciation right may be less than 100% of the fair market value of the common stock on the date such equity award is granted, except in specified situations. The 2013 LTIP prohibits option and stock appreciation right repricings (other than to reflect stock splits, spin-offs or certain other corporate events) without stockholder approval.

In 2003, we set up a deferred compensation plan for our executive officers, whereby executive officers elected to contribute their shares of restricted stock into the plan. There were 79,169 shares of restricted stock in the plan at December 31, 2013, 2012 and 2011.

The following table summarizes our stock option activity under the Prior Plans and the 2013 LTIP, or collectively, our Equity Compensation Plans, for the year ended December 31, 2013, in thousands (except per share data):

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2012	13,842	\$ 4.44		
Granted	2,082	7.58		
Exercised	(954)	2.49		
Forfeited/cancelled/expired	(289)	5.98		
Outstanding at December 31, 2013	14,681	\$ 4.99	6.19	\$ 31,782
Vested and expected to vest at December 31, 2013	14,186	\$ 4.97	6.15	\$ 30,961
Vested and exercisable at December 31, 2013	7,244	\$ 6.07	4.95	\$ 11,999

The aggregate intrinsic value in the above table is calculated as the difference between the closing price of our common stock at December 31, 2013, of \$5.85 per share and the exercise price of stock options that had strike prices below the closing price. The intrinsic value of all stock options exercised during the years ended December 31, 2013, and 2012 was \$4.6 million and \$5.4 million, respectively, and there were no stock options

**Table of Contents**

exercised in 2011. During the year ended December 31, 2013, cash of \$2.4 million was received from stock option exercises and cash of \$0.9 million was received from stock purchases under the employee stock purchase plans. There is no tax impact related to share-based compensation or stock option exercises because we are in a net operating loss position with a full valuation allowance.

In June 2013, we granted to our non-employee directors 131,096 RSUs that vest in equal monthly installments over one year from the date of grant, and will convert to the underlying common shares at the earliest of (i) the three-year anniversary of the grant date, (ii) the director's separation from service or (iii) a change in control of Arena. In December 2013, we granted to our executive officers 180,000 RSUs that vest 25% per year over four years from the date of grant. The following table summarizes activity with respect to our time-based RSUs under our Equity Compensation Plans for the year ended December 31, 2013, in thousands (except per share data):

	RSUs	Weighted-Average Grant-Date Fair Value	Aggregate Intrinsic Value
Unvested at January 1, 2013	165	\$ 8.87	
Granted	311	6.91	
Vested	(107)	8.83	
Forfeited/cancelled	0		
Unvested at December 31, 2013	369	\$ 7.23	
Outstanding at December 31, 2013	435	\$ 8.31	\$ 2,544

The total fair value of RSUs vested during the year ended December 31, 2013, was \$0.9 million.

In March 2013, we granted PRSU awards to our executive officers. The PRSUs may be earned and converted into outstanding shares of our common stock based on the TSR of our common stock relative to the TSR over a three-year performance period beginning March 1, 2013, of the NASDAQ Biotech Index. In the aggregate, the target number of shares of common stock that may be earned under the PRSUs is 780,000; however, the actual number of shares that may be earned ranges from 0% to 200% of such amount based on our TSR performance. As these awards contain a market condition, we used a Monte Carlo simulation model to estimate their grant-date fair value, which totaled \$5.9 million and will be recognized over the performance period. The aggregate intrinsic value of the outstanding PRSUs as of December 31, 2013, was \$4.6 million. All of the PRSUs were outstanding and unvested at December 31, 2013.

**Employee Stock Purchase Plans**

In June 2012, our stockholders approved our 2009 Employee Stock Purchase Plan, as amended, or 2009 ESPP, which (i) increased the shares of our common stock authorized and available for future issuance under the plan to a total of 1,500,000 as of June 15, 2012, (ii) modified the plan's automatic transfer to a lower price offering period to be based on the enrollment date of a new offering period instead of the exercise date of the immediately preceding offering period, (iii) eliminated references to our former 2001 Employee Stock Purchase Plan, as amended, and (iv) changed the termination date of the plan to the date our Board of Directors determines to terminate the plan. Under applicable accounting guidance, the 2009 ESPP is considered a compensatory plan. As of December 31, 2013, a total of 900,659 shares of common stock were available for issuance under the 2009 ESPP.

Under the 2009 ESPP, substantially all employees can choose to have up to 15% of their annual compensation withheld to purchase up to 625 shares of common stock per purchase period, subject to certain limitations. The shares of common stock may be purchased over an offering period with a maximum duration of

**Table of Contents**

24 months and at a price of not less than 85% of the lesser of the fair market value of the common stock on (i) the first trading day of the applicable offering period or (ii) the last trading day of the applicable three-month purchase period.

During the years ended December 31, 2013, 2012, and 2011, 334,360, 341,108 and 272,014 shares, respectively, were purchased under our 2009 ESPP.

**Share-based Compensation**

We estimate the grant-date fair value of all of our share-based awards in determining our share-based compensation expense. Our share-based awards include (i) stock options, (ii) options to purchase stock granted under our employee stock purchase plan, (iii) restricted stock unit awards, or RSUs, and (iv) Total Stockholder Return, or TSR, performance restricted stock unit, or PRSU, awards.

The table below sets forth the weighted-average assumptions and estimated fair value of stock options we granted under our Equity Compensation Plans during the years ended December 31, 2013, 2012, and 2011:

	December 31,		
	2013	2012	2011
Risk-free interest rate	1.3%	1.4%	2.2%
Dividend yield	0%	0%	0%
Expected volatility	80%	90%	86%
Expected life (years)	6.24	6.05	5.86
Weighted-average estimated fair value per share of stock options granted	\$ 5.25	\$ 2.27	\$ 1.06

The table below sets forth the assumptions and estimated fair value of the options to purchase stock granted under our employee stock purchase plan for multiple offering periods during the years ended December 31, 2013, 2012, and 2011:

	December 31,		
	2013	2012	2011
Risk-free interest rate	0.0% - 0.5%	0.0% - 0.7%	0.0% - 1.1%
Dividend yield	0%	0%	0%
Expected volatility	79% - 105%	85% - 106%	71% - 106%
Expected life (years)	0.25 - 2.0	0.25 - 2.0	0.25 - 2.0
Range of fair value per share of options granted under employee stock purchase plan	\$0.90 to \$5.44	\$0.56 to \$5.44	\$0.56 to \$3.28

The table below sets forth the assumptions and estimated fair value of PRSU awards at the March 5, 2013, date of grant:

Risk-free interest rate	0.4%
Dividend yield	0%
Expected volatility	89%
Remaining performance period (years)	2.99
Estimated fair value per share of PRSUs granted	\$ 7.50

**Table of Contents**

We recognized share-based compensation expense as follows, in thousands, except per share data:

	December 31,		
	2013	2012	2011
Cost of product sales	\$ 17	\$ 0	\$ 0
Research and development	4,318	1,822	1,958
General and administrative	4,689	3,250	1,696
Restructuring charges	0	0	94
<b>Total share-based compensation expense and impact on net loss allocable to common stockholders</b>	<b>\$ 9,024</b>	<b>\$ 5,072</b>	<b>\$ 3,748</b>
Impact on net loss per share allocable to common stockholders, basic and diluted	\$ 0.04	\$ 0.03	\$ 0.03
Share-based compensation capitalized into inventory	\$ 75	\$ 54	\$ 0

In June 2012, we began to capitalize into inventory share-based compensation related to awards granted to employees involved with the manufacturing of BELVIQ. Such compensation will subsequently be recognized as cost of product sales when the related inventory is sold.

The table below sets forth our total unrecognized estimated compensation expense at December 31, 2013, by type of award and the weighted-average remaining requisite service period over which such expense is expected to be recognized:

	December 31, 2013	
	Unrecognized Expense (in thousands)	Remaining Weighted-Average Recognition Period (in years)
Unvested stock options	\$ 16,055	2.35
RSUs	2,695	3.00
PRsUs	4,236	2.16

**Common Stock Reserved for Future Issuance**

The following shares of our common stock are reserved for future issuance at December 31, 2013, in thousands:

Outstanding warrants	1,965
Equity Compensation Plans	43,056
2009 ESPP	901
Deferred compensation plan	79
<b>Total</b>	<b>46,001</b>

**(12) Collaborations****Eisai**

In November 2013, Arena GmbH and Eisai entered into the Second Amended and Restated Marketing and Supply Agreement, or Eisai Agreement, which amended and restated the previous agreement and expanded Eisai's exclusive commercialization rights for BELVIQ to all of the countries in the world, except for South Korea, Taiwan, Australia, New Zealand and Israel. Eisai's commercialization rights are subject to applicable





**Table of Contents**

regulatory approval. In addition to providing commercialization rights, we provide services related to development and regulatory activities, and we manufacture and sell BELVIQ to Eisai. Under the Eisai Agreement, we are entitled to receive upfront payments, milestone payments based on the achievement of regulatory filings and approvals, one-time purchase price adjustment payments and other payments, and payments from sales of BELVIQ.

Arena GmbH and Eisai Inc. entered into the original marketing and supply agreement in July 2010, under which we granted Eisai Inc. exclusive commercialization rights for BELVIQ solely in the United States and its territories and possessions. In May 2012, Arena GmbH and Eisai Inc. amended and restated such agreement by entering into the first amended agreement, which expanded Eisai Inc.'s exclusive commercialization rights to include most of North and South America.

The following table summarizes the revenues we have recognized under our collaboration with Eisai for the periods presented, in thousands:

	December 31,			From Inception
	2013	2012	2011	Through December 31, 2013
Milestone payments	\$ 66,000	\$ 20,000	\$ 0	\$ 86,000
Net product sales	5,702	0	0	5,702
Amortization of upfront payments	4,035	3,503	3,434	12,895
Reimbursement of research and development expenses	2,020	27	3,336	5,383
Reimbursement of patent expenses	361	87	0	448
Total	\$ 78,118	\$ 23,617	\$ 6,770	\$ 110,428

The following table summarizes the deferred revenues under our collaboration with Eisai as of December 31, 2013, and 2012, in thousands:

	December 31,	
	2013	2012
Upfront payments	\$ 102,104	\$ 46,140
Net product sales	30,299	11,594
Total deferred revenues attributable to Eisai	132,403	57,734
Less current portion	(37,301)	(15,040)
Deferred revenues attributable to Eisai, less current portion	\$ 95,102	\$ 42,694

**Upfront and Milestone Payments**

In connection with entering into the Eisai Agreement, we received from Eisai an upfront payment of \$60.0 million. This payment is in addition to the \$50.0 million and \$5.0 million in upfront payments we received from Eisai in connection with entering into the original agreement and the first amended agreement, respectively. Revenues from these upfront payments have been deferred, as we determined that the exclusive rights did not have standalone value without our ongoing development and regulatory activities. Accordingly, these payments are recognized ratably as revenue over the periods in which we expect the services to be rendered, which are approximately 15, 16 and 15 years for the Eisai Agreement, original agreement and first amended agreement, respectively.

In addition to the upfront payments, we have received from Eisai a total of \$86.0 million in milestones payments, comprised of (i) \$65.0 million in 2013 earned upon the final scheduling designation for BELVIQ by the US Drug Enforcement Administration, or DEA, (ii) \$20.0 million earned in 2012 for the inclusion in the



---

**Table of Contents**

approved prescribing information of the FDA of the efficacy and safety data from the Phase 3 BLOOM-DM (Behavioral modification and Lorcaserin for Overweight and Obesity Management in Diabetes Mellitus) clinical trial in patients with type 2 diabetes, (iii) \$0.5 million earned in 2013 upon Eisai filing for regulatory approval of BELVIQ in Mexico and (iv) \$0.5 million earned in 2013 upon Eisai filing for regulatory approval of BELVIQ in Canada.

Under the Eisai Agreement, we are eligible to receive up to an aggregate of \$176.5 million in additional regulatory and development milestone payments.

**Product Purchase Price and Purchase Price Adjustment Payments**

We manufacture BELVIQ at our facility in Switzerland, and sell BELVIQ to Eisai for Eisai's commercialization in the United States and, subject to applicable regulatory approval, in the other territories under the Eisai Agreement (other than Europe, China and Japan) for a purchase price starting at 31.5% and 30.75%, respectively (and starting at 27.5% in Europe, China and Japan), of Eisai's aggregate annual net product sales (which are the gross invoiced sales less certain deductions described in the Eisai Agreement), or the Product Purchase Price, in the respective territory. The Product Purchase Price will increase on a tiered basis in the United States and the other territories (other than Europe, China and Japan) to as high as 36.5% and 35.75%, respectively, on the portion of Eisai's annual aggregate net product sales exceeding \$750.0 million in all territories other than Europe, China and Japan. The Product Purchase Price will increase to 35% in Europe, China and Japan on the portion of Eisai's annual aggregate net product sales exceeding \$500.0 million in such territories. The Product Purchase Price is subject to reduction (for sales in a particular country), including in the event of generic competition in the applicable country. The revenue we recognize for BELVIQ product revenue related to redemption of vouchers is based on our cost of goods sold.

In addition to payments for purchases of BELVIQ, we are eligible to receive up to an aggregate of \$1.56 billion in one-time purchase price adjustment payments and other payments. These payments include up to an aggregate of \$1.19 billion that are based on Eisai's annual net product sales of BELVIQ in all of the territories under the Eisai Agreement on an aggregate basis, with the first and last amounts payable with annual net product sales of \$250.0 million and \$2.5 billion, respectively. Of these payments, Eisai will pay us a total of \$330.0 million for annual net product sales of up to \$1.0 billion. The \$1.56 billion also includes \$370.0 million in one-time purchase price adjustment payments we are eligible to receive based on annual net product sales in the non-US territories, comprised of \$185.0 million based on Eisai's annual net product sales in the non-US territories in North and South America and \$185.0 million based on Eisai's annual net product sales the territories outside of North and South America. The first and last amounts are payable upon first achievement of annual net product sales of \$100.0 million and \$1.0 billion, respectively, with respect to each of the following areas: (i) the non-US territories in North and South America and (ii) the territories outside of North and South America. In addition, we are also eligible to receive certain payments by Eisai if certain annual minimum sales requirements in Mexico, Canada and Brazil are not met during the first ten years after initial commercial sale in such territories.

The amount that Eisai pays us for BELVIQ product supply is based on Eisai's estimated price at the time the order is shipped, which is Eisai's estimate of the Product Purchase Price, and is subject to change on April 1 and October 1 of each year. Eisai's estimate of the Product Purchase Price was changed as of October 1, 2013. At the end of Eisai's fiscal year (March 31), the estimated price paid to us for product that Eisai sold to their distributors is compared to the Product Purchase Price of such product, and the difference is either refunded back to Eisai (for overpayments) or paid to us (for underpayments). On a monthly basis, Eisai provides us the total amount of net product sales for the month, details of the total deductions from gross to net product sales and the sales in units. We recognize our revenues monthly based on our percentage of Eisai's monthly net product sales figures. When the revenues we recognize differ from the estimated price that Eisai paid us for such product, the difference is reclassified from deferred revenues to a receivable or payable account, as appropriate. We also adjust the deferred revenues balance for the product supply held at Eisai based on the most current net product sales figures provided to us, with the difference reclassified from deferred revenues to a receivable or payable account.

**Table of Contents**

We recognized total revenues from BELVIQ net product sales of \$5.7 million in the year ended December 31, 2013, of which \$5.3 million related to sales at the Product Purchase Price and \$0.4 million related to redemptions of vouchers. The Product Purchase Price for the product Eisai has sold to date was lower than the estimated price that Eisai paid us, primarily because the price that Eisai paid us did not include deductions for the use of vouchers, savings cards and deductions for certain items related to product launch. These excess payments, which reflect both the amounts Eisai has sold to date and the product supply remaining in Eisai's inventory at December 31, 2013, are included in the \$19.3 million classified as Payable to Eisai on our consolidated balance sheets.

**Development Payments**

In connection with the US approval of BELVIQ, the FDA is requiring (i) an evaluation as part of the cardiovascular outcomes trial, or CVOT, of the effect of long-term treatment with BELVIQ on the incidence of major adverse cardiovascular events, or MACE, in overweight and obese patients with cardiovascular disease or multiple cardiovascular risk factors and (ii) the conduct of postmarketing studies to assess the safety and efficacy of BELVIQ for weight management in obese pediatric patients. In addition to the FDA-required studies, we and Eisai are prioritizing the development areas of smoking cessation, a once-daily formulation, co-administration with phentermine, as well as exploring, including as part of the CVOT, BELVIQ's effect on conversion to type 2 diabetes and improvements in cardiovascular outcomes.

**Table of Contents**

The below chart summarizes the general agreement regarding cost sharing between Eisai and us for significant development activities under the Eisai Agreement. In addition, Eisai or we may from time to time conduct approved development of BELVIQ at such party's own expense. For example, Eisai is responsible for the expenses of the pilot study of 12-week duration to preliminarily assess BELVIQ and phentermine when co-administered.

**Eisai Second Amended and Restated Marketing and Supply Agreement: Cost Sharing for Development**

		<b>Rest of</b>	
	<b>United States</b>	<b>North and South America General</b>	<b>Remaining Territories</b>
<b>BELVIQ for weight management</b>	Not Applicable		Up to total of \$100.0 million -
<i>- Pre-approval*</i>		Eisai: 90%; Arena: 10%	Eisai: 50%; Arena: 50%
		<b>Certain stability work</b>	Thereafter, Eisai: 100%
		Eisai: 50%; Arena: 50%	
<b>BELVIQ for weight management</b>	<b>General</b> - Eisai: 90%; Arena 10%	<b>General</b>	Up to total of \$50.0 million -
<i>- Post-approval*</i>		Eisai: 90%; Arena: 10%	Eisai: 50%; Arena: 50%
	<b>Non-FDA required portion of CVOT</b>		
	Up to \$80.0 million -	<b>Certain stability work</b>	Thereafter, Eisai: 90%;
	Eisai: 50%; Arena: 50%	Eisai: 50%; Arena: 50%	Arena: 10%
	Thereafter, Eisai: 100%		
	<b>Certain pediatric studies</b>		
	Eisai: 50%; Arena: 50%		
<b>Products other than BELVIQ for weight management</b>	Up to total of \$250.0 million (as reduced by up to \$80.0 million for non-FDA required portion of CVOT) - Eisai: 50%; Arena: 50%		
<i>- Pre-approval</i>			
<b>Products other than BELVIQ for weight management</b>	Up to a total of \$100.0 million in the aggregate across all additional products -		
<i>- Post-approval</i>	Eisai: 50%; Arena: 50%		
	Thereafter, Eisai: 90%; Arena: 10%		

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

\* Development required by a regulatory authority, with the exception of the non-FDA required portions of the CVOT.

### Certain Other Terms

Eisai and we have agreed to limitations on the ability to commercialize outside of the Eisai Agreement any weight management product or addiction disorder product in the territories under the agreement. The agreement includes a stand-still provision limiting Eisai's ability to acquire our securities and assets.

Eisai may terminate the Eisai Agreement with respect to any country in the territory following the later of the expiration of all issued BELVIQ patents in such country and 12 years after the first commercial sale of BELVIQ in such country. Arena GmbH and Eisai each has the right to terminate the Eisai Agreement early in certain circumstances in its entirety or with respect to the applicable country or product, including (a) if the other party is in material breach, (b) for commercialization concerns, and (c) for certain intellectual property infringement. Eisai also has the right to terminate the Eisai Agreement early in its entirety or with respect to each country in certain circumstances, including (i) termination in a country if sales of generic equivalents of BELVIQ in such country exceed sales of BELVIQ in that country (based on volume), and (ii) if Eisai is acquired by a company that has a product that competes with BELVIQ. In addition, Arena GmbH can terminate the Eisai Agreement early in its entirety or with respect to each country in the non-US territories in North and South America in certain circumstances, including termination in each country if Eisai does not satisfy certain regulatory filing and commercialization diligence requirements in such country.

---

**Table of Contents**

Eisai will indemnify us for losses resulting from certain third-party claims, including for (a) Eisai's negligence, willful misconduct or violation of law, but excluding product liability claims, (b) Eisai's breach of the Eisai Agreement or related agreements, but excluding product liability claims, (c) certain uses or misuses of BELVIQ, (d) certain governmental investigations of Eisai related to BELVIQ, and (e) infringement relating to Eisai's use of certain trademarks, tag lines and logos related to BELVIQ. Arena GmbH will indemnify Eisai for losses resulting from certain third-party claims, including for (i) Arena GmbH's negligence, willful misconduct, failure to comply with law, breach of any agreement with a third party with respect to product development prior to the effective date of the original agreement with Eisai, but excluding product liability claims, (ii) Arena GmbH's negligence or willful misconduct with respect to certain uses or misuses of BELVIQ outside of the agreement, (iii) certain uses or misuses of BELVIQ after the term of the agreement, in any territory no longer under the agreement or with respect to any product after the termination of the agreement with respect to such product, (iv) Arena GmbH's negligence, willful misconduct or violation of law, but excluding product liability claims, (v) Arena GmbH's breach of the Eisai Agreement or related agreements, but excluding product liability claims, (vi) certain infringement of intellectual rights of a third party, and (vii) infringement relating to Eisai's use of certain trademarks related to BELVIQ. We are unable to predict the maximum potential amount of any indemnification claims. As of December 31, 2013, we have not incurred any losses under these indemnification provisions.

Arena GmbH and Eisai will, in general, share equally in losses resulting from third-party product liability claims, except where one party's acts or omissions did not contribute to the events or circumstances leading to such product liability claim and the other party's actual willful misconduct, violation of law or breach of its obligations under the Eisai Agreement or certain other agreements between Arena GmbH and Eisai were the sole and direct cause of the product liability claim. We are unable to predict the range of loss from future product liability claims.

**Other Collaborations**

In addition to the Eisai Agreement, Arena GmbH entered into the Marketing and Supply Agreement, or Ildong BELVIQ Agreement, with Ildong for South Korea in November 2012, and into the Marketing and Supply Agreement, or CYB Agreement, with CYB for Taiwan in July 2013. Under the Ildong BELVIQ Agreement, we received from Ildong an upfront payment of \$5.0 million, less withholding taxes, and will receive an additional \$3.0 million if and when BELVIQ is approved by the South Korean Ministry of Food and Drug Safety, as well as payments from sales of BELVIQ and purchase price adjustment payments based on Ildong's annual net product sales (which are the gross invoiced sales less certain deductions described in the Ildong BELVIQ Agreement). We recorded this upfront payment as deferred revenue and are recognizing it as revenue ratably over approximately 14 years, which is the period in which we expect to provide services under the arrangement. At December 31, 2013, our consolidated balance sheet included \$0.4 million and \$4.2 million for the current and non-current portion, respectively, of the deferred revenue attributable to such upfront payment. For the years ended December 31, 2013, and 2012, we recognized revenues of \$0.5 million and \$0.1 million, respectively, under the Ildong BELVIQ Agreement.

Under the CYB Agreement, we received from CYB an upfront payment of \$2.0 million, net of withholding taxes. We recorded this upfront payment as deferred revenue and are recognizing it as revenue ratably over approximately 14 years, which is the period in which we expect to provide services under the arrangement. At December 31, 2013, our consolidated balance sheet included \$0.2 million and \$2.0 million for the current and non-current portion, respectively, of the deferred revenue attributable to such upfront payment. For the year ended December 31, 2013, we recognized revenues of \$0.1 million under the CYB Agreement. Subject to regulatory approval of BELVIQ by the Taiwan Food and Drug Administration, or TFDA, we will receive payments from sales of BELVIQ, and are eligible to receive purchase price adjustment payments based on



## **Table of Contents**

CYB's annual net product sales (which are the gross invoiced sales less certain deductions described in the CYB Agreement), as well as a milestone payment upon approval of the first additional indication for BELVIQ by the TFDA.

Arena GmbH also entered into the Co-Development and License Agreement with Ildong for temanogrel, our internally discovered candidate intended for the treatment of thrombotic diseases. Under such agreement, we granted Ildong exclusive rights to commercialize temanogrel in South Korea for myocardial infarction, acute coronary syndrome, stroke, peripheral artery disease, and other cardiovascular diseases, subject to further development and regulatory approval of temanogrel. Initially, Ildong will be responsible for funding and conducting, under the direction of a joint steering committee, the next two planned clinical trials in this program: an additional Phase 1 trial in healthy volunteers and a Phase 2a proof-of-concept trial in patients. To date, we have not recognized any revenue under this agreement. We will maintain ownership of temanogrel outside of South Korea, and have the rights to use data generated by Ildong for the development and potential commercialization of temanogrel outside of South Korea by us or other Arena licensees. In addition, Ildong has agreed to pay us a \$2.0 million development milestone if the planned additional Phase 1 and Phase 2a clinical trials conducted by Ildong support continued development and we or another Arena licensee initiates a Phase 2b clinical trial of temanogrel. We are also eligible to receive a royalty on net product sales of temanogrel in South Korea, and Ildong is eligible to receive a share of future payments received by us related to licensing transactions and sales of temanogrel in other territories.

### **(13) Restructuring Charges**

In March 2011, we completed a reduction of our US workforce and recorded a charge of \$3.5 million in 2011, which is reflected as restructuring charges in the accompanying consolidated statements of operations and comprehensive loss.

### **(14) Employee Benefit Plans**

#### **401(k) Plan**

All of our US employees are eligible to participate in our defined contribution retirement plan that complies with Section 401(k) of the Internal Revenue Code. We match 100% of each participant's voluntary contributions, subject to a maximum of 6% of the participant's eligible compensation. Our matching portion, which totaled \$1.5 million, \$1.1 million and \$1.2 million in the years ended December 31, 2013, 2012, and 2011, respectively, vests over a five-year period from the date of hire.

#### **Pension Plan**

Arena GmbH contributes to a multiemployer defined benefit pension plan, established under an affiliated group of employers, for the purpose of providing mandatory occupational pension benefits for its employees. The risks of participating in a multiemployer plan are different from a single-employer plan in that (i) assets contributed to the multiemployer plan by one employer may be used to provide benefits to employees of other participating employers, (ii) if a participating employer stops contributing to the plan, the unfunded obligations of the plan may be borne by the remaining participating employers, (iii) if Arena GmbH elects to stop participating in the multiemployer plan, Arena GmbH may be required to pay the plan an amount based on the underfunded status of the plan, referred to as a withdrawal liability, and (iv) Arena GmbH has no involvement in the management of the multiemployer plan's investments. We currently have no intention of withdrawing from the multiemployer plan.

Our contributions to the multiemployer plan were \$0.7 million in the year ended December 31, 2013, and \$0.6 million in each of the years ended December 31, 2012, and 2011.

**Table of Contents****(15) Income Taxes**

Our loss before benefit for income taxes is summarized by region as follows, in thousands:

	2013	December 31, 2012	2011
United States	\$ 11,573	\$ (62,674)	\$ (75,209)
Foreign	(31,008)	(22,803)	(34,015)
<b>Total loss before income taxes</b>	<b>\$ (19,435)</b>	<b>\$ (85,477)</b>	<b>\$ (109,224)</b>

We have not recorded a benefit for income taxes for the years ended December 31, 2013, 2012, and 2011 because we have a full valuation allowance.

Our effective income tax rate differs from the statutory Federal rate of 34% at December 31, 2013, 2012, and 2011, due to the following, in thousands:

	2013	December 31, 2012	2011
Benefit for income taxes at statutory Federal rate	\$ (6,608)	\$ (29,062)	\$ (37,136)
State income tax, net of Federal benefit	(901)	(4,390)	(3,857)
Permanent differences and other	2,122	(2,770)	(1,124)
Gain (Loss) from valuation of derivative liabilities	(3,922)	5,244	123
Foreign losses at lower effective rates	9,527	6,744	8,509
Research and development credit	(2,594)	(1,005)	(1,955)
Adjustment to research and development credits and net operating losses, or NOLs	(59,790)	4,831	7,086
Valuation allowance	62,166	20,408	28,354
<b>Benefit for income taxes</b>	<b>\$ 0</b>	<b>\$ 0</b>	<b>\$ 0</b>

The components of our net deferred tax assets are as follows, in thousands:

	2013	December 31, 2012
Deferred tax assets:		
Foreign NOL carryforwards	\$ 9,678	\$ 8,264
Federal and California NOL carryforwards	231,450	210,005
Federal and California research and development credit carryforwards	40,948	0
Deferred revenues	21,109	23,346
Depreciation	4,245	8,055
Share-based compensation expense	7,223	5,698
Other, net	5,921	3,142
<b>Total deferred tax assets</b>	<b>320,574</b>	<b>258,510</b>
Deferred tax liabilities	(1,853)	(1,957)
<b>Net deferred tax assets</b>	<b>318,721</b>	<b>256,553</b>
Valuation allowance	(318,721)	(256,553)

Net deferred tax liabilities	\$	0	\$	0
------------------------------	----	---	----	---

**Table of Contents**

A valuation allowance is recorded against all of our deferred tax assets, as realization of such assets is not more-likely-than-not. The realization of our deferred tax assets is dependent upon future taxable income. Our ability to generate taxable income is analyzed regularly on a jurisdiction-by-jurisdiction basis. At such time as it is more-likely-than-not that we will generate taxable income in a jurisdiction, we will reduce or remove the valuation allowance. The valuation allowance increased by \$62.2 million in 2013, compared to 2012.

At December 31, 2013, we had Federal NOL carryforwards of \$586.4 million that will begin to expire in 2022 unless previously utilized. At the same date, we had California NOL carryforwards of \$607.1 million, which will begin to expire in 2014, and foreign NOL carryforwards of \$121.0 million, which will begin to expire in 2015. At December 31, 2013, approximately \$8.4 million of the Federal and California NOL carryforwards related to stock option exercise windfalls, which will result in an increase to additional paid-in capital, or APIC, and a decrease in income taxes payable at the time such carryforwards are utilized. We also had Federal and California research and development tax credit carryforwards, net of reserves, of \$27.2 million and \$20.8 million, respectively. Federal research and development credit carryforwards will begin to expire in 2026 unless previously utilized. The California research and development credit carryforwards carry forward indefinitely. No deferred tax assets were recognized in our 2012 financial statements for Federal or California research and development credits, as a formal study had not been performed to substantiate the validity of such credits. A formal analysis of Federal and California research and development credits earned in prior years was conducted in 2013, and we disclosed the credits as deferred tax assets as of December 31, 2013.

Sections 382 and 383 of the Internal Revenue Code, or IRC, limit the utilization of tax attribute carryforwards that arise prior to certain cumulative changes in a corporation's ownership. We have completed an IRC Section 382/383 analysis through 2013 and identified ownership changes that limit our utilization of tax attribute carryforwards. We have also adjusted our NOL carryforwards by jurisdiction based upon an additional analysis. We reduced deferred tax assets associated with such tax attribute carryforwards to remove deferred tax assets that will expire prior to utilization, as well as incorporating other adjustments based upon such additional analysis. No deferred tax assets associated with California NOLs were recognized in our 2012 financial statements as a California analysis of IRC Section 382 had not been completed. During 2013, we performed a formal IRC Section 382 analysis and we disclosed California NOLs as deferred tax assets as of December 31, 2013.

In accordance with authoritative guidance, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows, in thousands:

	December 31,		
	2013	2012	2011
Gross unrecognized tax benefits at the beginning of the year	\$ 0	\$ 0	\$ 0
Additions from tax positions taken in the current year	541	0	0
Additions from tax positions taken in prior years	4,088	0	0
Reductions from tax positions taken in prior years	0	0	0
Tax settlements	0	0	0
Gross unrecognized tax benefits at end of the year	\$ 4,629	\$ 0	\$ 0

Of our total unrecognized tax benefits, \$3.4 million will impact our effective tax rate in the event the valuation allowance is removed. We do not anticipate that there will be a substantial change in unrecognized tax benefits within the next 12 months.

---

**Table of Contents**

Our practice is to recognize interest and/or penalties related to income tax matters in income tax expense. Because we have incurred net losses since our inception, we did not have any accrued interest or penalties included in our consolidated balance sheets at December 31, 2013, or 2012, and did not recognize any interest and/or penalties in our consolidated statements of operations and comprehensive loss during the years ended December 31, 2013, 2012, or 2011.

During 2013, we elected the with and without method direct effects only, prescribed in accordance with authoritative guidance, with respect to recognition of stock option windfall tax benefits within APIC and will utilize general NOLs to offset taxable income before utilization of NOLs attributable to windfall tax benefits.

We are subject to income taxation in the United States at the Federal and state levels. All tax years are subject to examination by US and California tax authorities due to the carryforward of unutilized NOLs and tax credits. We are also subject to foreign income taxes in the countries in which we operate. To our knowledge, we are not currently under examination by any taxing authorities.

At December 31, 2013, no foreign subsidiaries have accumulated earnings and, as such, there are no unrepatriated earnings.

Our Swiss subsidiary, Arena GmbH, has been granted a conditional incentive tax holiday by the Canton of Aargau for its operations in Switzerland. Without a tax holiday or other tax incentives, the standard effective tax rate of a company located in Aargau is approximately 19%. As a result of the tax holiday and other tax incentives, we expect the effective tax rate for Arena GmbH to be approximately half of such rate. The tax holiday came into effect on January 1, 2013, and will continue for a period of up to 10 years, not to extend beyond December 31, 2022.

**(16) Legal Proceedings**

Beginning on September 20, 2010, a number of complaints were filed in the US District Court for the Southern District of California against us and certain of our current and former employees and directors on behalf of certain purchasers of our common stock. The complaints have been brought as purported stockholder class actions, and, in general, include allegations that we and certain of our current and former employees and directors violated federal securities laws by making materially false and misleading statements regarding our BELVIQ program, thereby artificially inflating the price of our common stock. The plaintiffs are seeking unspecified monetary damages and other relief. On November 19, 2010, eight prospective lead plaintiffs filed motions to consolidate, appoint a lead plaintiff, and appoint lead counsel. The Court took the motions to consolidate under submission on January 14, 2011. On August 8, 2011, the Court consolidated the actions and appointed a lead plaintiff and lead counsel. On November 1, 2011, the lead plaintiff filed a consolidated amended complaint. On December 30, 2011, we filed a motion to dismiss the consolidated amended complaint. On March 28, 2013, the Court granted our motion to dismiss the consolidated amended complaint without prejudice. On May 13, 2013, the lead plaintiff filed a new consolidated amended complaint. On June 14, 2013, we filed a motion to dismiss the new consolidated amended complaint. On July 15, 2013, the lead plaintiff filed an opposition to our motion to dismiss. On July 29, 2013, we filed our reply. On October 25, 2013, the Court heard oral argument on the motion to dismiss. On November 5, 2013, the Court granted our motion to dismiss the new consolidated amended complaint without prejudice as to all parties except for Robert E. Hoffman, who was dismissed from the action with prejudice. On November 27, 2013, the lead plaintiff filed a motion for leave to amend the now-dismissed new consolidated amended complaint. On December 20, 2013, we filed an opposition to the motion for leave to amend. On December 27, 2013, the lead plaintiff filed his reply. On December 30, 2013, the Court took the motion under submission without a hearing.

In addition to the class actions, a complaint involving similar legal and factual issues has been brought by at least one individual stockholder and is pending in federal court. On December 30, 2011, we filed a motion to dismiss the individual stockholder's complaint. On March 29, 2013, the Court granted our motion to dismiss, in part without prejudice. On May 13, 2013, the individual stockholder filed a new amended complaint. On

**Table of Contents**

June 14, 2013, we filed a motion to dismiss the new amended complaint. On July 10, 2013, the individual stockholder filed an opposition to our motion to dismiss. On July 29, 2013, we filed our reply. On October 22, 2013, the Court took the motion under submission without a hearing.

Due to the stage of these proceedings, we are not able to predict or reasonably estimate the ultimate outcome or possible losses relating to these claims.

**(17) Quarterly Financial Data (Unaudited)**

The following tables present quarterly data for the years ended December 31, 2013, and 2012, in thousands, except per share data:

<b>2013</b>	<b>Quarter ended December 31</b>	<b>Quarter ended September 30</b>	<b>Quarter ended June 30</b>	<b>Quarter ended March 31</b>	<b>Year ended December 31</b>
Revenues	\$ 6,516	\$ 3,578	\$ 68,927	\$ 2,373	\$ 81,394
Operating costs and expenses	\$ 28,487	\$ 23,444	\$ 29,021	\$ 23,377	\$ 104,329
Net income (loss) allocable to common stockholders	\$ (23,459)	\$ (17,200)	\$ 40,100	\$ (18,876)	\$ (19,435)
Net income (loss) per share allocable to common stockholders, basic and diluted	\$ (0.11)	\$ (0.08)	\$ 0.18	\$ (0.09)	\$ (0.09)

<b>2012</b>	<b>Quarter ended December 31</b>	<b>Quarter ended September 30</b>	<b>Quarter ended June 30</b>	<b>Quarter ended March 31</b>	<b>Year ended December 31</b>
Revenues	\$ 1,936	\$ 1,485	\$ 21,977	\$ 2,189	\$ 27,587
Operating costs and expenses	\$ 22,216	\$ 20,575	\$ 20,117	\$ 21,792	\$ 84,700
Net loss allocable to common stockholders	\$ (21,280)	\$ (15,521)	\$ (22,099)	\$ (29,401)	\$ (88,301)
Net loss per share allocable to common stockholders, basic and diluted	\$ (0.10)	\$ (0.07)	\$ (0.12)	\$ (0.18)	\$ (0.45)

## **Table of Contents**

### **Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.**

None.

### **Item 9A. Controls and Procedures.**

#### **Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures**

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Based on this evaluation, our principal executive officer and our principal financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of the end of the period covered by this Annual Report on Form 10-K.

Our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all potential errors and fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no system of controls can provide absolute assurance that all control issues and instances of fraud, if any, or misstatements due to error, if any, within the company have been detected. While we believe that our disclosure controls and procedures and internal control over financial reporting are and have been effective at the reasonable assurance level, we intend to continue to examine and refine our disclosure controls and procedures and internal control over financial reporting and to monitor ongoing developments in these areas.

#### **Management's Report on Internal Control Over Financial Reporting**

Our management is responsible for establishing and maintaining for us adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Under the supervision and with the participation of our management, including our President and Chief Executive Officer and our Senior Vice President, Finance and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control - Integrated Framework* (1992 framework) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under this framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2013.

The registered public accounting firm that audited our financial statements as of and for the year ended December 31, 2013, included in this Annual Report on Form 10-K has issued an attestation report on our internal control over financial reporting, and such report is included below.

#### **Changes in Internal Control Over Financial Reporting**

In connection with the commercial launch of BELVIQ in 2013, we have enhanced our internal control over financial reporting related to our inventory, cost of product sales and revenues from product sales.

Except as described above, there was no change in our internal control over financial reporting during the fourth quarter of the period covered by this Annual Report on Form 10-K that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

---

**Table of Contents**

**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders

Arena Pharmaceuticals, Inc.:

We have audited Arena Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2013, based on criteria established in *Internal Control - Integrated Framework (1992)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Arena Pharmaceuticals, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on Arena Pharmaceuticals, Inc.'s internal control over financial reporting 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 effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Arena Pharmaceuticals, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2013, based on criteria established in *Internal Control - Integrated Framework (1992)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Arena Pharmaceuticals, Inc. and subsidiaries as of December 31, 2013 and 2012, and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2013, and our report dated March 3, 2014 expressed an unqualified opinion on those consolidated financial statements.

/s/ KPMG LLP

San Diego, California

March 3, 2014



**Table of Contents**

**Item 9B. Other Information.**  
Not applicable.

**Table of Contents****PART III****Item 10. Directors, Executive Officers and Corporate Governance.**

We have adopted a Code of Business Conduct and Ethics that applies to our directors and employees (including our principal executive officer, principal financial officer, principal accounting officer and controller), and have posted the text of the policy on our website ([www.arenapharm.com](http://www.arenapharm.com)) in connection with Investor materials. In addition, we intend to promptly disclose on our website in the future (i) the date and nature of any amendment (other than technical, administrative or other non-substantive amendments) to the policy that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and relates to any element of the code of ethics definition enumerated in Item 406(b) of Regulation S-K, and (ii) the nature of any waiver, including an implicit waiver, from a provision of the policy that is granted to one of these specified individuals that relates to one or more of the elements of the code of ethics definition enumerated in Item 406(b) of Regulation S-K, the name of such person who is granted the waiver and the date of the waiver.

The other information required by this item is incorporated herein by reference from the information under the captions Election of Directors, Compensation and Other Information Concerning Executive Officers, Directors and Certain Stockholders and Section 16(a) Beneficial Ownership Reporting Compliance contained in our proxy statement for the annual meeting of stockholders to be held in June 2014, or the Proxy Statement.

**Item 11. Executive Compensation.**

The information required by this item is incorporated herein by reference from the information under the captions Compensation and Other Information Concerning Executive Officers, Directors and Certain Stockholders and Compensation Committee Interlocks and Insider Participation contained in the Proxy Statement.

**Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.**

The following table summarizes our compensation plans under which our equity securities are authorized for issuance as of December 31, 2013:

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	16,675,890*	\$ 4.39	26,738,631**
Equity compensation plans not approved by security holders	0		0
<b>Total</b>	<b>16,675,890*</b>	<b>\$ 4.39</b>	<b>26,738,631**</b>

\* Includes 14,681,044 stock options with a per share weighted-average exercise price of \$4.99. Also includes (i) 434,846 restricted stock unit awards with no exercise price and (ii) 780,000 performance restricted stock unit awards with no exercise price. In the aggregate, the target number of shares of common stock that may be earned under the performance restricted stock unit awards is 780,000; however, the actual number of shares that may be earned ranges from 0% to 200% of such amount, and this table reflects 200%.



**Table of Contents**

\*\* Includes 900,659 shares of common stock available for future issuance under our 2009 Employee Stock Purchase Plan, as amended. Stock options and stock appreciation rights granted under our 2013 Long-Term Incentive Plan, or 2013 LTIP, reduce the available number of shares under our 2013 LTIP by 1 share for every share issued while awards other than stock options and stock appreciation rights granted under our 2013 LTIP reduce the available number of shares by 1.25 shares for every share issued. In addition, shares that are released from awards granted under any of our prior long-term incentive plans or the 2013 LTIP because the awards expire, are forfeited or are settled for cash will increase the number of shares available under our 2013 LTIP by 1 share for each share released from a stock option or stock appreciation right and by 1.25 shares for each share released from a restricted stock award or restricted stock unit award. Each share we withhold to satisfy any tax withholding obligation with respect to an award other than an option or stock appreciation right under any of our prior long-term incentive plans or the 2013 LTIP will increase the share reserve by 1.25 shares.

In 2003, we set up a deferred compensation plan for our executive officers, whereby they may elect to defer their shares of restricted stock. At December 31, 2013, a total of 79,169 shares of restricted stock were in the plan. All of the shares contributed to this plan were previously granted to such officers under an equity compensation plan approved by our stockholders.

The other information required by this item is incorporated herein by reference from the information under the caption Security Ownership of Certain Beneficial Owners and Management contained in the Proxy Statement.

**Item 13. Certain Relationships and Related Transactions, and Director Independence.**

The information required by this item is incorporated herein by reference from the information under the captions Certain Relationships and Related Transactions and Election of Directors contained in the Proxy Statement.

**Item 14. Principal Accountant Fees and Services.**

The information required by this item is incorporated herein by reference from the information under the captions Independent Auditors Fees and Pre-approval Policies and Procedures contained in the Proxy Statement.

**Table of Contents****PART IV****Item 15. Exhibits, Financial Statement Schedules.****(a) 1. FINANCIAL STATEMENTS.**

Reference is made to the Index to Financial Statements under Item 8, Part II hereof.

**2. FINANCIAL STATEMENT SCHEDULES.**

The Financial Statement Schedules have been omitted either because they are not required or because the information has been included in the financial statements or the notes thereto included in this annual report.

**3. EXHIBITS****EXHIBIT  
NO.****DESCRIPTION**

2.1*	Agreement of Purchase and Sale, dated as of March 21, 2007, by and between Arena and BMR-6114-6154 Nancy Ridge Drive LLP (as assignee of BioMed Realty, L.P.) (incorporated by reference to Exhibit 2.1 to Arena's report on Form 8-K filed with the Securities and Exchange Commission on May 8, 2007, Commission File No. 000-31161)
3.1	Fifth Amended and Restated Certificate of Incorporation of Arena (incorporated by reference to Exhibit 3.1 to Arena's quarterly report on Form 10-Q for the quarter ended June 30, 2002, filed with the Securities and Exchange Commission on August 14, 2002, Commission File No. 000-31161)
3.2	Certificate of Amendment of the Fifth Amended and Restated Certificate of Incorporation of Arena (incorporated by reference to Exhibit 4.2 to Arena's registration statement on Form S-8 filed with the Securities and Exchange Commission on June 28, 2006, Commission File No. 333-135398)
3.3	Certificate of Amendment No. 2 of the Fifth Amended and Restated Certificate of Incorporation of Arena, as amended (incorporated by reference to Exhibit 4.3 to Arena's registration statement on Form S-8 filed with the Securities and Exchange Commission on June 30, 2009, Commission File No. 333-160329)
3.4	Certificate of Amendment No. 3 of the Fifth Amended and Restated Certificate of Incorporation of Arena, as amended (incorporated by reference to Exhibit 3.4 to Arena's registration statement on Form S-8 filed with the Securities and Exchange Commission on June 20, 2012, Commission File No. 333-182238)
3.5	Amended and Restated Bylaws of Arena (incorporated by reference to Exhibit 3.1 to Arena's current report on Form 8-K filed with the Securities and Exchange Commission on October 4, 2007, Commission File No. 000-31161)
4.4	Form of common stock certificate (incorporated by reference to Exhibit 4.2 to Arena's registration statement on Form S-1, as amended, filed with the Securities and Exchange Commission on July 19, 2000, Commission File No. 333-35944)
10.1**	Amended and Restated 2000 Equity Compensation Plan (incorporated by reference to Exhibit 10.2 to Arena's annual report on Form 10-K for the year ended December 31, 2001, filed with the Securities and Exchange Commission on March 15, 2002, Commission File No. 000-31161)
10.2**	2002 Equity Compensation Plan (incorporated by reference to Exhibit A to Arena's proxy statement regarding Arena's June 11, 2002, Annual Stockholders Meeting, filed with the Securities and Exchange Commission on April 23, 2002, Commission File No. 000-31161)

**Table of Contents**

<b>EXHIBIT NO.</b>	<b>DESCRIPTION</b>
10.3	Form of Warrant dated December 24, 2003 (incorporated by reference to Exhibit 10.3 to Arena's report on Form 8-K filed with the Securities and Exchange Commission on December 30, 2003, Commission File No. 000-31161)
10.4	Purchase and Sale Agreement and Joint Escrow Instructions, dated December 22, 2003, between Arena and ARE Nancy Ridge No. 3, LLC (incorporated by reference to Exhibit 10.1 to Arena's report on Form 8-K filed with the Securities and Exchange Commission on January 6, 2004, Commission File No. 000-31161)
10.5	Lease Agreement, dated December 30, 2003, between Arena and ARE Nancy Ridge No. 3, LLC (incorporated by reference to Exhibit 10.2 to Arena's report on Form 8-K filed with the Securities and Exchange Commission on January 6, 2004, Commission File No. 000-31161)
10.6**	Arena's Deferred Compensation Plan, effective November 11, 2003, between Arena and participating executive officers (incorporated by reference to Exhibit 10.29 to Arena's annual report on Form 10-K for the year ended December 31, 2003, filed with the Securities and Exchange Commission on March 1, 2004, Commission File No. 000-31161)
10.7**	Form of stock option grant for non-employee directors under Arena's 2002 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to Arena's report on Form 8-K filed with the Securities and Exchange Commission on January 21, 2005, Commission File No. 000-31161)
10.8**	2006 Long-Term Incentive Plan, as amended (incorporated by reference to Exhibit 10.1 to Arena's report on Form 8-K filed with the Securities and Exchange Commission on April 13, 2007, Commission File No. 000-31161)
10.9**	Form of Stock Option Grant Agreement under the Arena 2006 Long-Term Incentive Plan, as amended (incorporated by reference to Exhibit 10.1 to Arena's report on Form 8-K filed with the Securities and Exchange Commission on August 1, 2006, Commission File No. 000-31161)
10.10**	Form of Stock Option Grant Agreement Director under the Arena 2006 Long-Term Incentive Plan, as amended (incorporated by reference to Exhibit 10.2 to Arena's report on Form 8-K filed with the Securities and Exchange Commission on August 1, 2006, Commission File No. 000-31161)
10.11**	Form of Incentive Stock Option Grant Agreement under the Arena 2006 Long-Term Incentive Plan, as amended (incorporated by reference to Exhibit 10.3 to Arena's report on Form 8-K filed with the Securities and Exchange Commission on August 1, 2006, Commission File No. 000-31161)
10.12**	Form of Indemnification Agreement between Arena and its directors (incorporated by reference to Exhibit 10.1 to Arena's report on Form 8-K filed with the Securities and Exchange Commission on June 18, 2007, Commission File No. 000-31161)
10.13**	Form of Indemnification Agreement between Arena and its executive officers (incorporated by reference to Exhibit 10.2 to Arena's report on Form 8-K filed with the Securities and Exchange Commission on June 18, 2007, Commission File No. 000-31161)
10.14**	Form of Indemnification Agreement between Arena and individuals serving as its directors and executive officers (incorporated by reference to Exhibit 10.3 to Arena's report on Form 8-K filed with the Securities and Exchange Commission on June 18, 2007, Commission File No. 000-31161)
10.15	Lease agreement between BMR-6114-6154 Nancy Ridge Drive LLC and Arena for 6114 Nancy Ridge Drive, San Diego, California (incorporated by reference to Exhibit 10.5 to Arena's quarterly report on Form 10-Q for the quarter ended June 30, 2007, filed with the Securities and Exchange Commission on August 9, 2007, Commission File No. 000-31161)

**Table of Contents**

<b>EXHIBIT NO.</b>	<b>DESCRIPTION</b>
10.16	Lease agreement between BMR-6114-6154 Nancy Ridge Drive LLC and Arena for 6118 Nancy Ridge Drive, San Diego, California (incorporated by reference to Exhibit 10.6 to Arena's quarterly report on Form 10-Q for the quarter ended June 30, 2007, filed with the Securities and Exchange Commission on August 9, 2007, Commission File No. 000-31161)
10.17	Lease agreement between BMR-6114-6154 Nancy Ridge Drive LLC and Arena for 6122, 6124 and 6126 Nancy Ridge Drive, San Diego, California (incorporated by reference to Exhibit 10.7 to Arena's quarterly report on Form 10-Q for the quarter ended June 30, 2007, filed with the Securities and Exchange Commission on August 9, 2007, Commission File No. 000-31161)
10.18	Lease agreement between BMR-6114-6154 Nancy Ridge Drive LLC and Arena for 6154 Nancy Ridge Drive, San Diego, California (incorporated by reference to Exhibit 10.8 to Arena's quarterly report on Form 10-Q for the quarter ended June 30, 2007, filed with the Securities and Exchange Commission on August 9, 2007, Commission File No. 000-31161)
10.19*	Asset Purchase Agreement, dated as of December 18, 2007, by and between Arena Pharmaceuticals GmbH and Siegfried Ltd (incorporated by reference to Exhibit 10.38 to Arena's annual report on Form 10-K for the year ended December 31, 2007, filed with the Securities and Exchange Commission on March 5, 2008, Commission File No. 000-31161)
10.20	Amendment No. 1 to the Asset Purchase Agreement, dated effective as of January 1, 2011, by and between Arena Pharmaceuticals GmbH and Siegfried Ltd (incorporated by reference to Exhibit 10.2 to Arena's quarterly report on Form 10-Q for the quarter ended March 31, 2011, filed with the Securities and Exchange Commission on May 10, 2011, Commission File No. 000-31161)
10.21**	Amended and Restated Severance Benefit Plan, dated effective December 30, 2008, and providing benefits for Messrs. Lief, Hoffman and Spector and Drs. Behan and Shanahan (incorporated by reference to Exhibit 10.1 to Arena's Form 8-K filed with the Securities and Exchange Commission on December 31, 2008, Commission File No. 000-31161)
10.22**	Amendment No. 1 to Amended and Restated Severance Benefit Plan, dated as of February 10, 2012 (incorporated by reference to Exhibit 10.1 to Arena's Form 8-K filed with the Securities and Exchange Commission on February 14, 2012, Commission File No. 000-31161)
10.23**	Amendment No. 2 to Amended and Restated Severance Benefit Plan, dated as of October 4, 2013
10.24**	Form of Amended and Restated Termination Protection Agreement, dated December 30, 2008, by and among Arena and Messrs. Lief and Spector and Dr. Behan (incorporated by reference to Exhibit 10.2 to Arena's Form 8-K filed with the Securities and Exchange Commission on December 31, 2008, Commission File No. 000-31161)
10.25**	Arena's 2009 Long-Term Incentive Plan (incorporated by reference to Exhibit 99.1 to Arena's registration statement on Form S-8 filed with the Securities and Exchange Commission on June 30, 2009, Commission File No. 333-160329)
10.26**	Form of Incentive Stock Option Grant Agreement for Employees under the Arena 2009 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.7 to Arena's quarterly report on Form 10-Q for the quarter ended June 30, 2009, filed with the Securities and Exchange Commission on August 7, 2009, Commission File No. 000-31161)
10.27**	Form of Stock Option Grant Agreement for Employees or Consultants under the Arena 2009 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.8 to Arena's quarterly report on Form 10-Q for the quarter ended June 30, 2009, filed with the Securities and Exchange Commission on August 7, 2009, Commission File No. 000-31161)

**Table of Contents**

<b>EXHIBIT NO.</b>	<b>DESCRIPTION</b>
10.28**	Form of Stock Option Grant Agreement for Non-Employee Directors under the Arena 2009 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.9 to Arena's quarterly report on Form 10-Q for the quarter ended June 30, 2009, filed with the Securities and Exchange Commission on August 7, 2009, Commission File No. 000-31161)
10.29**	Arena's 2009 Employee Stock Purchase Plan, as amended (incorporated by reference to Exhibit 99.2 to Arena's registration statement on Form S-8 filed with the Securities and Exchange Commission on June 20, 2012, Commission File No. 333-182238)
10.30**	Arena's 2012 Long-Term Incentive Plan (incorporated by reference to Exhibit 99.1 to Arena's registration statement on Form S-8 filed with the Securities and Exchange Commission on June 20, 2012, Commission File No. 333-182238)
10.31**	Form of Incentive Stock Option Grant Agreement for Employees for grants prior to December 13, 2012, under the Arena 2012 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.3 to Arena's report on Form 8-K filed with the Securities and Exchange Commission on June 20, 2012, Commission File No. 000-31161)
10.32**	Form of Stock Option Grant Agreement for Employees or Consultants for grants prior to December 13, 2012, under the Arena 2012 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.4 to Arena's report on Form 8-K filed with the Securities and Exchange Commission on June 20, 2012, Commission File No. 000-31161)
10.33**	Form of Stock Option Grant Agreement for Non-Employee Directors under the Arena 2012 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.5 to Arena's report on Form 8-K filed with the Securities and Exchange Commission on June 20, 2012, Commission File No. 000-31161)
10.34**	Form of Restricted Stock Grant Agreement under the Arena 2012 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.6 to Arena's report on Form 8-K filed with the Securities and Exchange Commission on June 20, 2012, Commission File No. 000-31161)
10.35**	Form of Incentive Stock Option Grant Agreement for Employees for grants beginning on December 13, 2012, under the Arena 2012 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.45 to Arena's annual report on Form 10-K for the year ended December 31, 2013, filed with the Securities and Exchange Commission on March 1, 2013, Commission File No. 000-31161)
10.36**	Form of Stock Option Grant Agreement for Employees or Consultants for grants beginning on December 13, 2012, under the Arena 2012 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.46 to Arena's annual report on Form 10-K for the year ended December 31, 2013, filed with the Securities and Exchange Commission on March 1, 2013, Commission File No. 000-31161)
10.37**	Form of Restricted Stock Unit Grant Agreement under the Arena 2012 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.47 to Arena's annual report on Form 10-K for the year ended December 31, 2013, filed with the Securities and Exchange Commission on March 1, 2013, Commission File No. 000-31161)
10.38**	Form of Performance Restricted Stock Unit Grant Agreement under the Arena 2012 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.2 to Arena's quarterly report on Form 10-Q for the quarter ended March 31, 2013, filed with the Securities and Exchange Commission on May 9, 2013, Commission File No. 000-31161)
10.39**	Arena's 2013 Long-Term Incentive Plan (incorporated by reference to Exhibit 99.1 to Arena's registration statement on Form S-8 filed with the Securities and Exchange Commission on June 10, 2013, Commission File No. 333-189213)



**Table of Contents**

<b>EXHIBIT NO.</b>	<b>DESCRIPTION</b>
10.40**	Form of Stock Option Grant Agreement for Employees or Consultants under the Arena 2013 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.2 to Arena's current report on Form 8-K filed with the Securities and Exchange Commission on June 14, 2013, Commission File No. 000-31161)
10.41**	Form of Incentive Stock Option Grant Agreement for Employees under the Arena 2013 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.3 to Arena's current report on Form 8-K filed with the Securities and Exchange Commission on June 14, 2013, Commission File No. 000-31161)
10.42**	Form of Restricted Stock Unit Grant Agreement (other than for non-employee directors) under the Arena 2013 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.4 to Arena's current report on Form 8-K filed with the Securities and Exchange Commission on June 14, 2013, Commission File No. 000-31161)
10.43**	Form of Restricted Stock Unit Grant Agreement for Non-Employee Directors under the Arena 2013 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.5 to Arena's current report on Form 8-K filed with the Securities and Exchange Commission on June 14, 2013, Commission File No. 000-31161)
10.44**	Annual Incentive Plan for Arena's executive officers (incorporated by reference to Exhibit 10.1 to Arena's report on Form 8-K filed with the Securities and Exchange Commission on December 19, 2012, Commission File No. 000-31161)
10.45**	Summary of compensation for non-employee directors (incorporated by reference to Exhibit 10.1 to Arena's quarterly report on Form 10-Q for the quarter ended March 31, 2013, filed with the Securities and Exchange Commission on May 9, 2013, Commission File No. 000-31161)
10.46+	Second Amended and Restated Marketing and Supply Agreement, dated November 7, 2013, by and among Arena Pharmaceuticals GmbH, Eisai Inc. and Eisai Co., Ltd.
21.1	Subsidiaries of the registrant
23.1	Consent of Independent Registered Public Accounting Firm
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(A) promulgated under the Securities Exchange Act of 1934
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(A) promulgated under the Securities Exchange Act of 1934
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350 and Rule 13a-14(B) promulgated under the Securities Exchange Act of 1934
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

+ Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the SEC.

**Table of Contents**

- \* Exhibits and schedules to this agreement have been omitted pursuant to the rules of the Securities and Exchange Commission. We will submit copies of such exhibits and schedules to the Securities and Exchange Commission upon request.
- \*\* Management contract or compensatory plan or arrangement.

(b) **EXHIBITS**

See Item 15(a)(3) above.

(c) **FINANCIAL STATEMENT SCHEDULES**

See Item 15(a)(2) above.

**Table of Contents****SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Arena Pharmaceuticals, Inc.,

a Delaware corporation

Date: March 3, 2014

By: /s/ JACK LIEF  
**Jack Lief**

**President and Chief Executive Officer**

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

	<b>Signatures</b>	<b>Title</b>	<b>Date</b>
<b>By:</b>	/s/ JACK LIEF  <b>Jack Lief</b>	Chairman, President and Chief Executive Officer	March 3, 2014
<b>By:</b>	/s/ ROBERT E. HOFFMAN  <b>Robert E. Hoffman</b>	Senior Vice President, Finance and Chief Financial Officer (principal financial and accounting officer)	March 3, 2014
<b>By:</b>	/s/ DOMINIC P. BEHAN  <b>Dominic P. Behan, Ph.D., D.Sc.</b>	Director	March 3, 2014
<b>By:</b>	/s/ DONALD D. BELCHER  <b>Donald D. Belcher</b>	Director	March 3, 2014
<b>By:</b>	/s/ SCOTT H. BICE  <b>Scott H. Bice</b>	Director	March 3, 2014
<b>By:</b>	/s/ HARRY F. HIXSON, JR.  <b>Harry F. Hixson, Jr., Ph.D.</b>	Director	March 3, 2014
<b>By:</b>	/s/ TINA S. NOVA  <b>Tina S. Nova, Ph.D.</b>	Director	March 3, 2014
<b>By:</b>	/s/ PHILLIP M. SCHNEIDER  <b>Phillip M. Schneider</b>	Director	March 3, 2014

Edgar Filing: ARENA PHARMACEUTICALS INC - Form 10-K

<b>By:</b>	/s/ CHRISTINE A. WHITE	Director	March 3, 2014
	<b>Christine A. White, M.D.</b>		
<b>By:</b>	/s/ RANDALL E. WOODS	Director	March 3, 2014
	<b>Randall E. Woods</b>		

**Table of Contents****EXHIBIT INDEX**

<b>EXHIBIT NO.</b>	<b>DESCRIPTION</b>
2.1*	Agreement of Purchase and Sale, dated as of March 21, 2007, by and between Arena and BMR-6114-6154 Nancy Ridge Drive LLP (as assignee of BioMed Realty, L.P.) (incorporated by reference to Exhibit 2.1 to Arena's report on Form 8-K filed with the Securities and Exchange Commission on May 8, 2007, Commission File No. 000-31161)
3.1	Fifth Amended and Restated Certificate of Incorporation of Arena (incorporated by reference to Exhibit 3.1 to Arena's quarterly report on Form 10-Q for the quarter ended June 30, 2002, filed with the Securities and Exchange Commission on August 14, 2002, Commission File No. 000-31161)
3.2	Certificate of Amendment of the Fifth Amended and Restated Certificate of Incorporation of Arena (incorporated by reference to Exhibit 4.2 to Arena's registration statement on Form S-8 filed with the Securities and Exchange Commission on June 28, 2006, Commission File No. 333-135398)
3.3	Certificate of Amendment No. 2 of the Fifth Amended and Restated Certificate of Incorporation of Arena, as amended (incorporated by reference to Exhibit 4.3 to Arena's registration statement on Form S-8 filed with the Securities and Exchange Commission on June 30, 2009, Commission File No. 333-160329)
3.4	Certificate of Amendment No. 3 of the Fifth Amended and Restated Certificate of Incorporation of Arena, as amended (incorporated by reference to Exhibit 3.4 to Arena's registration statement on Form S-8 filed with the Securities and Exchange Commission on June 20, 2012, Commission File No. 333-182238)
3.5	Amended and Restated Bylaws of Arena (incorporated by reference to Exhibit 3.1 to Arena's current report on Form 8-K filed with the Securities and Exchange Commission on October 4, 2007, Commission File No. 000-31161)
4.4	Form of common stock certificate (incorporated by reference to Exhibit 4.2 to Arena's registration statement on Form S-1, as amended, filed with the Securities and Exchange Commission on July 19, 2000, Commission File No. 333-35944)
10.1**	Amended and Restated 2000 Equity Compensation Plan (incorporated by reference to Exhibit 10.2 to Arena's annual report on Form 10-K for the year ended December 31, 2001, filed with the Securities and Exchange Commission on March 15, 2002, Commission File No. 000-31161)
10.2**	2002 Equity Compensation Plan (incorporated by reference to Exhibit A to Arena's proxy statement regarding Arena's June 11, 2002, Annual Stockholders Meeting, filed with the Securities and Exchange Commission on April 23, 2002, Commission File No. 000-31161)
10.3	Form of Warrant dated December 24, 2003 (incorporated by reference to Exhibit 10.3 to Arena's report on Form 8-K filed with the Securities and Exchange Commission on December 30, 2003, Commission File No. 000-31161)
10.4	Purchase and Sale Agreement and Joint Escrow Instructions, dated December 22, 2003, between Arena and ARE Nancy Ridge No. 3, LLC (incorporated by reference to Exhibit 10.1 to Arena's report on Form 8-K filed with the Securities and Exchange Commission on January 6, 2004, Commission File No. 000-31161)
10.5	Lease Agreement, dated December 30, 2003, between Arena and ARE Nancy Ridge No. 3, LLC (incorporated by reference to Exhibit 10.2 to Arena's report on Form 8-K filed with the Securities and Exchange Commission on January 6, 2004, Commission File No. 000-31161)
10.6**	Arena's Deferred Compensation Plan, effective November 11, 2003, between Arena and participating executive officers (incorporated by reference to Exhibit 10.29 to Arena's annual report on Form 10-K for the year ended December 31, 2003, filed with the Securities and Exchange Commission on March 1, 2004, Commission File No. 000-31161)

**Table of Contents**

**EXHIBIT**

<b>NO.</b>	<b>DESCRIPTION</b>
10.7**	Form of stock option grant for non-employee directors under Arena's 2002 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to Arena's report on Form 8-K filed with the Securities and Exchange Commission on January 21, 2005, Commission File No. 000-31161)
10.8**	2006 Long-Term Incentive Plan, as amended (incorporated by reference to Exhibit 10.1 to Arena's report on Form 8-K filed with the Securities and Exchange Commission on April 13, 2007, Commission File No. 000-31161)
10.9**	Form of Stock Option Grant Agreement under the Arena 2006 Long-Term Incentive Plan, as amended (incorporated by reference to Exhibit 10.1 to Arena's report on Form 8-K filed with the Securities and Exchange Commission on August 1, 2006, Commission File No. 000-31161)
10.10**	Form of Stock Option Grant Agreement Director under the Arena 2006 Long-Term Incentive Plan, as amended (incorporated by reference to Exhibit 10.2 to Arena's report on Form 8-K filed with the Securities and Exchange Commission on August 1, 2006, Commission File No. 000-31161)
10.11**	Form of Incentive Stock Option Grant Agreement under the Arena 2006 Long-Term Incentive Plan, as amended (incorporated by reference to Exhibit 10.3 to Arena's report on Form 8-K filed with the Securities and Exchange Commission on August 1, 2006, Commission File No. 000-31161)
10.12**	Form of Indemnification Agreement between Arena and its directors (incorporated by reference to Exhibit 10.1 to Arena's report on Form 8-K filed with the Securities and Exchange Commission on June 18, 2007, Commission File No. 000-31161)
10.13**	Form of Indemnification Agreement between Arena and its executive officers (incorporated by reference to Exhibit 10.2 to Arena's report on Form 8-K filed with the Securities and Exchange Commission on June 18, 2007, Commission File No. 000-31161)
10.14**	Form of Indemnification Agreement between Arena and individuals serving as its directors and executive officers (incorporated by reference to Exhibit 10.3 to Arena's report on Form 8-K filed with the Securities and Exchange Commission on June 18, 2007, Commission File No. 000-31161)
10.15	Lease agreement between BMR-6114-6154 Nancy Ridge Drive LLC and Arena for 6114 Nancy Ridge Drive, San Diego, California (incorporated by reference to Exhibit 10.5 to Arena's quarterly report on Form 10-Q for the quarter ended June 30, 2007, filed with the Securities and Exchange Commission on August 9, 2007, Commission File No. 000-31161)
10.16	Lease agreement between BMR-6114-6154 Nancy Ridge Drive LLC and Arena for 6118 Nancy Ridge Drive, San Diego, California (incorporated by reference to Exhibit 10.6 to Arena's quarterly report on Form 10-Q for the quarter ended June 30, 2007, filed with the Securities and Exchange Commission on August 9, 2007, Commission File No. 000-31161)
10.17	Lease agreement between BMR-6114-6154 Nancy Ridge Drive LLC and Arena for 6122, 6124 and 6126 Nancy Ridge Drive, San Diego, California (incorporated by reference to Exhibit 10.7 to Arena's quarterly report on Form 10-Q for the quarter ended June 30, 2007, filed with the Securities and Exchange Commission on August 9, 2007, Commission File No. 000-31161)
10.18	Lease agreement between BMR-6114-6154 Nancy Ridge Drive LLC and Arena for 6154 Nancy Ridge Drive, San Diego, California (incorporated by reference to Exhibit 10.8 to Arena's quarterly report on Form 10-Q for the quarter ended June 30, 2007, filed with the Securities and Exchange Commission on August 9, 2007, Commission File No. 000-31161)
10.19*	Asset Purchase Agreement, dated as of December 18, 2007, by and between Arena Pharmaceuticals GmbH and Siegfried Ltd (incorporated by reference to Exhibit 10.38 to Arena's annual report on Form 10-K for the year ended December 31, 2007, filed with the Securities and Exchange Commission on March 5, 2008, Commission File No. 000-31161)

**Table of Contents**

<b>EXHIBIT NO.</b>	<b>DESCRIPTION</b>
10.20	Amendment No. 1 to the Asset Purchase Agreement, dated effective as of January 1, 2011, by and between Arena Pharmaceuticals GmbH and Siegfried Ltd (incorporated by reference to Exhibit 10.2 to Arena's quarterly report on Form 10-Q for the quarter ended March 31, 2011, filed with the Securities and Exchange Commission on May 10, 2011, Commission File No. 000-31161)
10.21**	Amended and Restated Severance Benefit Plan, dated effective December 30, 2008, and providing benefits for Messrs. Lief, Hoffman and Spector and Drs. Behan and Shanahan (incorporated by reference to Exhibit 10.1 to Arena's Form 8-K filed with the Securities and Exchange Commission on December 31, 2008, Commission File No. 000-31161)
10.22**	Amendment No. 1 to Amended and Restated Severance Benefit Plan, dated as of February 10, 2012 (incorporated by reference to Exhibit 10.1 to Arena's Form 8-K filed with the Securities and Exchange Commission on February 14, 2012, Commission File No. 000-31161)
10.23**	Amendment No. 2 to Amended and Restated Severance Benefit Plan, dated as of October 4, 2013
10.24**	Form of Amended and Restated Termination Protection Agreement, dated December 30, 2008, by and among Arena and Messrs. Lief and Spector and Dr. Behan (incorporated by reference to Exhibit 10.2 to Arena's Form 8-K filed with the Securities and Exchange Commission on December 31, 2008, Commission File No. 000-31161)
10.25**	Arena's 2009 Long-Term Incentive Plan (incorporated by reference to Exhibit 99.1 to Arena's registration statement on Form S-8 filed with the Securities and Exchange Commission on June 30, 2009, Commission File No. 333-160329)
10.26**	Form of Incentive Stock Option Grant Agreement for Employees under the Arena 2009 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.7 to Arena's quarterly report on Form 10-Q for the quarter ended June 30, 2009, filed with the Securities and Exchange Commission on August 7, 2009, Commission File No. 000-31161)
10.27**	Form of Stock Option Grant Agreement for Employees or Consultants under the Arena 2009 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.8 to Arena's quarterly report on Form 10-Q for the quarter ended June 30, 2009, filed with the Securities and Exchange Commission on August 7, 2009, Commission File No. 000-31161)
10.28**	Form of Stock Option Grant Agreement for Non-Employee Directors under the Arena 2009 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.9 to Arena's quarterly report on Form 10-Q for the quarter ended June 30, 2009, filed with the Securities and Exchange Commission on August 7, 2009, Commission File No. 000-31161)
10.29**	Arena's 2009 Employee Stock Purchase Plan, as amended (incorporated by reference to Exhibit 99.2 to Arena's registration statement on Form S-8 filed with the Securities and Exchange Commission on June 20, 2012, Commission File No. 333-182238)
10.30**	Arena's 2012 Long-Term Incentive Plan (incorporated by reference to Exhibit 99.1 to Arena's registration statement on Form S-8 filed with the Securities and Exchange Commission on June 20, 2012, Commission File No. 333-182238)
10.31**	Form of Incentive Stock Option Grant Agreement for Employees for grants prior to December 13, 2012, under the Arena 2012 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.3 to Arena's report on Form 8-K filed with the Securities and Exchange Commission on June 20, 2012, Commission File No. 000-31161)
10.32**	Form of Stock Option Grant Agreement for Employees or Consultants for grants prior to December 13, 2012, under the Arena 2012 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.4 to Arena's report on Form 8-K filed with the Securities and Exchange Commission on June 20, 2012, Commission File No. 000-31161)

**Table of Contents**

<b>EXHIBIT NO.</b>	<b>DESCRIPTION</b>
10.33**	Form of Stock Option Grant Agreement for Non-Employee Directors under the Arena 2012 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.5 to Arena's report on Form 8-K filed with the Securities and Exchange Commission on June 20, 2012, Commission File No. 000-31161)
10.34**	Form of Restricted Stock Grant Agreement under the Arena 2012 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.6 to Arena's report on Form 8-K filed with the Securities and Exchange Commission on June 20, 2012, Commission File No. 000-31161)
10.35**	Form of Incentive Stock Option Grant Agreement for Employees for grants beginning on December 13, 2012, under the Arena 2012 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.45 to Arena's annual report on Form 10-K for the year ended December 31, 2013, filed with the Securities and Exchange Commission on March 1, 2013, Commission File No. 000-31161)
10.36**	Form of Stock Option Grant Agreement for Employees or Consultants for grants beginning on December 13, 2012, under the Arena 2012 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.46 to Arena's annual report on Form 10-K for the year ended December 31, 2013, filed with the Securities and Exchange Commission on March 1, 2013, Commission File No. 000-31161)
10.37**	Form of Restricted Stock Unit Grant Agreement under the Arena 2012 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.47 to Arena's annual report on Form 10-K for the year ended December 31, 2013, filed with the Securities and Exchange Commission on March 1, 2013, Commission File No. 000-31161)
10.38**	Form of Performance Restricted Stock Unit Grant Agreement under the Arena 2012 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.2 to Arena's quarterly report on Form 10-Q for the quarter ended March 31, 2013, filed with the Securities and Exchange Commission on May 9, 2013, Commission File No. 000-31161)
10.39**	Arena's 2013 Long-Term Incentive Plan (incorporated by reference to Exhibit 99.1 to Arena's registration statement on Form S-8 filed with the Securities and Exchange Commission on June 10, 2013, Commission File No. 333-189213)
10.40**	Form of Stock Option Grant Agreement for Employees or Consultants under the Arena 2013 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.2 to Arena's current report on Form 8-K filed with the Securities and Exchange Commission on June 14, 2013, Commission File No. 000-31161)
10.41**	Form of Incentive Stock Option Grant Agreement for Employees under the Arena 2013 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.3 to Arena's current report on Form 8-K filed with the Securities and Exchange Commission on June 14, 2013, Commission File No. 000-31161)
10.42**	Form of Restricted Stock Unit Grant Agreement (other than for non-employee directors) under the Arena 2013 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.4 to Arena's current report on Form 8-K filed with the Securities and Exchange Commission on June 14, 2013, Commission File No. 000-31161)
10.43**	Form of Restricted Stock Unit Grant Agreement for Non-Employee Directors under the Arena 2013 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.5 to Arena's current report on Form 8-K filed with the Securities and Exchange Commission on June 14, 2013, Commission File No. 000-31161)
10.44**	Annual Incentive Plan for Arena's executive officers (incorporated by reference to Exhibit 10.1 to Arena's report on Form 8-K filed with the Securities and Exchange Commission on December 19, 2012, Commission File No. 000-31161)
10.45**	Summary of compensation for non-employee directors (incorporated by reference to Exhibit 10.1 to Arena's quarterly report on Form 10-Q for the quarter ended March 31, 2013, filed with the Securities and Exchange Commission on May 9, 2013, Commission File No. 000-31161)



**Table of Contents****EXHIBIT**

<b>NO.</b>	<b>DESCRIPTION</b>
10.46+	Second Amended and Restated Marketing and Supply Agreement, dated November 7, 2013, by and among Arena Pharmaceuticals GmbH, Eisai Inc. and Eisai Co., Ltd.
21.1	Subsidiaries of the registrant
23.1	Consent of Independent Registered Public Accounting Firm
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(A) promulgated under the Securities Exchange Act of 1934
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(A) promulgated under the Securities Exchange Act of 1934
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350 and Rule 13a-14(B) promulgated under the Securities Exchange Act of 1934
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

+ Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the SEC.

\* Exhibits and schedules to this agreement have been omitted pursuant to the rules of the Securities and Exchange Commission. We will submit copies of such exhibits and schedules to the Securities and Exchange Commission upon request.

\*\* Management contract or compensatory plan or arrangement.