

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

**FORM 10-K**

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the fiscal year ended December 31, 2019

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)

**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)

<u>Title of each class</u>	<u>Securities registered pursuant to 12(b) of the Act:</u> <u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, par value \$0.0001 per share	ARNA	The 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 every Interactive Data File required to be submitted 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 such files). Yes  No

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

Large accelerated filer	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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 \$2.9 billion as of June 28, 2019, 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 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 21, 2020, there were 50,249,149 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 2020, which will be filed with the Securities and Exchange Commission on or before April 29, 2020.

ARENA PHARMACEUTICALS, INC.  
FORM 10-K – ANNUAL REPORT  
For the Fiscal Year Ended December 31, 2019

Table of Contents

	<b>Page</b>
<b><u>PART I</u></b>	
Item 1.	<a href="#">Business</a> 2
Item 1A.	<a href="#">Risk Factors</a> 19
Item 1B.	<a href="#">Unresolved Staff Comments</a> 42
Item 2.	<a href="#">Properties</a> 43
Item 3.	<a href="#">Legal Proceedings</a> 43
Item 4.	<a href="#">Mine Safety Disclosures</a> 43
<b><u>PART II</u></b>	
Item 5.	<a href="#">Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</a> 44
Item 6.	<a href="#">Selected Financial Data</a> 46
Item 7.	<a href="#">Management’s Discussion and Analysis of Financial Condition and Results of Operations</a> 48
Item 7A.	<a href="#">Quantitative and Qualitative Disclosures About Market Risk</a> 56
Item 8.	<a href="#">Financial Statements and Supplementary Data</a> 57
Item 9.	<a href="#">Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</a> 89
Item 9A.	<a href="#">Controls and Procedures</a> 89
Item 9B.	<a href="#">Other Information</a> 92
<b><u>PART III</u></b>	
Item 10.	<a href="#">Directors, Executive Officers and Corporate Governance</a> 93
Item 11.	<a href="#">Executive Compensation</a> 93
Item 12.	<a href="#">Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</a> 93
Item 13.	<a href="#">Certain Relationships and Related Transactions, and Director Independence</a> 93
Item 14.	<a href="#">Principal Accounting Fees and Services</a> 93
<b><u>PART IV</u></b>	
Item 15.	<a href="#">Exhibits, Financial Statement Schedules</a> 93
Item 16.	<a href="#">Form 10-K Summary</a> 97

## 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,” “could,” “will,” “intend,” “plan,” “believe,” “anticipate,” “expect,” “estimate,” “predict,” “potential,” “prospect,” “continue,” “likely,” “opportunity,” “focused on,” “evaluating for,” “in development for,” the negative of these words or other similar words. Similarly, statements that describe our future plans, strategies, intentions, expectations, objectives, goals or prospects and other statements that are not historical facts are also forward-looking statements. Discussions containing these forward-looking statements may be found, among other places, in “Business” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in this Annual Report. 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 “Business,” “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in 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. In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely upon these statements. 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.

## TRADEMARKS AND CERTAIN TERMS

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.

Arena Pharmaceuticals ® and Arena ® are registered service marks of Arena. Any other brand names or trademarks appearing in this Annual Report are the property of their respective holders.

**Item 1. Business.**

**Overview**

We are a biopharmaceutical company focused on delivering novel, transformational medicines with optimized pharmacology and pharmacokinetics to patients globally. Our internally-developed pipeline includes multiple potentially first- or best-in-class assets with broad clinical utility.

Our most advanced investigational clinical programs include: etrasimod (APD334), being evaluated in a Phase 3 program for ulcerative colitis, or UC, a Phase 2b/3 program for Crohn's disease, or CD, and a Phase 2b program in atopic dermatitis, or AD. We also plan to evaluate etrasimod in a Phase 2b program for eosinophilic esophagitis, or EOE, and a Phase 2 program in alopecia areata, or AA. Olorinab (APD371) is being evaluated for a broad range of visceral pain conditions associated with gastrointestinal diseases and is currently in a Phase 2b trial for treatment of abdominal pain associated with irritable bowel syndrome, or IBS. APD418 is being evaluated in a Phase 1 trial for acute heart failure, or AHF.

We continue to leverage our two decades of world-class G-protein-coupled receptor, or GPCR, target discovery research to develop breakthrough drugs and ultimately deliver these to patients with large unmet needs. Our long-term pipeline prospects include an enhanced collaboration with Beacon Discovery across a broad range of immune-mediated inflammatory targets and compounds (which we refer to as Project Cabrillo) and the buildout of Arena Neuroscience to focus on treating neurological conditions with microglial neuroinflammation.

We have license agreements or collaborations with various companies, including United Therapeutics (ralinepag in a Phase 3 program for pulmonary arterial hypertension), Everest Medicines Limited (etrasimod in development in Greater China and select countries in Asia), Beacon Discovery (early research platform for GPCR targets), Boehringer Ingelheim International GmbH (undisclosed orphan GPCR program for central nervous system – preclinical), and Eisai Co., Ltd. and Eisai Inc., collectively, Eisai (BELVIQ®/BELVIQ XR®).

**Our Strategy**

The primary elements of our focus are to:

- Develop etrasimod – a modulator of the sphingosine 1-phosphate, or S1P, receptor intended for the treatment of a broad range of immune-mediated inflammatory diseases including gastrointestinal and dermatologic diseases;
- Develop olorinab – an agonist of the cannabinoid receptor 2, or CB<sub>2</sub>, intended for the treatment of a range of visceral pain associated with gastrointestinal conditions;
- Develop APD418 – a β<sub>3</sub>-AdR antagonist and cardiac myotrope for AHF;
- Progress a broad earlier stage pipeline build via Project Cabrillo and the Arena Neuroscience effort;
- Develop our pipeline by efficiently managing our cash and development timelines, which may include entering strategic agreements for certain clinical and preclinical programs;
- Progress additional pipeline programs over time in select therapeutic areas; and
- Prudently build a vibrant, sustainable, high-performing organization.

Arena Pharmaceuticals, Inc. was incorporated in the state of Delaware in April 1997 and is headquartered in San Diego, California. We also have operations in Boston, Massachusetts and Zug, Switzerland.

## Pipeline of Development Programs and Commercial Products

Below is a summary of our internally developed, proprietary portfolio:



We also own and have rights to other clinical and preclinical stage compounds that were internally discovered by us and have additional licensed or partnered programs that are not included in the above pipeline summary.

### Etrasimod Program

Etrasimod is a next-generation, oral, highly selective sphingosine 1-phosphate, or S1P, receptor modulator, discovered by Arena, designed to provide systemic and local cell modulation by selectively targeting S1P receptor subtypes 1, 4 and 5. S1P 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 subpopulations of lymphocytes in lymph nodes, fewer immune cells are available in the circulating blood to effect tissue damage. Etrasimod has therapeutic potential in immune-mediated inflammatory disease areas including gastroenterology and dermatology. We are currently evaluating etrasimod in ulcerative colitis, Crohn's disease, eosinophilic esophagitis, atopic dermatitis, and alopecia areata.

#### Gastrointestinal Diseases

##### Inflammatory bowel diseases

Inflammatory bowel diseases, or IBD, like UC and CD are chronic life-long immune-mediated inflammatory conditions of the gastrointestinal tract that affect approximately 1.8 million patients in the United States, or US, alone. The prevalence of UC and CD in the US are currently estimated at approximately 0.9 million and 0.8 million patients, respectively. The prevalence of IBD in United Kingdom, France, Germany, Italy and Spain collectively, or EU5, is estimated at 1.3 million with approximately 0.7 million patients with UC and 0.6 million patients with CD. Both conditions represent a significant burden to patients, including hospitalization, surgery, and a longer-term risk of colon cancer, as well as impaired quality of life, economic productivity and social functioning. Additionally, Japan has an estimated prevalence of approximately 0.2 million IBD patients. In aggregate, there are approximately 3.3 million patients across the US, EU5 and Japan that are currently living with IBD.

UC is characterized by contiguous mucosal inflammation limited to the colon which involves the rectum in approximately 95% of cases and may extend to involve parts or all of the large intestine. In contrast, CD is characterized by full thickness inflammation that can occur anywhere in the gastrointestinal, or GI, tract but most typically involves the terminal ileum and colon; and causes fistulation and scarring. Symptoms for UC and CD can vary, depending on the location and severity of inflammation, but some of the most common are diarrhea, abdominal cramps, and rectal bleeding.

Important goals of therapy for IBD are durable remission while improving the patient's quality of life. Although a number of therapies are approved for the treatment of IBD, they are often associated with an inability to induce or maintain remission, serious side effects, and complicated administration regimens. There is therefore an unmet medical need for novel oral agents with an enhanced risk-benefit profile and more convenient administration for the treatment of moderately to severely active IBD.

## *Eosinophilic Esophagitis*

Eosinophilic Esophagitis, or EOE, is a chronic, relapsing and remitting, immune mediated disease of the esophagus driven by an allergic Th2 T cell inflammatory profile. Histologically, EOE is characterized by the accumulation of eosinophils in the lining of the esophagus, a tissue that under normal conditions lacks these cells. In addition to eosinophils, CD4 and CD8 T cells, dendritic cells and mast cells increase in the tissue. The presence of these unwelcome inflammatory cells has been shown to have a direct effect on immune function and tissue damage. Both pediatric and adult populations can develop EOE, however, the disorder is most common in individuals between the ages of 20 and 40 years old. EOE also exhibits a strong heritability pattern and predominance for males and for Caucasians, and principally in socioeconomically developed countries. There are no approved therapies in the US for the treatment of EOE. We believe that etrasimod may represent a significant opportunity to provide an effective treatment to EOE due to its potential to modulate the trafficking of multiple immune subsets.

## ***Dermatologic Conditions***

### *Atopic Dermatitis*

Atopic Dermatitis, or AD, is a chronic, inflammatory skin disorder characterized by dry skin, pruritus, and relapsing lesions. AD has a severe impact on quality of life, including potential occupational, social, and psychological impairments. The adult diagnosed prevalence is approximately 8.5 million patients in the US, and 6.5 million patients in the EU5. According to a recent survey with dermatologists in the US, 62% of dermatologists reported a high unmet need in Atopic Dermatitis.

Long-term efficacy of these therapies also remains relatively unknown. Therefore, we believe a significant unmet need remains for differentiated, safe, oral agents that are effective and have a favorable side effect profile. AD pathology is driven by a combination of impaired skin epithelial barriers, altered microbiota, and aberrant inflammation driven by activated immune cells, including skin-infiltrating T cells and dendritic cells, or DCs. Etrasimod may have the potential to reduce DC migration/activation (S1P receptor subtypes 1 and 4 mediated) and T cell infiltration (S1P receptor subtype 1 mediated) in the skin. These effects could reduce the T cell-mediated inflammation in the skin that underlies atopic dermatitis pathogenesis.

### *Alopecia Areata*

Alopecia areata, or AA, is a T-cell-mediated autoimmune skin disorder with unmet medical need that causes non-scarring patchy hair loss, most often on the scalp. The prevalence is approximately 2.9 million patients in the US and 2.2 million in the EU.

The disease may be limited to 1 or more discrete, round or oval patches of hair loss the size of a coin on the scalp, or it may progress to full hair loss of the scalp (alopecia totalis) or the entire body (alopecia universalis). The course of disease is unpredictable, with spontaneous regrowth of hair occurring in 80% of patients within the first year, and sudden relapse at any given time. Patients with extensive disease (at least 50% total scalp hair loss) rarely have spontaneous hair regrowth. Patients with persistent moderate-to-severe AA also often suffer tremendous emotional and psychosocial distress and reduced quality of life as a result of their hair loss. Thus, psychosocial support and therapy is an important part of disease management, as this often-disfiguring disease can be psychosocially burdensome. The estimated lifetime risk of AA is 1.7% among the general population and represents the second most common form of human hair loss, second only to androgenetic alopecia. The current standard of care is injected corticosteroids which have limitations in terms of efficacy. Etrasimod may have the potential to reduce circulating CD4+ and CD8+ lymphocytes available to infiltrate the hair follicle which may decrease inflammation and restore hair growth.

## ***Etrasimod Development***

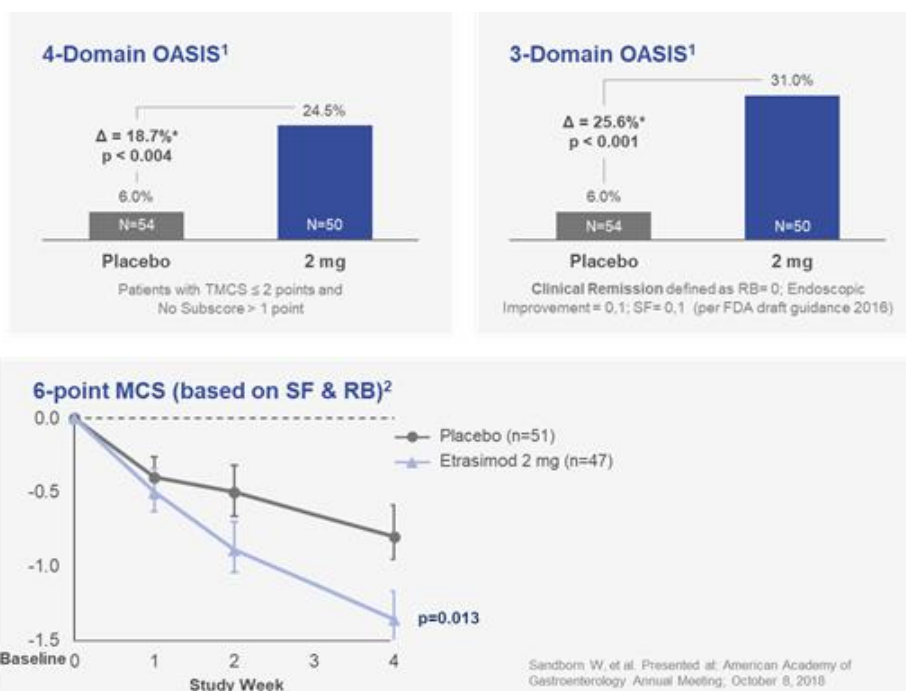
### *Inflammatory Bowel Disease*

We are currently in a Phase 3 program in UC and a Phase 2b/3 program in CD.

In 2019, we announced positive results from a 34-week open-label extension, or OLE, of the Phase 2 OASIS trial of etrasimod for the treatment of ulcerative colitis. The trial enrolled 118 patients (84% of OASIS study completers), of which 22 completers also received 2 mg in OASIS, for a total of 46 weeks of treatment with etrasimod. Overall, etrasimod demonstrated durable, long-term clinical remission and was generally well tolerated in this trial. Adverse events in the OLE study were generally mild to moderate in severity and no new safety findings were noted. Impact on heart rate and atrioventricular, or AV, conduction was minimal throughout the study with no discontinuations from study related to bradycardia or AV block.

In 2018, we announced topline results from OASIS, a dose finding 12-week randomized, double-blind, placebo-controlled multinational Phase 2 clinical trial of etrasimod in moderate to severe UC. The aim of the trial was to investigate dose response and compare the active arm(s) to placebo. The trial evaluated the effects of etrasimod at 1mg and 2mg versus placebo on multiple efficacy

measures including a three-component partial Mayo Clinic Score, clinical remission, clinical response, and endoscopic improvement in 156 patients. Etrasimod demonstrated a clear dose response and statistically significant improvements versus placebo in the primary, all secondary, and clinical remission endpoints at the 2 mg dose. There were fewer patients with serious adverse events, or SAEs, compared to placebo (0% in 2 mg, 5.8% in 1 mg and 11.1% in placebo). Impact on heart rate and atrioventricular, or AV, conduction was low throughout the study with no discontinuations from study related to bradycardia or AV block. There were no increases in liver function tests compared to placebo and no reports of macular edema or pulmonary function test abnormalities. In this trial, etrasimod was well tolerated.



$\Delta$ =% difference from placebo estimated using Mantel-Haenszel method adjusted with current oral corticosteroid use and prior exposure to TNF $\alpha$  antagonists.

<sup>2</sup>  $\Delta$  = LS mean change from baseline. The 6-point MCS is based on stool frequency and rectal bleeding. Least-squares mean and standard error were estimated using a mixed-effects model with current oral corticosteroid use, prior exposure to anti-TNF $\alpha$ , treatment, week, and treatment-by-week interaction as factors and baseline value as covariate.

#### *Eosinophilic Esophagitis*

We are preparing for a Phase 2b program in Eosinophilic Esophagitis.

#### *Atopic Dermatitis*

We are currently in a Phase 2b program in atopic dermatitis.

#### *Alopecia Areata*

We are preparing for a Phase 2 program in Alopecia Areata.

#### **Prior Development**

In January 2015, we announced top-line results from a Phase 1b multiple-ascending dose clinical trial for etrasimod. In this trial, etrasimod demonstrated a dose-dependent effect on lymphocyte count lowering in blood, with mean decreases from baseline of up to 69%. Lymphocyte counts, on average, recovered to baseline within one week of conclusion of dosing. There was a modest impact on heart rate, but none of the changes were classified by the investigator as clinically significant. There were also no findings with respect to pulmonary function or liver enzyme tests that were classified by the investigator as clinically significant. The most common treatment-emergent adverse events were mild or moderate contact dermatitis, headache, constipation and diarrhea, with none being clearly drug related. There were no discontinuations for adverse events, and no serious adverse events were observed.

The randomized, double-blind, placebo-controlled Phase 1b clinical trial evaluated the safety, tolerability, pharmacodynamics and pharmacokinetics of multiple-ascending doses of etrasimod. In five different dosing cohorts, 50 healthy volunteers received etrasimod and 10 healthy volunteers received placebo for 21 days.

Prior to commencing the Phase 1b multiple-ascending dose clinical trial for etrasimod, we completed a Phase 1 single-ascending dose clinical trial of the compound. This randomized, double-blind and placebo-controlled trial evaluated the safety, tolerability and pharmacokinetics of single-ascending doses of etrasimod in 40 healthy adult volunteers. In the trial, etrasimod demonstrated favorable pharmacokinetic and pharmacodynamic effects, a dose-responsive reduction in blood lymphocyte count and a slowing of heart rate that appears comparable to other S1P receptor modulators. The terminal half-life was approximately 35 hours.

### ***Etrasimod Intellectual Property***

As of February 14, 2020, we owned issued patents that cover compositions of matter for etrasimod and related compounds, methods of treatment utilizing etrasimod and related compounds, and various salts of etrasimod and crystalline forms thereof in 61 jurisdictions, including the United States, China, Japan, Germany, France, Italy, the United Kingdom, Spain, Canada, India, Russia, South Korea and Australia, and had an application pending in one other jurisdiction (Brazil). The earliest priority date for the patents on etrasimod is 2008. The terms of these patents are 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.

### **Olorinab Program**

Olorinab, a potentially first-in-class, orally available, potent, peripherally restricted, highly selective, full agonist of the CB2 receptor, is an internally discovered investigational drug candidate we are exploring for the treatment of visceral pain, specifically pain associated with the gastrointestinal system, such as IBD and irritable bowel syndrome, or IBS.

Visceral pain is defined as pain that originates within muscle, pleura, connective tissue, nervous system or solid organs within the abdomen or peritoneum. It is distinct from somatic or neuropathic pain, and is perceived as stretching, pulling and distention, rather than by cutting, crushing, or burning more commonly associated with neuropathic pain. Visceral pain is one of the most common types of pain. For example, abdominal pain affects approximately 20% of the general population. Visceral pain may be caused by a diverse set of organic causes, such as inflammation (e.g., IBD, including CD and UC, pancreatitis, prostatitis, and vaginitis), obstruction (e.g., bowel obstruction, and nephrolithiasis), ischemia, and malignancy, among others. Visceral pain may also be caused by functional disorders such as interstitial cystitis, dyspepsia, IBS, and vulvodynia.

There are approximately 1.8 million patients in the US diagnosed with IBD, with most patients experiencing abdominal pain or cramps. There are approximately 27 million patients in the US with IBS, with 78% reporting frequently recurring or continuous abdominal pain. Common treatments for visceral pain range from non-invasive, conservative approaches (e.g., physical therapy or acupuncture), to pharmacologic (e.g., tricyclic antidepressants acting as neurotransmitter reuptake inhibitors), and invasive interventions (e.g., bowel resection). Potent analgesics, such as opioids, can adversely affect GI function. Other commonly prescribed analgesics are often not potent enough and may lead to other GI side effects such as bleeding. Except for linaclotide and lubiprostone, prescribed for IBS, no visceral-specific analgesics are currently available. Approximately one in eight CD patients is chronically treated with opioids.

The CB2 receptor is expressed in the GI nervous system, and in many tissues and organs of the abdomen. CB2 receptors are found peripherally on immune cells but also on microglia, terminal neurons, dorsal root ganglia, and on visceral sensory neurons. We believe selectively targeting the CB2 receptor may provide therapeutic benefit for visceral pain without the potential for dependence, abuse, and GI and cardiovascular side effects associated with opiates or nonsteroidal anti-inflammatory drugs, or NSAIDs, which are among the most common pain relievers. In addition to analgesic effects, olorinab may have anti-inflammatory properties.

Olorinab is designed to be a peripherally restricted and selective CB2 receptor agonist and is intended to provide pain relief without the unwanted side effects associated with CB1 receptor activation.

### ***Olorinab Development***

In 2018, we announced positive topline results from our Phase 2a trial of olorinab in development for the treatment of pain associated with CD. This exploratory study was an open-label investigation to evaluate safety and tolerability of olorinab in this patient population and to gain initial insights into its efficacy via a pain visual analog scale, or VAS. Fourteen patients were enrolled into two cohorts at 25 mg and 100 mg administered three times daily for up to eight weeks. Reductions in pain were seen within the first week of treatment and statistically significant improvement from baseline in Average Abdominal Pain Score, or AAPS, at weeks



four and eight. In this trial, olorinab appeared generally well tolerated with no clinically significant changes in heart rate or blood pressure, no psychotropic effects, and no discontinuations due to adverse events.



In April 2016, we announced favorable results from a Phase 1b multiple-ascending dose clinical trial of olorinab. This randomized, double-blind, placebo-controlled Phase 1b clinical trial enrolled 36 healthy adults to evaluate the safety, tolerability and pharmacokinetics of multiple-ascending doses of olorinab. Cohorts of 12 subjects (nine active, three placebo) were administered doses of 50 mg, 100 mg, or 200 mg of olorinab or placebo three times daily for 10 days and, in connection with the pharmacokinetic evaluation, one time on the 11th day. The most common adverse events were headache and nausea. All adverse events were classified as mild, and there were no serious adverse events reported. There was one discontinuation in the high-dose group due to an adverse event of mild thirst and somnolence. Reductions in blood pressure and heart rate were observed, but none were symptomatic or resulted in an adverse event. Drug levels at all doses tested in the trial, including the lowest dose, were well above those believed to be needed to stimulate the CB2 receptor.

In April 2015, we announced favorable top-line results from a Phase 1 single-ascending dose clinical trial of olorinab. The randomized, double-blind and placebo-controlled trial enrolled 56 healthy adults to evaluate the safety, tolerability and pharmacokinetics of single-ascending doses of olorinab. Dose-responsive exposure was observed over the explored dose range of 10-400 mg with good tolerability at all doses administered.

### ***Olorinab Intellectual Property***

As of February 14, 2020, we owned issued patents covering compositions of matter for olorinab and related compounds, and methods of treatment utilizing olorinab and related compounds, in 21 jurisdictions, including the United States, China, Japan, Canada, Russia, South Korea and Australia, and we had applications pending in 11 other jurisdictions, of which the ones with the largest pharmaceutical markets were Europe, Venezuela, Brazil and India. The earliest priority date for the patents on olorinab is 2009. The terms of these patents are 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 the later filed patent applications.

### **APD418 Program**

APD418 is a first-in-class  $\beta_3$ -adrenergic receptor (AdrR) antagonist and cardiac myotrope designed to regulate myofilament calcium sensitivity in order to improve contractility without inducing the serious adverse events associated with currently available inotropes. APD418 is in early-stage clinical development for patients with acute heart failure, or AHF.

In January 2020, we announced acceptance of our investigational new drug, or IND, and were granted Fast Track designation for APD418. We have initiated a Phase 1 trial.

AHF is broadly defined as a rapid onset of new or worsening signs and symptoms of HF. It is a potentially life-threatening condition, requiring hospitalization, and emergency treatment is aimed predominantly at managing fluid overload and achieving hemodynamic stability. In most cases, hospitalization for AHF results when the neurohormonal compensatory mechanism, which acts to maintain hemodynamic stability in chronic heart failure, are inadequate.

Management of AHF is focused on treating clinical conditions and precipitating factors, immediate stabilization, and symptom relief. Most patients presenting to the emergency department with AHF are congested and have normal to high blood pressures. Diuretics are first line therapy to treat volume overload including congestion; vasodilators are also used as first line therapy for symptom relief in normotensive and hypertensive patients who fail to respond adequately to diuretics. Unfortunately, neither diuretics nor vasodilators have been associated with improved survival.

For patients presenting as hypotensive, who are at the highest risk of mortality, and patients who fail to adequately respond to initial therapy, treatment options are particularly limited and may require the use of inotropic agents. These agents aim increase cardiac contractility and restore hemodynamic status via stimulation of the myocardial  $\beta_1$ -AdR, but they are associated with significant risk of unwanted hemodynamic effects, arrhythmias, and pathway dependent cardiotoxicity, leading to adverse outcomes and increased mortality.

Arena is developing APD418, an internally discovered and developed this investigational drug candidate, to address the significant unmet need in AHF.

#### ***APD418 Intellectual Property***

As of February 14, 2020, we owned an issued patent covering compositions of matter for APD418 and related compounds, and methods of treatment utilizing APD418 and related compounds, in the United States, and we had applications pending in 42 other jurisdictions, of which the ones with the largest pharmaceutical markets were Europe, China, and Japan. The earliest priority date for the patent on APD418 is 2016. The term of this patent is capable of continuing into 2037 without taking into account any patent term extension.

#### **Additional Internal Preclinical and Clinical Programs**

We have initiated Project Cabrillo for the development of multiple novel, early stage, oral autoimmune programs. The multiple G-protein-coupled receptors, or GPCRs, targets in this collaboration with Beacon Discovery and their associated chemistry, represent the next generation of oral compounds which, if successfully developed and approved, may transform the way autoimmune diseases are approached and treated. Project Cabrillo includes both novel and validated targets and compounds.

We are progressing early-stage neuroscience assets in an underlying platform focused on microglial neuroinflammation. These programs have applications in multiple diseases and will be placed into a new subsidiary, Arena Neuroscience.

We have additional assets, including temanogrel and other 5-HT<sub>2A</sub> modulators, which are either in or being evaluated for future clinical and preclinical development. We are also evaluating additional delivery forms of the products in our pipeline to extend clinical utility or improve the product profile.

#### **Collaborations and License Agreements**

In addition to our primary focus on developing our proprietary, unencumbered clinical pipeline, we have strategic collaborations and licenses with pharmaceutical companies, including United Therapeutics, Everest Medicines Limited, or Everest, Boehringer Ingelheim International GmbH, or Boehringer Ingelheim, Beacon Discovery, Inc., or Beacon, and Eisai.

##### ***United Therapeutics License Agreement***

In November 2018, we entered into a collaboration and license agreement with United Therapeutics. Under the United Therapeutics Agreement, we granted United Therapeutics an exclusive, worldwide, royalty-bearing license to develop, manufacture and commercialize ralinepag. This transaction was completed in January 2019. At the closing of the transaction, we transferred to United Therapeutics certain other assets relating to ralinepag, including, among others, related domain names and trademarks, permits, certain contracts, inventory, regulatory documentation, IND, and non-clinical, pre-clinical and clinical trial data. United Therapeutics has agreed to assume certain limited liabilities, including, among others, all post-closing obligations under assumed contracts and the IND. United Therapeutics is responsible for all development, manufacture and commercialization of the licensed products globally.

Upon the closing of this transaction, in January 2019, we received an upfront payment of \$800.0 million. We are eligible to receive a payment of \$150.0 million upon first marketing approval of ralinepag in a major non-US market, and a payment of \$250.0 million upon US marketing approval of an inhaled formulation of ralinepag. In addition, we are entitled to receive low double-digit, tiered royalties on net sales of ralinepag products, subject to certain adjustments for third party license payments.

The United Therapeutics Agreement contains various representations and warranties of Arena and United Therapeutics, and various covenants of the parties, including covenants to cooperate in seeking regulatory approvals, as well as our agreement not to

compete, during the period in which royalties are payable (or during the five-year period following the closing if we are subject to a change of control transaction) in the development of a prostacyclin to treat pulmonary arterial hypertension, or PAH.

### *Ralinepag Program*

Ralinepag is in a Phase 3 program for PAH. Ralinepag is a next-generation potent, highly selective oral IP receptor agonist intended for the treatment of PAH. Ralinepag was designed by us to deliver intravenous prostacyclin-like potency and pharmacokinetics in an oral tablet. In non-clinical experiments, ralinepag demonstrated potentially best-in-class activation of the IP receptor resulting in vasodilation, inhibition of smooth muscle cell proliferation and inhibition of platelet aggregation. Additionally, early stage studies of ralinepag pharmacokinetics in humans revealed an approximately 24-hour half-life and a low peak-to-trough ratio supporting therapeutic blood levels with once daily dosing.

Ralinepag was granted orphan drug status for the treatment of PAH by the US Food and Drug Administration, or FDA, in September 2014, and by the European Medicines Agency in January 2019.

PAH is a progressive, life-threatening disorder characterized by increased pressure in the pulmonary arteries that carry blood from the heart to the lungs. PAH occurs when the pulmonary arteries thicken or grow rigid. This makes blood flow more difficult. The heart must work harder to push blood through the arteries, and the arteries are unable to carry adequate blood to the lungs. The increased pressure strains the heart, which can limit physical activity, result in heart failure and reduce life expectancy. PAH will continue to worsen over time, even with proper treatment. Based on data from the Registry to Evaluate Early And Long-term PAH disease management, or REVEAL, of patients in the US, there is an estimated five-year survival rate of 57% from diagnosis.

PAH involves several interrelated mechanisms, with prostacyclin and thromboxane A2 playing a major role in maintaining pulmonary vascular tone through their balanced activity. Prostacyclin, released by endothelial cells, promotes vasodilation and inhibits platelet aggregation. Prostacyclin also has antiproliferative effects on vascular smooth muscle. Despite treatment guidelines, targeting the prostacyclin pathway has been primarily reserved for patients with advanced disease due to limitations of currently available options including parenteral prostacyclins which are the only PAH treatment that have demonstrated a mortality benefit.

### *Everest Collaboration*

In December 2017, we entered into a Collaboration and License Agreement, or the Everest Agreement, with Everest regarding the development and commercialization of ralinepag and etrasimod in China, Taiwan, Hong Kong, Macau and South Korea, or the Everest Territories. In January 2019, we and Everest amended the Everest Agreement by entering into two separate agreements, one for each of ralinepag and etrasimod, with the terms for each program that are substantially the same as in the original Everest Agreement. Under the United Therapeutics Agreement, we assigned the separate Everest Agreement related to ralinepag to United Therapeutics.

Under the separate Everest Agreement related to etrasimod, we granted Everest an exclusive, royalty-bearing license to develop, manufacture and commercialize etrasimod (in oral formulations only), in the Everest Territories.

Everest is responsible for all development, manufacture and commercialization of the licensed products in the Everest Territories, and may participate in the portion of our global clinical trials that is conducted in the Everest Territories.

We are eligible to receive development, regulatory and commercial milestone payments from Everest, as well as tiered royalties on net sales ranging from the high single digits to low double digits. Following an initial royalty term, we are eligible to receive a lower trademark royalty if Everest continues to use our licensed product-related trademarks.

In the fourth quarter of 2018, the National Medical Products Administration of China, formerly known as the China Food and Drug Administration, or CFDA, accepted the initial clinical trial applications for an oral formulation of ralinepag and for etrasimod. Subsequently, in the fourth quarter of 2019, Everest announced that the first subject has been dosed in a Phase 3 trial evaluating etrasimod in development for the treatment of UC in Greater China and South Korea.

### *Boehringer Ingelheim Collaboration*

In 2015, we entered into an exclusive agreement with Boehringer Ingelheim, to conduct joint research to identify drug candidates targeting a GPCR that belongs to a group of orphan central nervous system, or CNS, receptors. An “orphan receptor” is structurally related to a family of proteins that are known to act as functional cell-surface receptors but whose ligand has not yet been identified. In December 2018, Boehringer Ingelheim opted to start the preclinical development of the subject compound.

In the past, we contracted with Beacon to perform our research obligations under the Boehringer Ingelheim collaboration. In exchange, we agreed to share limited near-term milestones with Beacon as well as the full-time equivalent funding paid to us by Boehringer Ingelheim. We have retained the longer-term success milestones and all royalties.

### ***Beacon Discovery Agreements***

In January 2020, we entered into a new multi-year strategic Collaboration and License Agreement with Beacon, aimed at building novel medicines across a range of GPCR targets believed to play a role in immune and inflammatory diseases. Under the terms of this agreement, referred to as Project Cabrillo, Beacon is responsible for early drug discovery activities and Arena will be responsible for any potential future development and, ultimately, commercialization activities. We are required to pay to Beacon research initiation fees, make quarterly research funding payments for the duration of Beacon's research activities as well as research, development and regulatory milestone payments. We are also obligated to pay Beacon tiered royalties on net sales of low single digits levels.

Prior to Project Cabrillo, beginning in September 2016, we entered into a series of agreements with Beacon.

In 2016, we entered into a License and Collaboration Agreement with Beacon, pursuant to which we granted Beacon a non-exclusive, non-assignable and non-sublicensable license to certain database information relating to compounds, receptors and pharmacology, and transferred certain equipment to Beacon. Beacon will seek to engage global partners to facilitate discovery and development. Beacon has agreed to assign to us any intellectual property relating to our existing research and development programs developed in the course of performing research for us, and grant us a non-exclusive license to any intellectual property developed outside the course of performing work for us that is reasonably necessary or useful for developing or commercializing the products under our research and development programs. We are also entitled to rights of negotiation and rights of first refusal to potentially obtain licenses to certain compounds discovered and developed by Beacon. In addition, we are entitled to receive (i) a percentage of any revenue received by Beacon on or after the second anniversary of the effective date of the agreement from any third party pursuant to a third-party license, including upfront payments, milestone payments and royalties; (ii) single-digit royalties on the aggregate net sales of any related products sold by Beacon and its affiliates; and (iii) in the event that Beacon is sold, a percentage of the consideration for such sale transaction.

In 2016, we also entered a Master Services Agreement with Beacon, pursuant to which Beacon performs certain other research services for us relating to our proprietary pipeline.

Beacon was founded and is owned by several of our former employees.

### ***BELVIQ and BELVIQ XR (lorcaserin) Agreement***

In December 2016, we entered into a Transaction Agreement with Eisai regarding lorcaserin. Pursuant to the Transaction Agreement, we granted Eisai an exclusive, royalty-bearing license, or transferred intellectual property, to develop, manufacture and commercialize lorcaserin in all countries and territories of the world. Under the Transaction Agreement we are entitled to receive tiered royalty payments starting at 9.5% on net sales of lorcaserin.

Eisai is solely responsible for all costs and expenses in connection with the development of lorcaserin. Eisai has the exclusive right and responsibility to plan and implement all research and development of lorcaserin at its own cost and expense, including conducting all regulatory activities and all clinical and development activities.

Under the Transaction Agreement, Eisai is solely responsible for development, manufacturing, and commercialization of lorcaserin including all regulatory activities.

Eisai is solely responsible for any expenses and losses associated with product liability claims, except we and Eisai share 50% of losses for any alleged defective manufacturing of lorcaserin that was manufactured by us prior to entering into the Transaction Agreement.

Lorcaserin was approved for marketing in the U.S., and in certain other territories, for the indication of weight management. On February 13, 2020, the FDA issued a drug safety communication announcing that it requested Eisai voluntarily withdraw lorcaserin from the U.S. market based on the FDA's analysis of data from the Cardiovascular and Metabolic Effects of Lorcaserin in Overweight and Obese Patients – Thrombolysis in Myocardial Infarction 61 (CAMELLIA-TIMI 61) study, and that Eisai has submitted a request to voluntarily withdraw lorcaserin from the U.S. market.

### **Intellectual Property**

Our success depends in large part on our ability to protect our 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 methods of treatment.

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 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 exclusivity afforded by any patent on our drug candidates will likely be substantially less than 20 years.

In the United States, patent term adjustment is available for certain delays in patent office proceedings. In addition, 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 be eligible for patent term extension, or PTE. PTE permits patent term restoration of a US patent as 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 an 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.

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.

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, 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 generally require our consultants and collaborators that have access to proprietary property and information to execute confidentiality and invention rights agreements in our favor. 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 many organizations with drugs or drug candidates that do or may compete 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. Developments by others may render our drug candidates obsolete or noncompetitive, and we or our collaborators may not be successful in developing either first or best in class drugs.

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 longer 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 collaboration 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, import, export, 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;
- 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, performed in accordance with the FDA's Good Clinical Practice, or GCP, regulations, to establish the safety and efficacy of the drug candidate for each proposed indication;
- submission to the FDA of a New Drug Application, or 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 of the manufacturing facilities at which the active pharmaceutical ingredient and finished drug product are produced and tested to assess compliance with Current Good Manufacturing Practices, or cGMP, regulations;
- FDA review and approval of the NDA prior to any commercial marketing or sale of the drug in the United States; and
- Prior to commercialization, centrally acting drugs may be subject to review and potential scheduling by the DEA.

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 initial IND becomes effective 30 days after receipt by the FDA, following its initial safety review. During the 30-day time period the FDA may require additional information. The FDA may institute a clinical hold at the 30-day time period if any questions are not fully addressed or because of other concerns 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. The FDA may place an IND on partial or full clinical hold at any time during a product candidate's development. 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.
- 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 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. The FDA reviews all NDAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing, which occurs, if at all, 60 days after submission by the NDA sponsor. 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, six 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 an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee. The FDA may deny approval of an NDA by issuing a 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.

**Expedited Development and Review Programs.** The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new drug products that meet certain criteria. Specifically, new investigational drugs are eligible for Fast Track designation if they are intended to treat a serious or life threatening disease or condition and nonclinical or clinical data demonstrate the potential to address unmet medical needs for the disease or condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. The FDA may consider for review sections of the NDA for a Fast Track product on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

Any product submitted to the FDA for approval, including a product with a Fast Track designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A product is eligible for priority review if it is designed to treat a serious condition, and if approved, would provide a significant improvement in safety or effectiveness compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug designated for priority review in an effort to facilitate the review. The FDA endeavors to NDAs for new molecular entities with priority review designations within six months of the filing date as compared to ten months under its standard review goals.

In addition, a product may be eligible for accelerated approval. Drug products intended to treat serious or life threatening diseases or conditions may be eligible for accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well controlled post marketing clinical trials to verify the predicted clinical benefit. Products receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required post-market studies or if such studies fail to verify the predicted clinical benefit. In addition, the FDA currently requires, as a condition for accelerated approval, pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

The Food and Drug Administration Safety and Innovation Act established a category of drugs and biologics referred to as “breakthrough therapies” that may be eligible to receive Breakthrough Therapy Designation. A sponsor may seek FDA designation of a drug candidate as a “breakthrough therapy” if the product is intended, alone or in combination with one or more other products, to treat a serious or life threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the Fast Track program features, as well as more intensive FDA interaction and guidance. The Breakthrough Therapy Designation is a distinct status from both accelerated approval and priority review, which can also be granted to the same drug if relevant criteria are met. If a product is designated as breakthrough therapy, the FDA will expedite the development and review of such drug. All requests for breakthrough therapy designation will be reviewed within 60 days of receipt, and the FDA will either grant or deny the request.

Fast Track designation, Breakthrough Therapy designation and priority review do not change the standards for approval but may expedite the development or approval process.

**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 cGMP 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 or after the appropriate FDA office review of the Establishment Inspection Report prepared by the investigator, can list conditions the FDA believes may have violated cGMP or other FDA regulations. FDA guidelines specify that a warning letter be issued 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, recall of product, 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 healthcare professional marketing activities and materials, 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 confines of the pivotal studies and the approved label. Further, we may be required 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 for changes to, among other things, the indications, labeling, or manufacturing processes or facilities of a drug. 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.

**Drug Enforcement Administration 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.

**Hatch-Waxman Exclusivity.** 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, or NCE, subject to an NDA is entitled to a five-year period of non-patent marketing exclusivity in the United States. A drug is an NCE 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.

**Orphan drug designation and exclusivity.** Under the Orphan Drug Act, the FDA may designate a drug product as an "orphan drug" if it is intended to treat a rare disease or condition (generally meaning that it affects fewer than 200,000 individuals in the United States, or more in cases in which there is no reasonable expectation that the cost of developing and making a drug product available in the United States for treatment of the disease or condition will be recovered from sales of the product). A company must request orphan product designation before submitting an NDA. If the request is granted, the FDA will disclose the identity of the therapeutic agent and its potential use. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product with orphan status receives the first FDA approval for the disease or condition for which it has such designation or for a select indication or use within the rare disease or condition for which it was designated, the product generally will receive orphan product exclusivity. Orphan product exclusivity means that the FDA may not approve any other applications for the same product for the same indication for seven years, except in certain limited circumstances. Competitors may receive approval of different products for the indication for which the orphan product has exclusivity and may obtain approval for the same product but for a different indication or the same product for the same indication if demonstrated to be clinically superior. If a drug or drug product designated as an orphan product ultimately receives marketing approval for an indication broader than what was designated in its orphan product application, it may not be entitled to exclusivity.

**Pediatric exclusivity.** Under Section 505(A) of the Food and Drug Administration Modernization Act (FDAMA), the FDA may issue Written Requests for pediatric studies prior to approval of a new drug application, if the FDA has determined that information related to the use of the drug in the pediatric population may produce health benefits. As an incentive to industry to conduct such studies requested by the FDA, Section 505(A) provides for a 6-month period as an add-on to existing marketing exclusivity periods and patent terms (“pediatric exclusivity”).

### ***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. Whether or not we obtain FDA approval for a product candidate, we must obtain the requisite approvals from regulatory authorities in foreign jurisdictions prior to the commencement of clinical studies or marketing and sale of the product in those countries. Approval in the United States does not guarantee approval in other countries and vice-versa.

**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 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, which has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. 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 the ACA, 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. There have been judicial and Congressional challenges to certain aspects of the ACA. For example, since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or TCJA, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate”. Additionally, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the PPACA-mandated “Cadillac” tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. Further, the Bipartisan Budget Act of 2018, or the BBA, among other

things, amended the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole”. In December 2018, the United States Department of Health and Human Services’ Centers for Medicare & Medicaid Services, or CMS, published a new final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress as part of the TCJA. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the PPACA are invalid as well. It is unclear how this decision, future decisions, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA and our business. 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.

Further, the Trump administration’s budget proposal for fiscal year 2021 includes a \$135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. The Trump administration previously released a “Blueprint” to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The Department of Health and Human Services, or HHS, has solicited feedback on some of these measures and has implemented others under its existing authority. While some measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

In countries 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 countries 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 countries 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.

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” or “the practice of medicine,” if deemed appropriate in the physicians’ 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.

In addition, the federal transparency requirements under the Physician Payments Sunshine Act require applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to track and annually report to the Centers for Medicare & Medicaid Services, or CMS, payments and other transfers of value provided to physicians, as defined by such law, and teaching hospitals, and certain ownership and investment interests held by physicians or their immediate family members.

We may also be subject to state equivalents of these fraud and abuse laws.

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, possible exclusion from federal healthcare programs (including Medicare and Medicaid), and integrity oversight and reporting obligations to resolve allegations of non-compliance with these laws. 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. The federal transparency requirements under the ACA require certain manufacturers of drugs, devices, biologics and medical supplies to annually report to the Department of Health and Human Services information related to payments and other transfers of value to physicians and teaching hospitals and physician ownership and investment interests. 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 and other privacy and security laws.** We are subject to numerous laws and regulations regarding the privacy, protection, and security of health information and other personal information. These laws and regulations impose obligations and restrictions on us with respect to the collection, storage, use, disclosure, transfer and security of personal information.

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, imposes obligations with respect to safeguarding the privacy, security and transmission of individually identifiable health information. We may be subject to, or our collaborators' marketing activities may be limited by, HIPAA and its implementing regulations. In addition, many state laws apply to the use and disclosure of health and other personal information.

For example, as of January 1, 2020, we are subject to the California Consumer Privacy Act, or CCPA. The CCPA has created new individual privacy rights for California residents and places increased privacy and security obligations on entities handling the personal information of such residents. Among other obligations, the CCPA requires covered businesses to provide new disclosures to California residents and to respond to requests to access and/or delete personal information. The CCPA also allows for a private right of action for data breaches.

The European General Data Protection Regulation, or GDPR, imposes many requirements and restrictions that impact our collection, transfer, use and retention of personal data of clinical trial subjects and other individuals in the European Union. For example, the GDPR dictates mandatory contractual terms for service providers that process personal data for us and restricts our ability to transfer data from the European Economic Area to our offices and service providers in the United States and other countries. Penalties for non-compliance with the GDPR are steep, with potential fines of up to 4% of our global revenue.

Because we have operations in Switzerland, we also are required to comply with the data privacy and security laws and regulations of that country. As we conduct clinical trials and other activities that involve the collection of personal data from individuals in other countries and regions, we may be subject to additional data privacy and security laws and regulations.

Across the United States and globally, laws and regulations governing data privacy and security continue to develop and evolve. The data privacy and security laws and regulations to which we are subject will likely impact (possibly significantly) our business activities. Many of the laws and regulations that apply to us contain ambiguous provisions or impose requirements that differ from country to country, creating uncertainty. Compliance with the enhanced obligations imposed by such laws and regulations may require us to revise our business practices, allocate more resources to privacy and security, and implement new technologies. Such efforts may result in significant costs to our business.

Failure to comply with data privacy and security laws and regulations could result in regulatory penalties and significant legal liability, and could have a material adverse impact on our financial results.

## **Manufacturing, Revenues from External Customers, and Sources and Availability of Materials**

Our revenues of \$806.4 million for the year ended December 31, 2019, included \$800.0 million of upfront payment from United Therapeutics, \$5.0 million from Everest, and \$1.7 million from Boehringer Ingelheim. Our revenues of \$18.0 million for the year ended December 31, 2018, included \$6.6 million from Eisai, \$4.4 million from Boehringer Ingelheim, \$2.8 million from Outpost Medicine, \$2.2 million from Axovant, and \$2.0 million from Everest. Our revenues of \$21.3 million for the year ended December 31, 2017, included \$12.0 million from Everest, \$5.1 million from Boehringer Ingelheim and \$1.7 million from Eisai. This information excludes revenue activity reported within discontinued operations. See Note 8 to our consolidated financial statements included in this Annual Report for additional information. We do not currently engage in manufacturing activities and we are not dependent on availability of materials for our core business operations.

## **Compliance with Environmental Regulations**

Our business involves the controlled use of hazardous materials, chemicals, biological materials and various radioactive compounds. In the United States, we are subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the US Environmental Protection Agency, the California Environmental Protection Agency, the Toxic Substances Control Act, the Resource Conservation and Recovery Act, the CSA and other federal, state or local regulations.

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.

## **Employees**

As of February 14, 2020, we had a total of 320 employees, including 233 in research and development and 87 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.**

*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.*

**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 clinical and preclinical development and are prone to the risks of failure inherent in research and development. Clinical trials and preclinical studies are needed to demonstrate that drug candidates are safe and effective to the satisfaction of the FDA, and similar non-US regulatory authorities, and the FDA or other regulatory authority may require us to, or we or others may decide to, conduct additional research and development even after a drug is approved. The commencement or completion of our clinical trials or preclinical studies could be substantially delayed or prevented by several factors, including the following:

- limited number of, and competition for, suitable patients required for enrollment in our clinical trials or animals to conduct our preclinical studies;
- limited number of, and competition for, suitable sites to conduct our clinical trials or preclinical studies;
- delay or failure to obtain a meeting, approval or agreement from the applicable regulatory authority to commence a clinical trial or approve 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.

For example, recruitment for the indications in our ongoing and planned clinical studies is competitive and challenging, and it is difficult to predict when such trials will be fully enrolled or when data will be available, if at all.

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 those listed above affecting the commencement or completion of trials and the following:

- side effects experienced by study participants or other safety issues;
- lack of effectiveness of any drug candidate during clinical trials;
- slower than expected rates of patient recruitment and enrollment or lower than expected patient retention rates;
- inadequacy of or changes in the 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 clinical trials or preclinical studies, including those conducted by us, our partners or our licensees;
- 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 at one or more clinical trial sites;
- inability or unwillingness of medical investigators to follow our clinical protocols;
- failure of participating clinicians and clinical institutions to comply with all legal, regulatory and contractual requirements or otherwise perform in a timely or acceptable manner;
- 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. In addition, even if the earlier-stage results of our development programs are favorable, these programs may take significantly longer than expected to complete or may not be completed at all. If we or our collaborators abandon or are delayed in our development efforts related to any drug or drug candidate, we may not be able to generate sufficient revenues to continue our operations at the current or planned 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.

We may not be successful in initiating, enrolling patients in, 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 our clinical programs.

**We will need to obtain additional funds or enter into collaboration agreements to execute on our corporate strategy, and we may not be able to do so at all or on terms you view as favorable; your ownership may be substantially diluted if we do obtain additional funds; you may not agree with the manner in which we allocate our available resources; and we may not be profitable.**

It takes many years and potentially hundreds of millions of dollars to successfully develop a compound into a marketed drug. We have accumulated a large deficit that has primarily resulted from the significant expenditures we have made in research and development since our inception. We expect that our losses and operating expenses will continue to be substantial.

All of our internal programs are in the development stage, and we may not have adequate funds to develop all of our compounds into marketed drugs.

We may seek to obtain additional funding through the capital markets or other financing sources. Additional funding may not be available to us or may not be available on terms we or others believe are favorable. Our ability to obtain additional funding may depend on many factors, including those outside our control. Should we obtain additional funding, your ownership interest may be diluted or otherwise negatively impacted.

We have entered into, and may in the future seek to enter into, collaboration or other agreements with other entities to continue to develop and, if successful, commercialize one or more of our drug candidates. We may not be able to enter into any such agreements on terms that we or third parties, including investors or analysts, view as favorable, if at all. Our ability to enter into any such agreement for any of our programs or drug candidates depends on many factors, potentially including the outcomes of additional testing (including clinical trial results) or regulatory applications for marketing approval, and we do not control these outcomes.

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. We may also eliminate, scale back or delay some or all of our research and development programs, and any such reductions or failure to apply our resources effectively or to obtain additional funding could narrow, slow or otherwise adversely impact the development and commercialization of one or more of our drug candidates, which could reduce our opportunities for success and have a material adverse effect on our business, our prospects and the market price of our common stock.

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.

**Our business may be negatively impacted based on the clinical trials and preclinical studies of, and decisions affecting, one or more of our drug candidates.**

The results and timing of clinical trials and preclinical studies obtained by us or our collaborators or licensees, as well as related decisions by us, collaborators, licensees and regulators, can affect our stock price. Results of clinical trials and preclinical studies are uncertain and subject to different interpretations by regulatory agencies, us or others. The design of these trials and studies (which may change significantly and be more expensive than anticipated depending on results and regulatory decisions), as well as related analyses of such results, including adverse effects, may not be viewed favorably by us or third parties, including investors, analysts,

current or potential collaborators, the academic and medical communities, and regulators, which could adversely impact the development and opportunities for regulatory approval of drug candidates and commercialization (and even result in withdrawal from the market) of approved drugs. The same may be true of decisions regarding the focus and prioritization of our research and development efforts. 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.

**The development, approval or commercialization of any of our drug candidates could be negatively affected by circumstances related to other drug candidates or approved products.**

Information on our drug candidates in clinical development is preliminary and incomplete, and for such drug candidates, particularly in the earlier stages of development, information on approved products in the same or related drug classes may indicate potential risks related to the development of our drug candidates. In particular, safety issues affecting other drugs or drug candidates may result in increased regulatory scrutiny of the safety of our drugs or drug candidates, may raise potential adverse publicity and may affect product sales or result in litigation. For example, etrasimod is an orally available modulator of the S1P receptors. An approved drug that is also an orally available modulator of the S1P receptors, Gilenya, is associated with risks such as adverse cardiovascular effects, including lowering of the heart rate and heart blocks, infection, macular edema, respiratory effects, fetal risk, a rare brain infection, and elevations in liver enzymes. These adverse reactions and risks may be associated with S1P receptor modulation and could be found to be associated with the use of etrasimod. Such adverse reactions and risks, either actual or perceived, could negatively impact the development, approval or commercialization of etrasimod, or our ability to enter into a collaboration on acceptable terms.

**Topline data may not accurately reflect the complete results of a particular study or trial.**

We may publicly disclose topline or interim data from time to time, which are based on a preliminary analysis of then-available efficacy and safety data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial.

We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and others, including regulatory agencies, may not accept or agree with our assumptions, estimations, calculations, conclusions 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. In addition, the information we may publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you, regulators or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, drug candidate or our business.

**Our hypothesis that selectively targeting receptors can lead to more efficacious or safer drugs may not be correct.**

In general, we have designed and optimized the drug candidates that we or our collaborators and licensees are developing (including etrasimod, olorinab, APD418 and ralinepag) to selectively target certain receptors found on cells in humans. Our hypothesis is that selectivity may allow our drug candidates to address diseases more efficaciously or without some of the negative effects associated with less selective drugs. In certain cases, we believe early research and, if available, early clinical testing, provides preliminary support for our hypothesis. However, our hypothesis may not be correct, early research and early phase clinical testing may not be predictive of efficacy or safety in later trials, and our drug candidates may not be approved or, if approved, have the desired efficacy or safety profile.

It is generally our strategy to develop drug candidates that we believe will be first-in-class, best-in-class, or similar descriptions, or otherwise have broad clinical utility, optimized pharmacology or optimized pharmacokinetics. Some or all of our drug candidates may not achieve these goals. For example, failure to complete enrollment in clinical trials on schedule or at all could prevent a drug candidate from being first-in-class. Similarly, comparing data from different trials, or making predictions based on preclinical data, may not allow us to correctly determine whether our drug candidates are superior to competitive drugs or drug candidates in the same way that comparisons can be made from conducting trials in which our and a competitive drug is tested “head to head” in the same trial. The failure of our drugs or drug candidates to be first-in-class, best-in-class, or similar descriptions, or have broad clinical utility, optimized pharmacology, or optimized pharmacokinetics, or a lack of “head to head” data, could adversely affect development, regulatory approval, third-party payor support, or market adoption, which would have a material adverse impact on our business.



**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 be further developed or 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 confirmed in later studies or trials, including preclinical studies that continue or that are initiated after earlier clinical trials and large-scale clinical trials, and our drug candidates or drugs in subsequent trials or studies may fail to show desired safety and efficacy despite having progressed through earlier-stage trials. For example, we have announced positive topline Phase 2 results for etrasimod in patients with ulcerative colitis, but these results may not be confirmed in any subsequent Phase 3 study. By way of another example, the impact of etrasimod on heart rate that was observed in completed clinical trials may not be observed in subsequent trials, and it could be viewed negatively by the FDA or other regulatory agencies.

Unfavorable results from clinical trials or preclinical studies could result in delays, modifications or abandonment of ongoing or future clinical trials, or abandonment of a program. Clinical and preclinical 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 such trials or studies could cause a clinical trial to be delayed, repeated or terminated; a program to be abandoned; or negatively impact a related marketed drug, which could have a material adverse effect on our business, financial condition and results of operations.

**Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.**

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

**Drug discovery and development is intensely competitive in the therapeutic areas on which we focus. If the number of 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 attempting 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 etrasimod, there are other drugs that have a similar mechanism of action that entered Phase 3 clinical development before etrasimod for the same indications that we are pursuing, such as ulcerative colitis.

Our competitors, particularly large pharmaceutical companies, may have substantially greater research, development and marketing and sales 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.

**Our revenues in the future will be substantially dependent on the success of our or our collaborators' and licensees' marketing of drugs we have discovered or developed. To the extent such drugs are 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.**

We believe our revenues will be substantially dependent on the success of the drugs we or our collaborators and licensees successfully develop. We do not know whether or when such drug candidates will be approved by regulatory authorities for sale or commercialized. Even if approved and commercialization begins, we do not know if such commercialization will be successful or otherwise meet our, your, analysts' or others' expectations, and the market price of our common stock could decline significantly. For example, sales of lorcaserin to date have been less than we and others initially anticipated, and, in February 2020, Eisai (as well as its distributor in South Korea) determined to withdraw lorcaserin (commercialized as BELVIQ and BELVIQ XR) from the market based on concerns raised by the FDA.

We cannot guarantee future product sales or achievement of milestones under our collaborations and license agreements. For example, our license agreement with United Therapeutics for ralinepag does not contain a covenant obligating United Therapeutics to use any particular efforts to develop or commercialize any product, and we may never receive any milestone or royalty payments under this license agreement. In addition, our collaboration and license agreements, may be terminated in certain circumstances, which may result in us not receiving additional milestone or other payments under the terminated agreement.

The degree of market acceptance and commercial success of a drug will depend on a number of factors, including the following, as well as risks identified in other risk factors:

- the number of patients treated with the drug and their results;
- market acceptance and use of the drug, which may depend on the public's awareness and view of the drug, economic changes, national and world events, potentially seasonal and other fluctuations in demand, the timing and impact of current or new competition, and the drug'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);
- the actual and perceived safety and efficacy of the drug 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 the drug, including as a result of additional studies, trials or analyses of the drug or related drugs or drug candidates, whether conducted by us or by others;
- physicians' awareness of the drug, and the willingness of physicians to prescribe and of patients to use the drug;
- the claims, limitations, warnings and other information in the drug's current or future labeling;
- any current or future scheduling designation for the drug by the U.S. Drug Enforcement Administration, or DEA, or any comparable foreign authorities;
- our or our collaborators' maintenance of an effective sales force, marketing team, strategy and program, and medical affairs group and related functions, as well as its sales, marketing and other representatives accurately describing the drug consistent with its approved labeling;
- the price and perceived cost-effectiveness of the drug, including as compared to possible alternatives;
- the ability of patients and physicians and other providers to obtain and maintain coverage and 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 the drug to their constituencies;
- introduction of counterfeit or unauthorized versions of the drug;

- to the extent the drug 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 of the drug into the higher-priced territory; and
- the availability of adequate commercial manufacturing and supply chain for the drug.

**Our 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' and licensee's ability to successfully 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. We expect government and third-party payers will continue their efforts to contain healthcare costs by limiting coverage and reimbursement levels for new drugs. In addition, many countries outside of the U.S. have nationalized healthcare systems in which the government pays for all such products and services and must approve product pricing, and some U.S. politicians advocate for implementation of a comparable system in the United States. A government or third-party payer decision not to approve pricing, or provide adequate coverage and reimbursements, for our drugs, if any, could limit market acceptance of and demand for our drugs.

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 these competitors may have significantly more negotiating leverage or success with respect to individual payers than we or our collaborators may have.

Federal and state healthcare reform measures that have been or may be implemented in the future, may result in more rigorous coverage criteria, more limited coverage and downward pressure on the price that we may receive for any approved product, which could seriously decrease our future revenues. The Patient Protection and Affordable Care Act, as amended, or the ACA, which was enacted in 2010, is one such healthcare reform measure that has made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. In the years since its enactment, there have been, and continue to be, significant developments in, and continued legislative, executive, and judicial activity around, attempts to repeal, replace, or modify the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or TCJA, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Additionally, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". In December 2018, the United States Department of Health and Human Services' Centers for Medicare & Medicaid Services, or CMS, published a new final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the TCJA. On December 18, 2019, the U.S. Court of Appeals for the Fifth Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. It is unclear how this decision, future decisions, subsequent appeals and other efforts to repeal and replace the ACA will impact the ACA and our business and operations.

Further, the Trump administration's budget proposal for fiscal year 2021 includes a \$135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. The Trump administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The Department of Health and Human Services, or HHS, has solicited feedback on some of these measures and has implemented others under its existing authority. While some measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that they will

continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

In addition, there has been heightened scrutiny in the United States and other countries of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. In the United States, such scrutiny has resulted in congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of additional cost containment measures or other healthcare reforms may also limit our commercial opportunities by reducing the amount a potential collaborator or licensee is willing to pay to license our programs or drug candidates in the future, which may prevent us from being able to establish and maintain collaborations and license agreements, generate revenue, attain profitability, or commercialize our products.

**Forecasting potential sales for drugs will be difficult, and if our projections are inaccurate, our business may be harmed and our stock price may be adversely affected.**

Our business planning requires us to forecast or make assumptions regarding demand and revenues for our drugs if they are approved despite numerous uncertainties. These uncertainties may be increased if we rely on our collaborators to conduct commercial activities and provide 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 particular market, including fluctuations in demand for various reasons, such as fluctuations related to economic changes, national and world events, holidays and seasonal changes;
- pricing (including discounting or other promotions), reimbursement, product returns or recalls, competition, labeling, DEA scheduling, adverse events and other items that impact commercialization;
- lack of patient and physician familiarity with the drug;
- lack of patient use and physician prescribing history;
- lack of commercialization experience with the drug;
- actual sales to patients may significantly differ from expectations based on sales to wholesalers;
- uncertainty relating to when the drug may become commercially available to patients and rate of adoption in other territories; and
- other changes in regulatory or commercial conditions.

Revenues from drug sales may 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, projections or previously reported results. Expected and actual product sales and quarterly and other results may greatly fluctuate, 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.

**Our efforts will be seriously jeopardized if we are unable to attract and retain 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 may impact our ability to hire and retain key and other personnel. If we do not recruit and retain effective management and other key employees, particularly our executive officers, our operations, our ability to generate or raise additional capital, and our business in general, may be adversely impacted. For example, to execute our clinical programs, our strategy is to maintain a sufficient and robust program management function with clinical expertise. We are in the process of modifying and building this function, and we may not be able to establish the function we believe necessary to support our clinical goals and meet our corporate objectives.

**We are expanding our organization and may experience difficulties in managing this growth, which could disrupt our operations.**

We are seeking to expand our employee base to increase our managerial, scientific, operational, manufacturing supply, commercial, financial and other resources and to hire more consultants and contractors, including in and outside of headquarters in San Diego, California. For example, in addition to our headquarters in San Diego, we currently have operations in Boston, Massachusetts and Zug, Switzerland. Future growth will impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our future growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. Moreover, if our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenues could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to develop and then commercialize any approved products and compete effectively will depend, in part, on our ability to effectively manage any future growth.

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

An NDA holder (or the equivalent outside the United States) is responsible for assessing and monitoring the safety of a drug that has been approved for marketing, including reviewing reports of adverse safety events. In addition, NDA holders often conduct additional studies or trials or analyze new or previous data related to an approved drug, including with respect to required postmarketing studies and in connection with seeking additional regulatory approvals in new territories.

Any new data generated, including from adverse event reports or required postmarketing, registration or other studies or trials, may result in label changes, adversely affect sales or development, result in withdrawal of the drug from the market, or result in litigation. In addition, analyses of previous data can have similar risks. Regulatory agencies may consider the new data or analyses in reviewing marketing applications for drug candidates in their territories or impose post-approval requirements that require significant additional expenditures. For example, in February 2020, the FDA requested Eisai withdraw lorcaserin (commercialized as BELVIQ and BELVIQ XR) from the U.S. market. Furthermore, the discovery of significant problems with a product or class of products similar to any approved drug could have an adverse effect on our or our collaborator's or licensee's commercialization.

**If we license or otherwise partner our drugs, our failure to maintain such agreements or poor performance or results under such agreements could negatively impact our business.**

Our collaborators and licensees may have primary responsibility for the regulatory approval, marketing and distribution, and, in certain circumstances, development, of our drug candidate(s) in the territory or territories under the applicable collaboration. We may have limited or no control over our collaborator's decisions, including the amount and timing of resources that any of these collaborators will dedicate to such activities. This is the case for our ralinepag exclusive license agreement with United Therapeutics and our lorcaserin Transaction Agreement with Eisai.

When we enter collaboration and license agreements, we are subject to a number of other risks, including:

- our collaborators and licensees may not comply with applicable laws or regulatory guidelines, which could adversely impact the development or commercialization of the drug candidate;
- there could be disagreements regarding the agreements or the study or development that delay or terminate the commercialization, research, study or development, delay or eliminate potential payments under the agreements or increase our costs under or outside of the agreements;
- our collaborators and licensees may not effectively allocate adequate resources, may have limited experience in a particular territory, or may generate unfavorable data or results; and
- our collaborators and licensees 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 or our collaborators or licensees might terminate our agreements in certain circumstances or amend the terms of our agreement, and investors and analysts may not view any termination or amendment as favorable.

**We rely on other companies, including third-party manufacturers and sole-source suppliers, to manufacture all our drugs and drug candidates, and we or such other companies may encounter failures or difficulties or not receive or provide adequate supply, which could adversely affect development or commercialization.**

We do not own or operate manufacturing facilities that can produce active pharmaceutical ingredient, or API, intermediates and other material required to make our drug candidates or lorcaserin. Instead, we rely on 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, could result in substantial delay and greater cost. Our and our manufacturers' dependence on single or limited sources of materials 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 result in a product recall or seizure, delay or otherwise adversely affect sales of an approved product or the clinical development or regulatory approval of one or more of our other 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.

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;
- ability to accommodate changes in dosage or formulation;
- 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;
- 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. 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 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. If we or one of our manufacturers or other company in the supply chain fail to maintain compliance or otherwise experience setbacks, we or they could be subject to civil or criminal penalties, the production of one or more of our drug candidates or any approved products could be interrupted or suspended, or our product could be recalled or withdrawn, resulting in delays, additional costs and potentially lost revenues.

**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.**

Preclinical and clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, marketing and distribution, and other activities relating to developing and manufacturing drugs are subject to extensive regulation by the FDA and other regulatory agencies. We and others we contract with are subject to periodic inspections (which may be unannounced) by the FDA, the DEA 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 research and development or commercialization, or otherwise negatively impact our business. Regulatory agencies have in the past inspected certain aspects of our business, and we were provided with observations of objectionable conditions or practices with respect to our business. 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.

Regulatory approval of a drug candidate is not guaranteed, and our business and reputation may be harmed by any failure or significant delay in receiving regulatory approval. 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.

We cannot predict when or whether, or assure you that, our collaborators' or our past or any future regulatory submissions or responses will be sufficient to the applicable regulatory authority or others, that the applicable regulatory authority or others will consider data or our analyses, interpretations or procedures related to any of our drug candidates as sufficient or persuasive, or that any regulatory authority will ever approve any of our drug candidates in the future.

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. Approval by the FDA or any other regulatory authority does not assure or predict with any certainty that any other regulatory authority will approve the drug.

In addition, existing regulatory policies and laws may change. We cannot predict the likelihood, nature or extent of new government regulation, either in the United States or in other countries, or the impact on our drug candidates or drugs. For example, new FDA regulation could delay or prevent marketing approvals, increase the cost of research and development, and result in narrower product labeling and expensive post-marketing requirements.

**Fast Track, Breakthrough Therapy, Accelerated Approval, Priority Review, or similar designations by the FDA or other applicable regulatory agencies may not lead to a faster development or review process.**

The FDA may grant Fast Track, Breakthrough Therapy, Accelerated Approval, Priority Review, or other designation to product candidates that meet applicable guidelines in order to speed the availability of certain drugs. Other applicable regulatory agencies may grant similar designations. These designations may apply only to the combination of a product candidate and a specific indication or patient population. Product candidates that receive these designations may not actually receive faster clinical development or regulatory review or approval any sooner than other product candidates that do not have such designation, or at all. Furthermore, a product's receipt of such a designation does not increase the likelihood that the product candidate will receive marketing approval. The FDA or other regulatory agency may also withdraw a designation if it determines that the product candidate no longer meets the relevant criteria.

For example, the FDA has granted Fast Track designation for APD418 for treatment of decompensated heart failure, or DHF, in patients who have heart failure with reduced ejection fraction, or HFrEF. Despite receiving Fast Track designation, such designation may be withdrawn in the future, and in any event APD418 may not actually receive faster clinical development or regulatory review or approval any sooner than other product candidates that do not have such designation, or at all.

**Our activities and 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. 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. Unfavorable trial results from postmarketing studies could negatively impact market acceptance of the drug, limit the revenues we generate from sales, result in the drug's withdrawal from the market, negatively impact the potential approval of the drug in other territories and result in litigation.

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 Risk Evaluation and Mitigation Strategies, or REMS, study, 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 any of drug that receives 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 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, and the DEA periodically inspects facilities for compliance with its rules and regulations.

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

Any drug 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;
- physician and patient awareness of our drugs;
- actual and perceived efficacy and safety of our drugs;
- incidence and severity of any side effects;
- potential or perceived advantages or disadvantages as compared to alternative treatments;
- effectiveness 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 adequate 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.

**Collaboration and license agreement relationships may lead to disputes, divert management's attention, expose us to liability and delay drug development and commercialization, and we may not realize the full commercial potential of our drug candidates or drugs.**

We may have conflicts with our prospective, current or past collaborators or licensees, such as conflicts concerning rights and obligations under our agreements (including, for example, relating to indemnification for product liability claims and losses), 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, litigation or other strategy. Collaborators or licensees 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 or licensees 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 or licensees, 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 or cause us to incur liabilities:

- unwillingness or inability on the part of a collaborator or licensee 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 collaboration or license agreement activities, which could prevent us from entering into additional collaborations;
- unwillingness on the part of a collaborator or licensee 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 or licensee's research, development, regulatory or commercialization efforts with respect to our drug candidates or drugs; or
- litigation or arbitration with our collaborator or licensee, or with third parties (including relating to product liability, intellectual property or other subject matters).

**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 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 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 obligations 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 rely on third parties, including investigators, clinical research organizations, manufacturers and laboratories, 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 legal, 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 legal and 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.

**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, asset purchases and spin-offs. Additional potential transactions we may consider include a variety of different business arrangements, such as strategic collaborations, joint ventures, 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.

When we evaluate significant proposed 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.

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

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 a risk with the commercialization of lorcaserin (marketed as BELVIQ and BELVIQ XR) as well as any other drug that may be approved for marketing.

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 have limited product liability insurance that covers our clinical trials and products, as well as indemnification protection in certain of our collaboration or license agreements. We may not be able to maintain or obtain insurance coverage at a reasonable cost, we may not have insurance coverage that will be adequate to satisfy any liability that may arise, and our collaborators or licensees may not indemnify us, which could have an adverse effect on our results of operations and financial condition.

Our subsidiary Arena Pharmaceuticals GmbH in Liquidation (“Arena GmbH”) manufactured BELVIQ and other products for commercialization or clinical trials, up until the sale of our manufacturing business to Siegfried effective March 31, 2018. We could be subject to liability for manufacturing defect claims relating to our manufacturing activities that preceded the closing of the sale. For example, under our agreement with Eisai, we and Eisai will each bear 50% of losses arising from any alleged defective manufacturing of BELVIQ by Arena GmbH prior to the date of the sale to Siegfried.

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

We have long-term leases on real properties and other contractual obligations, and limited revenues. If we are unable to generate cash from operations in the future sufficient to meet our financial obligations we will need to obtain additional funds from other sources, and we may not be able to do so at all or on terms favorable to our stockholders or us.

Also, if we do not have sufficient cash in the future and are unable to generate cash from operations or obtain additional funds from other sources sufficient to meet our contractual obligations, we may have to delay or curtail some or all of our development and commercialization programs, sell or license some or all of our assets on terms that you or others may view as unfavorable, or default on obligations under our agreements.

**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 Federal 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 ACA, among other things, amended the intent requirement of the Federal Anti-Kickback Statute and certain 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 ACA 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 Federal Civil 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 Civil 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 Federal Civil 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 Federal Civil False Claims Act action. When an entity is determined to have violated the Federal Civil 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 Civil False Claims Act, some of which are broader in scope and may apply regardless of payer.

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 Payments Sunshine Act, created under the ACA, 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 U.S. 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. Further, we may also be subject to state health information privacy and data breach notification laws which govern the collection, use, disclosure, and protection of health-related and other personal information, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus requiring additional compliance efforts.

Additionally, the Drug Supply Chain Security Act imposes obligations on manufacturers of pharmaceutical products, among others, related to product tracking and tracing. Among the requirements, 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, 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, integrity oversight and reporting obligations to resolve allegations of non-compliance with these laws, 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, manage or maintain our international operations, and such difficulty could adversely affect our business operations, financial condition, results of operations and stock price.**

We have certain clinical operations personnel in Switzerland, and we engage in clinical trials and manufacturing activities in many territories outside of the United States. There are significant risks associated with foreign operations, including, but not limited to, compliance with local laws and regulations, the protection of our intellectual property, the ability to integrate our corporate culture with local customs and cultures, the distraction to our management, foreign currency exchange rates and the impact of shifts in the United States 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.

With respect to local laws and regulations, the European Union, Switzerland and certain other foreign territories have restrictions on the transfer, use and maintenance of certain personal data, including providing that transfers of personal data outside of their territories may only take place if the country to which the personal data is transferred ensures an "adequate" level of privacy protection. The European Commission has previously found that the United States did not provide adequate levels of protection. In addition, the European Commission has approved a data protection regulation, known as the General Data Protection Regulation, or GDPR, which became effective on May 25, 2018. The GDPR contains provisions specifically directed at the processing of health information, higher sanctions and extra-territoriality measures intended to bring non-EU companies under the regulation. We conduct clinical trials in the EU, and in the future we may expand our business operations to include additional operations in the EU. With such expansion, we would be subject to increased governmental regulation, including the GDPR, in the EU countries in which we operate, including restrictions on data transfers that may negatively impact our ability and increase our costs to maintain international operations. Penalties for non-compliance with the GDPR are steep, with potential fines of up to 4% of our global revenue.

Additionally, the California Consumer Privacy Act, or CCPA, went into effect on January 1, 2020. The CCPA creates new individual privacy rights for consumers (as that word is broadly defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. It requires covered companies to provide new disclosures to California consumers, provide such consumers new ways to opt-out of certain sales of personal information, and allow for a new cause of action for data breaches. The CCPA may impact our business activities and exemplifies the vulnerability of our business to not only cyber threats but also the evolving regulatory environment related to personal data and protected health information.

Across the United States and globally, laws and regulations governing data privacy and security continue to develop and evolve. The data privacy and security laws and regulations to which we are subject will likely impact (possibly significantly) our business activities. Many of the laws and regulations that apply to us contain ambiguous provisions or impose requirements that differ from country to country, creating uncertainty. Compliance with the enhanced obligations imposed by such laws and regulations may require us to revise our business practices, allocate more resources to privacy and security, and implement new technologies. Such efforts may result in significant costs to our business.

Failure to comply with data privacy and security laws and regulations could result in regulatory penalties and significant legal liability and could have a material adverse impact on our financial results.

### **We and third parties we contract with use hazardous materials in our operations.**

Our activities involve the use of materials that could be hazardous to human health and safety or the environment. We cannot completely eliminate the risks associated with their use, storage or disposal, which could cause:

- interruption of our 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 disrupted or adversely affected by catastrophic events and security breaches, including any cybersecurity incidents.**

Our U.S. operations are primarily located in a business park in San Diego. We also have certain operations in Boston, Massachusetts, and Zug, Switzerland. We depend on our facilities and on collaborators, licensees, contractors and vendors for the continued operation of our business, some of whom are located in Europe and Asia. As a result, natural disasters or other catastrophic events in various parts of the world, 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, wars and public health issues (including, for example, the outbreak of the novel strain of coronavirus first reported in Wuhan, China in December 2019) could disrupt our operations or those of our collaborators, contractors and vendors or contribute to unfavorable economic or other conditions that could adversely impact us.

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 financial data, intellectual property and other proprietary business information.

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. 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 interruptions in our operations and can result in a material disruption of our research and development programs 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 and our licensees rely on third parties to conduct studies and clinical trials of our drug candidates, manufacture our drug candidates and lorcaserin, and warehouse, market and distribute lorcaserin, and similar events relating to these third parties' 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 drugs 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.

### **We and our employees and directors may be named as defendants in litigation that could result in substantial costs and divert management's attention.**

Securities class action litigation may be brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because companies in the pharmaceuticals industry often experience significant stock price volatility. For example, beginning in 2010, a number of lawsuits were filed against us and certain of our employees and directors alleging we

and the other defendants violated the federal securities laws by making materially false and misleading statements regarding our lorcasein trials, thereby artificially inflating the price of our common stock. These lawsuits were settled in 2018.

While we carry liability insurance, any losses we incur in connection with any future lawsuits may not be covered by insurance in an amount sufficient to cover our losses or at all, and our assets may be insufficient to cover any amounts that exceed our insurance coverage. We may have to pay damage awards or otherwise may enter into settlement arrangements in connection with any future claims. A settlement of any of future lawsuit against us could also 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, any future lawsuit against us and/or our directors or executive officers could result in substantial costs and significantly and adversely impact our reputation and divert our management's attention and resources, which could have a material adverse effect on our business, operating results or financial condition. In addition, any 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.

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

Negative conditions in the U.S. 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 any drugs we and our collaborators and licensees 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, 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 deterioration in credit markets, may have an adverse effect on the fair value of our investment holdings and cash position.

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

We primarily spend and generate cash in U.S. dollars and present our consolidated financial statements in U.S. dollars. However, a portion of our expected and potential payments and receipts, including relating to our Swiss operations and under certain of our agreements, are in foreign currencies. A fluctuation of the exchange rates of foreign currencies versus the U.S. 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, including 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, judicial rulings and other laws and regulations, including, for example, of state, federal and foreign governments and relating to privacy, may result in increased costs to us, particularly as we continue to develop the required capabilities in the United States and abroad to develop and 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. These laws, rules and regulations 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.

**Changes in funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business.**

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

**The withdrawal of the United Kingdom, from the European Union, commonly referred to as “Brexit,” may adversely impact our ability to obtain regulatory approvals of our product candidates in the European Union, result in restrictions or imposition of taxes and duties for importing our product candidates into the European Union, and may require us to incur additional expenses in order to develop, manufacture and commercialize our product candidates in the European Union.**

Following the result of a referendum in 2016, the United Kingdom left the European Union on January 31, 2020, commonly referred to as “Brexit.” Pursuant to the formal withdrawal arrangements agreed between the United Kingdom and the European Union, the United Kingdom will be subject to a transition period until December 31, 2020, or the Transition Period, during which EU rules will continue to apply. Negotiations between the United Kingdom and the European Union are expected to continue in relation to the customs and trading relationship between the United Kingdom and the European Union following the expiry of the Transition Period.

Since a significant proportion of the regulatory framework in the United Kingdom applicable to our business and our product candidates is derived from EU directives and regulations, Brexit, following the Transition Period, could materially impact the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the United Kingdom or the European Union. For example, as a result of the uncertainty surrounding Brexit, the EMA relocated to Amsterdam from London. Following the Transition Period, the United Kingdom will no longer be covered by the centralized procedures for obtaining EU-wide marketing authorization from the EMA and, unless a specific agreement is entered into, a separate process for authorization of drug products, including our product candidates, will be required in the United Kingdom, the potential process for which is currently unclear. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the United Kingdom or the European Union and restrict our ability to generate revenue and achieve and sustain profitability. In addition, we may be required to pay taxes or duties or be subjected to other hurdles in connection with the importation of our product candidates into the European Union, or we may incur expenses in establishing a manufacturing facility in the European Union in order to circumvent such hurdles. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom or the European Union for our product candidates, or incur significant additional expenses to operate our business, which could significantly and materially harm or delay our ability to generate revenues or achieve profitability of our business. Any further changes in international trade, tariff and import/export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the impacted nations and the United Kingdom.

**Our disclosure controls and procedures and our internal control over financial reporting may not prevent potential errors and fraud**

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. There are inherent limitations in all control systems, and 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.

**Our ability to use net operating losses to offset future taxable income may be subject to limitations.**

As of December 31, 2019, we had federal and state net operating loss carryforwards of \$933.2 million. Our federal net operating loss carryforwards of \$539.3 million will begin to expire, if not utilized, beginning in 2029, and our state net operating loss carryforwards of \$393.9 million begin expiring in 2028. Our net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities. In January 2019, a taxable income-generating event, the transaction pursuant to the United Therapeutics Agreement, resulted in it being more likely than not that a portion of our net operating loss carryforwards would be used to offset our estimates of taxable income in 2019. If the estimates we have made, or the assumptions on which we relied, in estimating our taxable income in 2019 prove inaccurate, our net operating loss carryforwards to be used to offset our taxable income in 2019 may vary from our estimates. Under the TCJA, federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. It is uncertain if and to what extent various states will conform to the TCJA. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an “ownership change,” which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We have experienced ownership changes in the past and we may experience additional ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our net operating loss carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

**Current and future tax laws and regulation could adversely affect our business and financial condition.**

The TCJA significantly revised the Internal Revenue Code of 1986, as amended. The TCJA among other things, contained significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits (including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions). Notwithstanding the reduction in the corporate income tax rate, the overall impact of the TCJA is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to this federal tax law.

**Changes or modifications in financial accounting standards, including those related to revenue recognition, may harm our results of operations.**

From time to time, the Financial Accounting Standards Board, or FASB, either alone or jointly with other organizations, promulgates new accounting principles that could have an adverse impact on our financial position, results of operations or reported cash flows. Any difficulties in adopting or implementing any new accounting standard, or updating or modifying our internal controls as needed on a timely basis, could result in our failure to meet our financial reporting obligations, which could result in regulatory discipline and harm investors’ confidence in us. In addition, if we were to change our critical accounting estimates, including those related to the recognition of revenue, our operating results could be significantly affected.

***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, maintain and defend patents. In particular, the patents directed to our drug candidates and drugs are important to developing and commercializing drugs and to our revenue. We have numerous U.S. and foreign patents issued and 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 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 jeopardize our patent protection. 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, time consuming and expensive. Our patent position is very uncertain and we do not know when, or if, we will obtain additional patents, 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 in litigation or administrative proceedings. We cannot make assurances as to how much protection, if any, our patents will provide 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 patent 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 other proprietary information.

Some of our research and development collaborators and scientific consultants have rights to publish data and information to which we have rights. We generally seek to prevent our collaborators and consultants 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 relationships we are limited to relatively short periods to review a proposed publication and file a patent application. If we cannot maintain confidentiality in connection with our collaborations and relationships, 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 U.S. 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 how it would impact 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 issued patents and pending patent applications owned by others relating to research 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 issued patents and pending patent applications owned by others exist in the areas of our research and development, including some which purport to allow the patent holder to control the use of all drugs that modulate a particular drug target 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 issued patents and pending patent applications owned by others also exist in the therapeutic areas in which we are developing drugs. There are also numerous issued patents and pending patent applications owned by others that are directed to chemical compounds or synthetic processes that may be necessary or useful to 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 owned by others, of which we are not aware, that our drug candidates or technologies may infringe. Further, there may be issued patents or pending patent applications owned by others in fields relevant to our business, of which we are or may become aware, that we believe (i) are invalid, unenforceable, or we do not infringe; (ii) relate to immaterial portions of our overall research and 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 and seek damages or enjoinder of our activities. We also cannot assure you that, in the event of litigation, we will be able to successfully assert non-infringement, unenforceability, invalidity or immateriality, or that any infringement claims will be resolved in our favor.

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

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 research and development, manufacturing and commercialization activities could:

- require us, or our collaborators, to obtain a license which may not be available on commercially reasonable terms, if at all;
- prevent us from importing, making, using, selling or offering to sell the subject matter claimed in patents held by others and subject us to potential liability for damages;
- consume a substantial portion of our managerial, scientific and financial resources; or
- be costly, regardless of the outcome.

Furthermore, because of the substantial amount of pre-trial document and witness discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised. In addition, during the course of intellectual property 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 are aware of third-party patents, as well as third-party patent applications, that could adversely affect the potential commercialization of etrasimod. For example, we are aware of third-party patents, as well as a third-party patent application, with broad claims to administering an S1P modulator by starting with a lower dose and then increasing to a higher, standard daily dose. While we do not believe that any such claims that would cover the potential commercialization of etrasimod are valid and enforceable, we may be incorrect in this belief.

We have been contacted from time to time by third parties regarding their intellectual property rights, sometimes asserting that we may need a license to use their technologies. If we fail to obtain any required licenses or make any necessary changes to our technologies, we may 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 predict the outcome of any litigation matter. For example, our existing patents could be invalidated, found unenforceable or found not to cover a generic form of our drugs.

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

Filing, prosecuting, defending and enforcing patents on all of our drug candidates throughout the world would be prohibitively expensive. 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 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, 2018, to February 21, 2020, the market price of our stock was as low as \$30.00 per share and as high as \$64.48 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:

- results or decisions affecting the development or commercialization of any of our drug candidates or drugs, including the results of studies, trials and other analyses;
- the success, failure or setbacks of our or a perceived competitor's drugs or drug candidates;
- the timing of the development of our drug candidates;
- discussions or recommendations affecting our drugs or drug candidates by the FDA or other reviewers of preclinical or clinical data or other information related to our drug candidates or drugs;
- regulatory actions or decisions or legislation affecting drugs or drug candidates, including ours and those of our competitors;
- the commercial availability and success or failure of any of our drug candidates or lorcaserin;
- the development and implementation of our continuing development and research plans, including outcome studies for lorcaserin;
- 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, expenses and other operating results) or inaccurate sales or cash forecasting;
- accounting restatements and changes;
- supply chain or manufacturing issues;
- 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;
- expenses related to, and the results of, litigation, other disputes and other proceedings;
- financing strategy or decisions;
- the allocation of our resources;
- our ability, or the perception by investors of our ability, to continue to meet all applicable requirements for continued listing of our common stock on The Nasdaq Stock Market, and the possible delisting of our common stock if we are unable to do so;
- developments in intellectual property rights or related announcements; and
- capital market and other macroeconomic conditions.

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.

**Any future equity or debt issuances or other financing transactions may have dilutive or adverse effects on our existing stockholders.**

We have been opportunistic in our efforts to obtain cash, and we expect we will evaluate various funding alternatives from time to time. 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. We have effective registration statements to sell shares of our common stock and certain other securities, and we may elect to sell shares pursuant to such registration from time to time.

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 or other financing transaction, and the investors may have rights superior to your rights in the event we are not successful and are forced to seek the protection of bankruptcy laws or the transaction may otherwise adversely affect our business prospects and existing stockholders.

**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 Rule 10b5-1 of the SEC.

**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 21, 2020, there were (i) options to purchase 8,623,463 shares of our common stock outstanding under our equity incentive plans at a weighted-average exercise price of \$34.76 per share, (ii) 23,564 restricted stock unit awards outstanding under our equity incentive plans, (iii) performance restricted stock units outstanding under our equity incentive plans under which up to 416,045 shares of common stock may be issuable upon achievement of all specified performance goals, (iv) 3,868,097 additional shares of common stock remaining issuable under our Amended and Restated 2017 Long-Term Incentive Plan, and (v) 1,000,000 shares issuable under our 2019 Employee Stock Purchase 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 21, 2020, there were 50,249,149 shares of our common stock outstanding.

**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, may support transactions that we or you do not believe are favorable, and may 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 transaction 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 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;
- 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.**

We lease real property to support our business, including research and development, sales, marketing and administration. We believe our leased properties are not material to our business. We believe our facilities are suitable and adequate for our current and near-term needs, and that we will be able to locate additional facilities as needed.

**Item 3. Legal Proceedings.**

We are not currently subject to any material legal proceedings.

**Item 4. Mine Safety Disclosures.**

Not applicable.

**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.”

**Holders**

As of February 21, 2020, there were approximately 83 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.

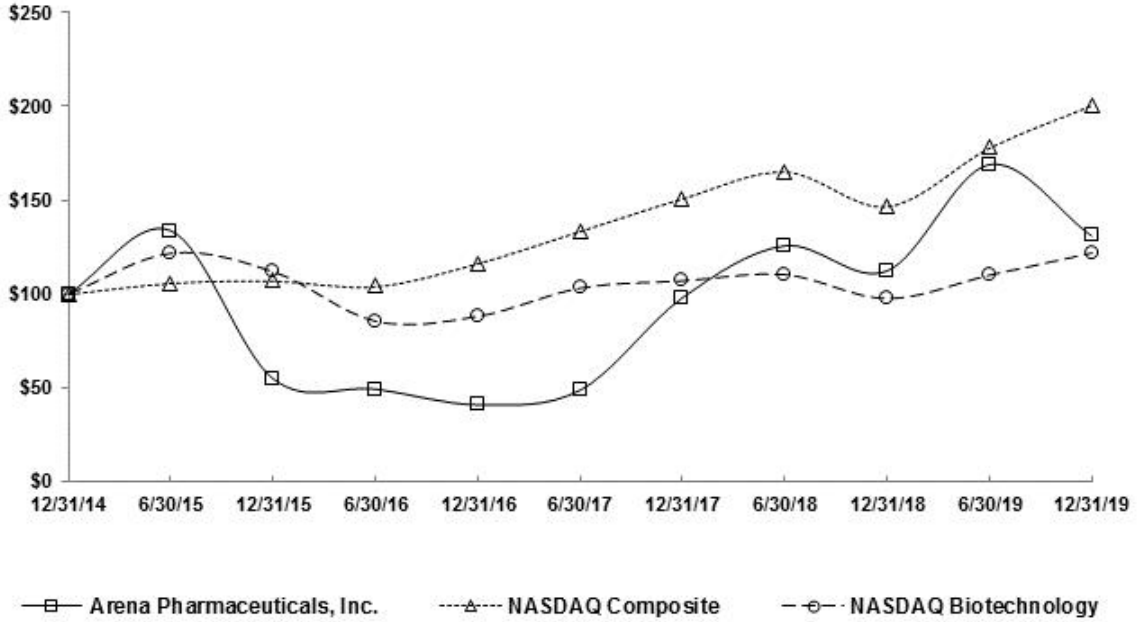
**Performance graph**

The graph below compares the cumulative five-year total return on our common stock from December 31, 2014, through December 31, 2019, 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, 2014, 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 5 YEAR CUMULATIVE TOTAL RETURN\*

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



\*\$100 invested on 12/31/14 in stock or index, including reinvestment of dividends. Fiscal year ending December 31.

**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.

The following amounts related to earnings per share and shares outstanding have been adjusted for all periods reported for the 1-for-10 reverse stock split that we effected in June 2017.

	Years ended December 31,				
	2019	2018	2017	2016	2015
(In thousands, except per share data)					
<b>Consolidated Statement of Operations Data:</b>					
<b>Revenues</b>					
United Therapeutics revenue	\$ 800,000	\$ —	\$ —	\$ —	\$ —
Collaboration revenue	7,284	11,402	19,632	92,163	13,398
Royalty revenue	(853)	6,568	1,705	—	—
Total revenues	<u>806,431</u>	<u>17,970</u>	<u>21,337</u>	<u>92,163</u>	<u>13,398</u>
<b>Operating Costs and Expenses</b>					
Research and development	231,496	115,029	70,988	63,782	83,283
General and administrative	77,616	45,257	30,341	27,529	30,281
Transaction costs	14,573	2,467	—	—	—
Litigation settlement expense, net	—	—	11,975	—	—
Restructuring charges	—	—	—	6,115	3,346
Total operating costs and expenses	<u>323,685</u>	<u>162,753</u>	<u>113,304</u>	<u>97,426</u>	<u>116,910</u>
Interest and other income (expense), net	25,142	5,949	(3,887)	(7,037)	(7,195)
Income (loss) from continuing operations before income taxes	507,888	(138,834)	(95,854)	(12,300)	(110,707)
Income tax (provision) benefit	(110,333)	110,265	—	—	—
Income (loss) from continuing operations	397,555	(28,569)	(95,854)	(12,300)	(110,707)
Income (loss) from discontinued operations	—	(830)	3,122	(10,596)	2,728
Net income (loss)	397,555	(29,399)	(92,732)	(22,896)	(107,979)
Less net loss attributable to noncontrolling interest in consolidated variable interest entity	—	—	1,325	380	—
Net income (loss) attributable to common stockholders	<u>\$ 397,555</u>	<u>\$ (29,399)</u>	<u>\$ (91,407)</u>	<u>\$ (22,516)</u>	<u>\$ (107,979)</u>
<b>Amounts attributable to stockholders of Arena:</b>					
Income (loss) from continuing operations	\$ 397,555	\$ (28,569)	\$ (94,529)	\$ (11,920)	\$ (110,707)
Income (loss) from discontinued operations	—	(830)	3,122	(10,596)	2,728
	<u>\$ 397,555</u>	<u>\$ (29,399)</u>	<u>\$ (91,407)</u>	<u>\$ (22,516)</u>	<u>\$ (107,979)</u>
<b>Net income (loss) attributable to stockholders of Arena per share, basic:</b>					
Continuing operations	\$ 7.99	\$ (0.61)	\$ (2.87)	\$ (0.49)	\$ (4.60)
Discontinued operations	—	(0.02)	0.10	(0.44)	0.11
	<u>\$ 7.99</u>	<u>\$ (0.63)</u>	<u>\$ (2.77)</u>	<u>\$ (0.93)</u>	<u>\$ (4.49)</u>
<b>Net income (loss) attributable to stockholders of Arena per share, diluted:</b>					
Continuing operations	\$ 7.69	\$ (0.61)	\$ (2.87)	\$ (0.49)	\$ (4.60)
Discontinued operations	—	(0.02)	0.10	(0.44)	0.11
	<u>\$ 7.69</u>	<u>\$ (0.63)</u>	<u>\$ (2.77)</u>	<u>\$ (0.93)</u>	<u>\$ (4.49)</u>
Shares used in calculating net income (loss) per share allocable to common stockholders, basic	<u>49,779</u>	<u>47,041</u>	<u>32,990</u>	<u>24,313</u>	<u>24,067</u>
Shares used in calculating net income (loss) per share allocable to common stockholders, diluted	<u>51,698</u>	<u>47,041</u>	<u>32,990</u>	<u>24,313</u>	<u>24,067</u>



	As of December 31,				
	2019	2018	2017	2016	2015
	(In thousands)				
<b>Consolidated Balance Sheet Data:</b>					
Cash and cash equivalents	\$ 243,274	\$ 161,037	\$ 158,837	\$ 90,712	\$ 156,184
Total available-for-sale securities	867,229	367,006	112,482	—	—
Total assets	1,174,123	686,903	339,275	169,010	256,792
Total lease financing obligations	49,427	52,709	61,748	65,266	68,245
Accumulated deficit	(1,102,997)	(1,500,552)	(1,490,187)	(1,398,736)	(1,376,220)
Total equity	1,071,465	606,258	207,144	40,395	53,542

## 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. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain.

### OVERVIEW AND RECENT DEVELOPMENTS

We are a biopharmaceutical company focused on delivering novel, transformational medicines with optimized pharmacology and pharmacokinetics to patients globally. Our internally-developed pipeline includes multiple potentially first- or best-in-class assets with broad clinical utility.

Our most advanced investigational clinical programs include:

- **Etrasimod**, which we are evaluating in a Phase 3 program for ulcerative colitis, or UC, a Phase 2b/3 program for Crohn's disease, or CD, and a Phase 2b program in atopic dermatitis, or AD. We also plan to evaluate etrasimod in a Phase 2b program for eosinophilic esophagitis, or EOE, and a Phase 2 program in alopecia areata, or AA.
- **Olorinab**, which we are evaluating for a broad range of visceral pain conditions associated with gastrointestinal diseases and is currently in a Phase 2b trial for treatment of abdominal pain associated with irritable bowel syndrome, or IBS.
- **APD418**, which we are evaluating in a Phase 1 trial for acute heart failure, or AHF.

We continue to leverage our two decades of world-class G-protein-coupled receptor, or GPCR, target discovery research to develop breakthrough drugs and ultimately deliver these to patients with large unmet needs. Our long-term pipeline prospects include an enhanced collaboration with Beacon Discovery across a broad range of immune-mediated inflammatory targets and compounds and the buildout of Arena Neuroscience to focus on treating neurological conditions with microglial neuroinflammation.

We have license agreements or collaborations with various companies, including:

- United Therapeutics (ralinepag in a Phase 3 program for pulmonary arterial hypertension),
- Everest Medicines Limited (etrasimod in Greater China and select countries in Asia),
- Beacon Discovery (early research platform for GPCR targets),
- Boehringer Ingelheim International GmbH (undisclosed orphan GPCR program for central nervous system – preclinical), and
- Eisai Co., Ltd. and Eisai Inc., collectively, Eisai (BELVIQ®/BELVIQ XR®).

#### Program development update.

In January 2020, we announced acceptance of our investigational new drug application and were granted Fast Track designation for APD418. We have initiated a Phase 1 clinical trial.

In December 2019, we initiated our Phase 2/3 program to evaluate etrasimod in Crohn's disease. The program consists of a Phase 2 dose ranging trial that is intended to provide an operationally seamless transition into the Phase 3. CULTIVATE is a Phase 2b dose-ranging multicenter, randomized, double-blinded, placebo-controlled study to assess the safety and efficacy of once-daily etrasimod in subjects with moderate to severely active Crohn's disease. The primary efficacy endpoint in the CULTIVATE trial will be endoscopic response at Week 14, in addition to a variety of scales of Crohn's disease activity, including abdominal pain and stool

frequency. The CULTIVATE trial aims to enroll approximately 225 patients in study sites globally. The Phase 3 will include two induction trials with re-randomization of clinical responders into a single maintenance trial.

In October 2019, we announced that the first subject has been dosed in the Phase 2 ADVISE trial evaluating two dose levels etrasimod in development for the treatment of AD. ADVISE is a multicenter, randomized, double-blinded, placebo-controlled 16-week study (with a 52-week open-label extension) to assess the safety and efficacy of once-daily etrasimod in approximately 120 subjects with moderate-to-severe AD.

In July 2019, we announced the first subject dosed in the Phase 2 CAPTIVATE trial evaluating olorinab in development for the treatment of visceral pain associated with IBS. The trial will evaluate the efficacy and safety of three dose levels of olorinab for 12-weeks in approximately 240 subjects experiencing abdominal pain associated with IBS, including IBS with constipation or IBS with diarrhea. CAPTIVATE is a Phase 2, multi-center, randomized, double-blind, placebo-controlled, 12-week study. We expect data in the second half of 2020.

In June 2019, we announced that the first subject has been dosed in ELEVATE UC 52, the first of two planned pivotal trials within the Phase 3 ELEVATE UC registrational program evaluating etrasimod 2 mg in subjects with moderately to severely active ulcerative colitis. ELEVATE UC 52 is a treat-through trial with a 12-week induction period followed by 40 weeks of maintenance.

#### Collaborations and license agreement update.

In October 2019, Everest announced that the first subject has been dosed in a Phase 3 trial evaluating etrasimod in development for the treatment of ulcerative colitis in Greater China and South Korea. Everest paid us a \$5.0 million milestone payment earned from this achievement.

#### Other corporate events.

In January 2019, we announced that Steven Spector, our Executive Vice President, General Counsel and Secretary, will retire from his positions with Arena in March 2020. Joan Schmidt was appointed as Executive Vice President, General Counsel and Secretary and will join Arena in March 2020.

In general, developing drugs and obtaining marketing approval is a long, uncertain and expensive process, and our ability to execute on our plans and achieve our goals depends on numerous factors, many of which we do not control. To date, we have generated limited revenues. We expect to continue to incur substantial net losses for at least the short term as we advance our clinical development programs and support our collaborators.

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. This summary excludes our revenues, research and development expenses and general and administrative expenses associated with our Manufacturing Operations, which are reported within loss from discontinued operations for the year ended December 31, 2018. See Note 5 to our consolidated financial statements included in this Annual Report for additional information regarding the Manufacturing Operations. The dollar values in the following tables are in millions.

For our discussion of the year ended December 31, 2018, compared to the year ended December 31, 2017, please read Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations located in our 2018 Form 10-K.

#### Research and development expenses

Type of expense	Years ended December 31,		% change from 2018 to 2019
	2019	2018	
External clinical and preclinical study fees	\$ 141.1	\$ 69.7	*
Salary and other personnel costs (excluding non-cash share-based compensation)	48.3	28.4	69.9%
Non-cash share-based compensation	27.4	8.4	*
Facility and equipment costs	6.2	5.2	20.3%
Other	8.5	3.3	*
Total research and development expenses	<u>\$ 231.5</u>	<u>\$ 115.0</u>	*

\* The change is more than 100%.

## General and administrative expenses

Type of expense	Years ended December 31,		% change from 2018 to 2019
	2019	2018	
Non-cash share-based compensation	\$ 25.7	\$ 11.2	*
Legal, accounting and other professional fees	21.8	14.4	52.1%
Salary and other personnel costs (excluding non-cash share-based compensation)	20.8	13.3	56.1%
Facility and equipment costs	5.9	4.5	29.3%
Other	3.4	1.9	82.2%
Total general and administrative expenses	\$ 77.6	\$ 45.3	71.5%

\* The change is more than 100%.

## YEAR ENDED DECEMBER 31, 2019, COMPARED TO YEAR ENDED DECEMBER 31, 2018

**Revenues.** We recognized revenues of \$806.4 million for the year ended December 31, 2019, compared to \$18.0 million for the year ended December 31, 2018. This increase resulted primarily from the revenue associated with the upfront payment of \$800.0 million we received in January 2019 pursuant to the collaboration and license agreement with United Therapeutics. In connection with the United Therapeutics transaction we incurred transaction expenses of \$17.0 million, consisting of \$14.6 million incurred in the first quarter of 2019 and \$2.4 million incurred in the fourth quarter of 2018, which are presented as transaction costs in our consolidated statements of operations.

Absent any new collaborations, we expect our 2020 revenues will primarily consist of potential milestone payments from our existing collaborations and license agreements.

Revenues from milestones and royalties are difficult to predict, and our overall revenues will likely continue to vary from quarter to quarter and year to year. In the short term, we expect the amount of revenue we earn to fluctuate.

**Research and development expenses.** Research and development expenses, which account for the majority of our expenses, consist primarily of clinical trial costs (including payments to contract research organizations, or CROs), salaries and other personnel costs, preclinical study fees, manufacturing costs for non-commercial products, 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 \$116.5 million to \$231.5 million for the year ended December 31, 2019, from \$115.0 million for the year ended December 31, 2018. This increase was primarily due to an increase of \$71.4 million in external clinical and preclinical study fees, \$19.9 million in salary and other personnel costs, and \$19.0 million in non-cash share-based compensation expense. The increases in compensation costs are primarily due to an increase in the number of research and development employees, and an incremental expense associated with performance-based restricted stock units granted in the first quarter of 2019, which is reflected in the non-cash share-based compensation expense.

We expect to incur substantial research and development expenses in 2020 and for the aggregate amount in 2020 to be greater than the amount incurred in 2019. We expect our internal costs to be higher primarily due to higher external clinical trial costs and increasing headcount in connection with advancing the etrasimod and olorinab programs. Our actual expenses may be higher or lower than anticipated due to various factors, including our progress and results. For example, patient enrollment in our Phase 3 clinical program for etrasimod is expected to be competitive and challenging, and could take longer than originally projected, which may result in our related external expenses being lower in 2020 than anticipated (but which might increase the overall costs for completing this multi-year program).

Included in the \$141.1 million of total external clinical and preclinical study fees noted in the table above in this section for the year ended December 31, 2019, were the following:

- \$108.6 million related to etrasimod, and
- \$17.8 million related to olorinab.

Included in the \$69.7 million of total external clinical and preclinical study fees noted in the table above in this section for the year ended December 31, 2018, were the following:

- \$31.4 million related to ralinepag,
- \$25.7 million related to etrasimod, and
- \$3.9 million related to olorinab.

Cumulatively from our inception through December 31, 2019, we have recognized (i) external clinical and preclinical study fees of \$307.8 million for lorcaserin, \$196.5 million for etrasimod, \$63.5 million for ralinepag, \$43.8 million for nelotanserin and \$31.9 million for olorinab and (ii) \$53.2 million for non-commercial manufacturing and other development costs for lorcaserin and, to a lesser extent, nelotanserin.

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 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, enrollment and withdrawal;
- 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 and maintain regulatory approvals.

**General and administrative expenses.** General and administrative expenses increased by \$32.3 million to \$77.6 million for the year ended December 31, 2019, from \$45.3 million for the year ended December 31, 2018. This increase was primarily due to increases of \$14.5 million in non-cash share-based compensation expenses, \$7.5 million in salary and other personnel costs, and \$7.4 million in legal, accounting and other professional fees. The increases in compensation costs are primarily due to an increase in the number of general and administrative employees, and an incremental expense associated with performance-based restricted stock units granted in the first quarter of 2019, which is reflected in the non-cash share-based compensation expense. We expect that our 2020 general and administrative expenses will be higher than in 2019.

**Interest and other income (expense), net.** Interest and other income, net, was \$25.1 million for the year ended December 31, 2019, compared to \$5.9 million for the year ended December 31, 2018. This change was primarily due to an increase of \$18.1 million in interest income from our available-for-sale investments activity and a decrease of \$0.9 million in interest expense.

**Income tax expense.** Income tax provision was \$110.3 million for the year ended December 31, 2019, as a result of the treatment of the agreement with United Therapeutics income as a discrete item during the first quarter of 2019 and the utilization of the deferred tax assets that were recorded in the fourth quarter of 2018.

## 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 develop compounds that could become marketed drugs. We expect to continue to incur substantial losses for at least the short term.

To date, we have obtained cash and funded our operations primarily through the sale of common and preferred stock, the issuance of debt and related financial instruments, payments from collaborators and customers and sale leaseback transactions. From our inception through December 31, 2019, we have generated \$3.5 billion in cash from these sources, of which approximately \$2.0 billion was through sales of equity, \$1.4 billion was through payments from collaborators and customers, \$96.9 million was through the issuance of debt and related financial instruments and \$77.1 million was from sale and leaseback transactions.

We believe our cash resources are sufficient to allow us to continue operations for at least the next 12 months from the date this Annual Report is filed with the SEC. There is no guarantee that adequate funds will be available when needed from additional debt or equity financing, development and commercialization partnerships or from other sources, or on terms acceptable to us. If our efforts to obtain sufficient additional funds are not successful, we would be required to delay, scale back, or eliminate some or all of our research or development, manufacturing operations, administrative operations, and clinical or regulatory activities, which could negatively affect our ability to achieve certain corporate goals.

### **Short term liquidity**

At December 31, 2019, we had \$1.1 billion in cash and cash equivalents, and available-for-sale investments. Our potential sources of liquidity in the short term include (i) milestone and other payments from collaborators, (ii) entering into new collaboration, licensing or commercial agreements for one or more of our drug candidates or programs, (iii) the lease of our facilities or sale of other assets and (iv) sale of equity, issuance of debt or other transactions.

### **Long term liquidity**

It will require 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 collaboration, licensing or other commercial agreements for one or more of our drug candidates and programs or patent portfolios, or from other potential sources of liquidity, which may include the sale of equity, issuance of debt or other transactions.

In addition to potential payments from our 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 obtain regulatory approval to commercialize on our own. The length of time that our current cash and cash equivalents and any available borrowings will sustain our operations will be based on, among other things, the rate of adoption and commercial success of any drugs we or our collaborators obtain regulatory approval to market, regulatory decisions affecting our and our collaborator's drug candidates, 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.

We evaluate from time to time potential acquisitions, 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 provided in operating activities was \$568.7 million in the year ended December 31, 2019, compared to net cash used in operating activities of \$132.2 million in the year ended December 31, 2018. This increase was primarily the result of an \$800.0 million upfront payment from United Therapeutics received in 2019, partially offset by an increase of \$66.0 million in payments made for external clinical study fees, an increase in cash expenditures of approximately \$24.4 million for personnel costs resulting primarily from an increase in the number of employees, a payment of \$14.6 million for the expenses related to the United Therapeutics transaction in the first quarter of 2019, reduced by a class action litigation settlement payment of \$12.0 million in the second quarter of 2018.

Net cash used in investing activities increased by \$245.6 million to \$496.9 million in the year ended December 31, 2019, compared to \$251.3 million in the year ended December 31, 2018. This increase was primarily due to \$493.1 million in net purchases of available-for-sale investments, net of proceeds from the sales and maturity of available-for-sale investments in the year ended December 31, 2019, compared to \$254.0 million in net purchases of available-for-sale investments in the year ended December 31, 2018.

Net cash of \$9.9 million was provided by financing activities in the year ended December 31, 2019, as a result of net proceeds of \$13.1 million from stock option exercises and stock award releases, partially offset by \$3.3 million of principal payments on our lease financing obligations. Net cash of \$385.0 million was provided by financing activities in the year ended December 31, 2018, as a result of net proceeds of \$383.1 million from our March 2018 offering of our common stock and net proceeds of \$5.9 million from stock option exercises, partially offset by \$4.0 million of principal payments on our lease financing obligations.

### Contractual Obligations

The following table summarizes our contractual obligations at December 31, 2019, in thousands:

Contractual Obligations	Payments due by period				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Financing obligations	\$ 65,650	\$ 7,576	\$ 17,133	\$ 18,000	\$ 22,941
Operating leases	16,804	2,236	5,037	4,864	4,667
Total	<u>\$ 82,454</u>	<u>\$ 9,812</u>	<u>\$ 22,170</u>	<u>\$ 22,864</u>	<u>\$ 27,608</u>

Our financing obligations relate to sale and leaseback transactions for certain of our properties. We have applied the financing method to these sale and leaseback transactions, which requires that the book value of the properties and related accumulated depreciation remain on our balance sheet with no sale recognized. The sales price of the properties is recorded as a financing obligation and a portion of each lease payment is recorded as interest expense. At December 31, 2019, we expect our interest expense over the remaining term of these leases to total \$21.2 million. Our other properties are under operating leases and are included under operating leases above.

### Off-balance sheet arrangements

We do not have and did not have at December 31, 2019, 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.

### 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 the US generally accepted accounting principles, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosures. We base our estimates on historical experience and on various assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ significantly from those estimates.

Our significant accounting policies are more fully described in Note 1 of the consolidated financial statements included in this Annual Report. As disclosed in Note 1, the preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions about future events that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ significantly from those estimates. We believe that the following discussion addresses our most critical accounting policies, which are those that are most important to the portrayal of our financial condition and results of operations and require management's most difficult, subjective and complex judgments.

**Revenue recognition.** Our revenues to date have been generated primarily through collaboration or license agreements. Our collaboration and license agreements frequently contain multiple types of promised goods or services including (i) intellectual property licenses, (ii) product research, development and regulatory services and (iii) product manufacturing. Consideration we receive under these arrangements may include upfront payments, research and development funding, cost reimbursements, milestone payments, payments for product sales and royalty payments.

We recognize revenue when a customer obtains control of promised goods or services. The amount of revenue recognized reflects the consideration that we expect to be entitled to receive in exchange for these services and excludes sales incentives and amounts collected on behalf of third parties. We analyze the nature of these performance obligations in the context of individual collaboration and license agreements in order to assess the distinct performance obligations. We apply the following five steps to recognize revenue:

i) *Identify the contract with a customer.* We consider the terms and conditions of our collaboration and license agreements to identify contracts within the scope of ASC 606. We consider that we have a contract with a customer when the contract is approved, we can identify each party's rights regarding the goods and services to be transferred, we can identify the payment terms for the goods and services, we have determined the customer has the ability and intent to pay and the contract has commercial substance. We use judgment in determining the customer's ability and intent to pay, which is based upon factors including the customer's historical payment experience or, for new customers, credit and financial information pertaining to the customers.

ii) *Identify the performance obligations in the contract.* Performance obligations in our collaboration and license agreements are identified based on the goods and services that will be transferred to the customer that are both capable of being distinct, whereby the customer can benefit from the service either on its own or together with other resources that are readily available from third parties or from us, and are distinct in the context of the contract, whereby the transfer of the services is separately identifiable from other promises in the contract. Our performance obligations generally consist of intellectual property licenses, research, development and/or regulatory services and manufacturing and supply commitments. Determining whether a promised goods or service is a separate performance obligation requires the use of significant judgment. A change in such judgment could result in a significant change in the period in which revenue is recognized.

Most of our collaboration and license agreements with customers contain multiple promised goods or services. Based on the characteristics of the promised goods and services we analyze whether they are separate or combined performance obligations. The transaction price is allocated to the separate performance obligations on a relative standalone selling price basis. We determine standalone selling price based on our overall pricing and discounting objectives, taking into consideration the type of services, estimates of hourly market rates, and stage of the research, development or clinical trials.

iii) *Determine the transaction price.* We determine the transaction price based on the consideration to which we expect to be entitled in exchange for transferring goods and services to the customer. In determining the transaction price, any variable consideration would be considered, to the extent applicable, if, in our judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. In accordance with the royalty exception under ASC 606 for licenses of intellectual property, the transaction price excludes future royalty payments to be received from our customers. None of our collaboration and license agreements contain consideration payable to our customer or a significant financing component. The process for determining the transaction price involves significant judgment and includes consideration of multiple factors such as estimated revenues, market size, and development risk, among other factors contemplated in negotiating the arrangement with the customer.

Our contracts with customers primarily include two types of variable consideration: (i) development and regulatory milestone payments, which are due to us upon achievement of specific development and regulatory milestones and (ii) one-time sales-based payments and sales-based royalties associated with sold or licensed intellectual property.

Due to uncertainty associated with achievement of the development and regulatory milestones, the related milestone payments are excluded from the contract consideration and the corresponding revenue is not recognized until we conclude it is probable that reversal of such milestone revenue will not occur.

Product sales-based royalties under licensed intellectual property and one-time payments are accounted for under the royalty exception. We recognize revenue for sales-based royalties under licensed intellectual property and one-time payments at the later of when the sales occur or the performance obligation is satisfied or partially satisfied.

iv) *Allocate the transaction price to performance obligations in the contract.* If the contract contains a single performance obligation, the entire transaction price is allocated to that performance obligation. Contracts that contain multiple performance obligations require an allocation of the transaction price to each performance obligation based on a relative standalone selling price.

v) *Recognize revenue when or as we satisfy a performance obligation.* Revenue is recognized at the time the related performance obligation is satisfied by transferring the promised goods or services to a customer. We recognize revenue when we transfer control of the goods or services to our customers for an amount that reflects the consideration that we expect to receive in exchange for those services.

#### **Performance Obligations.**

The following is a description of principal goods and services from which we generate revenue.

##### *Intellectual property licenses*

We generate revenue from licensing our intellectual property including know-how and development and commercialization rights. These licenses provide customers with a term-based license to further research, develop and commercialize our internally-



discovered drug candidates. The consideration we receive in the form of nonrefundable upfront consideration related to the functional intellectual property licenses is recognized when we transfer such license to the customer unless the license is combined with other goods or services into one performance obligation, in which case the revenue is recognized over a period of time based on our estimated pattern in which we satisfy the combined performance obligation. Our licensing agreements are generally cancelable. Customers have the right to terminate their contracts upon notice. We have the right to terminate the contracts generally only if the customer is in breach of the contract and fails to remedy the breach in accordance with the contractual terms.

#### *Intellectual property sales*

We generate royalty revenue from sales of our intellectual property. We estimate the future royalty payments and recognize revenue with a corresponding contract asset at a point in time when we transfer the intellectual property to the customer. We periodically reassess our estimate of the future royalty payments and recognize any estimate adjustments as revenue in the current period.

#### *Research, development and regulatory services*

We generate revenue from research, development and regulatory services we provide to our customers in connection with the licensed intellectual property. The services we provide to our customers primarily include scientific research activities, preparation for and management of clinical trials, and assistance during the regulatory approval application process. Revenue associated with these services is recognized based on our estimate of total consideration to be received for such services and the pattern in which we perform the services. The pattern of performance is generally determined to be the amount of incurred expenses reimbursed by the customer as a percentage of total expected reimbursable expenses associated with the contract.

**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 enrollment, 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 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.

**Share-based compensation.** Our share-based awards are measured at fair value and recognized over the requisite service or performance period. We estimate the fair value of each stock option on the date of grant using the Black-Scholes option pricing model which requires the input of subjective assumptions, including price volatility of the underlying stock, risk-free interest rate, dividend yield, and expected life of the option. Expected volatility is computed using historical volatility for a period equal to the expected term. The expected term 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. We account for the forfeitures in the period they occur. The fair value of each restricted stock unit award is determined based on the market price of the underlying common stock on the date of the grant. We estimate the fair value of restricted stock unit awards that include market-based performance conditions 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.

**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.

On December 22, 2017, the US government enacted comprehensive tax legislation referred to as the Tax Cuts and Jobs Act, or the Tax Act. Shortly after the Tax Act was enacted, the SEC staff issued Staff Accounting Bulletin No. 118, *Income Tax Accounting Implications of the Tax Cuts and Jobs Act*, or SAB 118, which provides guidance on accounting for the Tax Act’s impact. SAB 118

provides a measurement period, which should not extend beyond one year from the Tax Act enactment date, during which a company acting in good faith may complete the accounting for the impacts of the Tax Act under ASC Topic 740, *Income Taxes*, or ASC 740. In accordance with SAB 118, the companies are required to reflect the income tax effects of the Tax Act in the reporting period in which the accounting under ASC 740 is complete. In 2018, we completed our accounting analysis of the impacts of the Tax Act. See Note 9 to our consolidated financial statements included in this Annual Report for additional information.

*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.*

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

### ***Interest Rate Risk***

We invest our excess cash in investment-grade, interest-bearing securities. The primary objective of our investment activities is to preserve principal and liquidity. To achieve this objective, we invest in money market funds, US Treasury notes, and high-quality marketable debt instruments of corporations and government-sponsored enterprises with contractual maturity dates of generally less than two years. All investment securities have a credit rating of at least A or better, as determined by Moody's Investors Service, Standard & Poor's or Fitch Ratings. If a 10% change in interest rates were to have occurred on December 31, 2019, this change would not have had a material effect on the fair value of our investment portfolio as of that date.

### ***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 Swiss 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 equity section of our consolidated balance sheets.

Foreign currency transaction gains and losses recorded in continuing operations are insignificant. If a 10% change in the US dollar-to-Swiss franc exchange rate were to have occurred on December 31, 2019, this change would not have had a material effect on the financial results of our continuing operations.

We have not hedged exposures denominated in foreign currencies, but may do so in the future.

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

**ARENA PHARMACEUTICALS, INC.**

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

	<b>Page</b>
<a href="#">Report of Independent Registered Public Accounting Firm</a>	58
<a href="#">Consolidated Balance Sheets</a>	60
<a href="#">Consolidated Statements of Operations and Comprehensive Income (Loss)</a>	61
<a href="#">Consolidated Statements of Equity</a>	63
<a href="#">Consolidated Statements of Cash Flows</a>	64
<a href="#">Notes to Consolidated Financial Statements</a>	66

To the Stockholders and Board of Directors  
Arena Pharmaceuticals, Inc.:

*Opinion on the Consolidated Financial Statements*

We have audited the accompanying consolidated balance sheets of Arena Pharmaceuticals, Inc. and subsidiaries (the Company) as of December 31, 2019 and 2018, the related consolidated statements of operations and comprehensive income (loss), equity, and cash flows for each of the years in the three-year period ended December 31, 2019, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2019, 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) (PCAOB), the Company's internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission, and our report dated February 27, 2020 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

*Changes in Accounting Principle*

As discussed in Note 1 to the consolidated financial statements, the Company has changed its method of accounting for revenue recognition as of January 1, 2018 due to the adoption of Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers*, and for leases as of January 1, 2019 due to the adoption of Accounting Standards Codification Topic 842, *Leases*.

*Basis for Opinion*

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 are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

*Critical Audit Matters*

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

*Assessment of the United Therapeutics revenue recognition*

As discussed in Note 8 to the consolidated financial statements, the Company entered into an exclusive license agreement with United Therapeutics Corporation in November 2018. Under the agreement, the Company received an upfront payment of \$800.0 million. The upfront payment was recognized as revenue at a point in time upon the closing of this transaction in the first quarter of fiscal year 2019 when the performance obligation was satisfied upon providing access to the license.

We identified the assessment of the United Therapeutics revenue recognition as a critical audit matter. The determination of the nature of the performance obligation and when it was satisfied was complex and involved subjective auditor judgment.

The primary procedures we performed to address this critical audit matter included the following. We tested certain internal controls over the Company's process to record revenue, including controls related to the nature of the performance obligation and when it was satisfied. We examined the collaboration and license agreement between the Company and United Therapeutics. We evaluated the Company's assessment of the accounting treatment of this transaction, including the determination that the Company's performance obligation was satisfied upon the transfer of the license.

*Evaluation of the accrued clinical and preclinical study fees*

As discussed in Note 1 to the consolidated financial statements, research and development costs associated with the Company's clinical trials are expensed as incurred when these expenditures have no alternative future uses. The Company has entered into various contracts with contract research organizations (CROs) to perform research and development activities. When billing terms under these contracts do not coincide with the timing of when the work is performed, the Company is required to make estimates of outstanding obligations as of year-end to those CROs. These estimates are based on a number of factors, including the Company's knowledge of the status of each of the clinical trials, invoicing to date, and the provisions in the contracts. The accrued clinical and preclinical study fees were \$15.7 million and the clinical and preclinical study fees included within research and development expenses were \$141.1 million as of and for the year ended December 31, 2019, respectively.

We identified the evaluation of the accrued clinical and preclinical study fees as a critical audit matter. Challenging auditor judgment was involved in evaluating the status of each of the clinical trials.

The primary procedures we performed to address this critical audit matter included the following. We tested certain internal controls over the Company's process to estimate the outstanding obligations for the work performed by the CROs over clinical trials, including controls over the status of the clinical trials. We selected contracts with CROs, evaluated the provisions in the contracts, confirmed costs incurred with the respective CRO, and examined underlying invoices to assess the amount billed to date. Furthermore, to assess that services received prior to December 31, 2019 were included within the Company's accrued clinical and preclinical study fees balance, we (1) inquired of the individuals who are responsible for monitoring and tracking the status of the clinical trials; (2) inspected government clinical trial databases; and (3) examined invoices received after December 31, 2019.

/s/ KPMG LLP

We have served as the Company's auditor since 2010.

San Diego, California  
February 27, 2020

**ARENA PHARMACEUTICALS, INC.**

**Consolidated Balance Sheets**

(In thousands, except share and per share data)

	December 31,	
	2019	2018
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 243,274	\$ 161,037
Short-term investments, available-for-sale	496,291	284,594
Accounts receivable	1,654	5,086
Prepaid expenses and other current assets	18,715	10,008
Total current assets	759,934	460,725
Investments, available-for-sale	370,938	82,412
Land, property and equipment, net	25,128	23,114
Deferred tax assets	—	110,333
Other non-current assets	18,123	10,319
Total assets	<u>\$ 1,174,123</u>	<u>\$ 686,903</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable and other accrued liabilities	\$ 25,499	\$ 16,181
Accrued clinical and preclinical study fees	15,654	10,454
Current portion of lease financing obligations	3,814	3,283
Total current liabilities	44,967	29,918
Lease financing obligations, less current portion	45,613	49,426
Other long-term liabilities	12,078	1,301
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.0001 par value, 7,500,000 shares authorized, no shares issued and outstanding at December 31, 2019, and 2018	—	—
Common stock, \$0.0001 par value, 73,500,000 shares authorized at December 31, 2019, and 2018; 50,170,953 shares issued and outstanding at December 31, 2019; 49,422,991 shares issued and outstanding at December 31, 2018	5	5
Additional paid-in capital	2,173,154	2,106,960
Accumulated other comprehensive income (loss)	1,303	(155)
Accumulated deficit	(1,102,997)	(1,500,552)
Total stockholders' equity	1,071,465	606,258
Total liabilities and equity	<u>\$ 1,174,123</u>	<u>\$ 686,903</u>

See accompanying notes to consolidated financial statements.

**ARENA PHARMACEUTICALS, INC.**

**Consolidated Statements of Operations and Comprehensive Income (Loss)**

(In thousands, except per share data)

	Years ended December 31,		
	2019	2018	2017
<b>Revenues</b>			
United Therapeutics revenue	\$ 800,000	\$ —	\$ —
Collaboration and other revenue	7,284	11,402	19,632
Royalty revenue	(853)	6,568	1,705
<b>Total revenues</b>	<b>806,431</b>	<b>17,970</b>	<b>21,337</b>
<b>Operating costs and expenses</b>			
Research and development	231,496	115,029	70,988
General and administrative	77,616	45,257	30,341
Transaction costs	14,573	2,467	—
Litigation settlement expense, net	—	—	11,975
<b>Total operating costs and expenses</b>	<b>323,685</b>	<b>162,753</b>	<b>113,304</b>
Income (loss) from operations	482,746	(144,783)	(91,967)
<b>Interest and other income (expense)</b>			
Interest income	26,872	8,772	492
Interest expense	(4,791)	(5,695)	(6,119)
Other income	3,061	2,872	1,740
<b>Total interest and other income (expense), net</b>	<b>25,142</b>	<b>5,949</b>	<b>(3,887)</b>
Income (loss) from continuing operations before income taxes	507,888	(138,834)	(95,854)
Income tax (provision) benefit	(110,333)	110,265	—
Income (loss) from continuing operations	397,555	(28,569)	(95,854)
Income (loss) from discontinued operations	—	(830)	3,122
Net income (loss)	397,555	(29,399)	(92,732)
Less net loss attributable to noncontrolling interest in consolidated variable interest entity	—	—	1,325
<b>Net income (loss) attributable to stockholders of Arena</b>	<b>\$ 397,555</b>	<b>\$ (29,399)</b>	<b>\$ (91,407)</b>
<b>Amounts attributable to stockholders of Arena:</b>			
Income (loss) from continuing operations	\$ 397,555	\$ (28,569)	\$ (94,529)
Income (loss) from discontinued operations	—	(830)	3,122
	<b>\$ 397,555</b>	<b>\$ (29,399)</b>	<b>\$ (91,407)</b>
<b>Net income (loss) attributable to stockholders of Arena per share, basic:</b>			
Continuing operations	\$ 7.99	\$ (0.61)	\$ (2.87)
Discontinued operations	—	(0.02)	0.10
	<b>\$ 7.99</b>	<b>\$ (0.63)</b>	<b>\$ (2.77)</b>
<b>Net income (loss) attributable to stockholders of Arena per share, diluted:</b>			
Continuing operations	\$ 7.69	\$ (0.61)	\$ (2.87)
Discontinued operations	—	(0.02)	0.10
	<b>\$ 7.69</b>	<b>\$ (0.63)</b>	<b>\$ (2.77)</b>
Shares used in calculating net income (loss) attributable to stockholders of Arena per share, basic	49,779	47,041	32,990
Shares used in calculating net income (loss) attributable to stockholders of Arena per share, diluted	51,698	47,041	32,990
<b>Comprehensive Income (Loss):</b>			
Net income (loss)	\$ 397,555	\$ (29,399)	\$ (92,732)

Foreign currency translation adjustment	(11)	72	2,016
Unrealized gain (loss) on available-for-sale investments	<u>1,469</u>	<u>(113)</u>	<u>(133)</u>
Comprehensive income (loss)	399,013	(29,440)	(90,849)
Less comprehensive loss attributable to noncontrolling interest in consolidated variable interest entity	—	—	1,325
Comprehensive income (loss) attributable to stockholders of Arena	<u>\$ 399,013</u>	<u>\$ (29,440)</u>	<u>\$ (89,524)</u>

See accompanying notes to consolidated financial statements.



ARENA PHARMACEUTICALS, INC.

Consolidated Statements of Equity

(In thousands, except share data)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Equity Attributable to Stockholders of Arena	Equity Attributable to Noncontrolling Interest in Consolidated Variable Interest Entity	Total Equity
	Shares	Amount						
<b>Balance at December 31, 2016</b>	<b>24,340,080</b>	<b>\$ 2</b>	<b>\$ 1,441,737</b>	<b>\$ (3,099)</b>	<b>\$ (1,398,736)</b>	<b>\$ 39,904</b>	<b>\$ 491</b>	<b>\$ 40,395</b>
Adoption of ASU No. 2016-09	—	—	44	—	(44)	—	—	—
Issuance of common stock to underwriters, net	14,087,500	2	236,386	—	—	236,388	—	236,388
Issuance of common stock under the ATM facility, net	489,023	—	6,987	—	—	6,987	—	6,987
Issuance of common stock upon exercise of options	323,431	—	5,404	—	—	5,404	—	5,404
Issuance of common stock under employee stock purchase plan and upon vesting of restricted stock unit awards	40,653	—	12	—	—	12	—	12
Share-based compensation expense	—	—	7,973	—	—	7,973	17	7,990
Unrealized loss on available-for-sale investments	—	—	—	(133)	—	(133)	—	(133)
Translation gain	—	—	—	2,016	—	2,016	—	2,016
Net loss	—	—	—	—	(91,407)	(91,407)	(1,325)	(92,732)
Deconsolidation of variable interest entity	—	—	—	—	—	—	817	817
<b>Balance at December 31, 2017</b>	<b>39,280,687</b>	<b>4</b>	<b>1,698,543</b>	<b>(1,216)</b>	<b>(1,490,187)</b>	<b>207,144</b>	<b>—</b>	<b>207,144</b>
Adoption of ASC 606	—	—	—	1,102	19,034	20,136	—	20,136
Issuance of common stock to underwriters, net	9,775,000	1	383,141	—	—	383,142	—	383,142
Issuance of common stock upon exercise of options	317,636	—	5,888	—	—	5,888	—	5,888
Issuance of common stock upon vesting of restricted stock unit awards	49,668	—	(166)	—	—	(166)	—	(166)
Share-based compensation expense	—	—	19,554	—	—	19,554	—	19,554
Unrealized loss on available-for-sale investments	—	—	—	(113)	—	(113)	—	(113)
Translation gain	—	—	—	72	—	72	—	72
Net loss	—	—	—	—	(29,399)	(29,399)	—	(29,399)
<b>Balance at December 31, 2018</b>	<b>49,422,991</b>	<b>5</b>	<b>2,106,960</b>	<b>(155)</b>	<b>(1,500,552)</b>	<b>606,258</b>	<b>—</b>	<b>606,258</b>
Issuance of common stock upon exercise of options	625,757	—	15,184	—	—	15,184	—	15,184
Issuance of common stock upon vesting of restricted stock unit awards	122,205	—	(2,037)	—	—	(2,037)	—	(2,037)
Share-based compensation expense	—	—	53,047	—	—	53,047	—	53,047
Unrealized gain on available-for-sale investments	—	—	—	1,469	—	1,469	—	1,469
Translation loss	—	—	—	(11)	—	(11)	—	(11)
Net income	—	—	—	—	397,555	397,555	—	397,555
<b>Balance at December 31, 2019</b>	<b>50,170,953</b>	<b>\$ 5</b>	<b>\$ 2,173,154</b>	<b>\$ 1,303</b>	<b>\$ (1,102,997)</b>	<b>\$ 1,071,465</b>	<b>\$ —</b>	<b>\$ 1,071,465</b>

See accompanying notes to consolidated financial statements.

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

	Years ended December 31,		
	2019	2018	2017
<b>Operating activities:</b>			
Net income (loss)	\$ 397,555	\$ (29,399)	\$ (92,732)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
(Income) loss from discontinued operations	—	830	(3,122)
Depreciation and amortization	3,233	3,759	4,278
Deferred income taxes	110,333	(110,333)	—
Non-cash collaboration revenue	—	(1,500)	—
Non-cash royalty revenue	3,744	(3,315)	—
Share-based compensation	53,047	19,543	7,855
Litigation settlement expense, net	—	—	11,975
Amortization of prepaid financing costs	90	110	136
Amortization of original issue discounts, net of premiums, on available-for-sale investments	(5,628)	(664)	—
Loss (gain) on disposal of property and equipment	112	(791)	(379)
Changes in operating assets and liabilities:			
Accounts receivable	3,432	(2,760)	10,787
Prepaid expenses and other assets	(8,133)	(2,929)	585
Payables and accrued liabilities	12,347	10,871	1,803
Accrued litigation settlement	—	(11,975)	—
Deferred revenues	(1,438)	(2,061)	(4,401)
Other long-term liabilities	—	(1,265)	(577)
Net cash provided by (used in) operating activities - continuing operations	568,694	(131,879)	(63,792)
Net cash used in operating activities - discontinued operations	—	(333)	(2,850)
Net cash provided by (used in) operating activities	568,694	(132,212)	(66,642)
<b>Investing activities:</b>			
Purchases of available-for-sale investments	(1,469,220)	(364,539)	(112,615)
Proceeds from sale and maturity of available-for-sale investments	976,093	110,564	—
Deconsolidation of variable interest entity	—	—	(406)
Purchases of property and equipment	(4,819)	(692)	(113)
Proceeds from sale of property and equipment	—	—	789
Other non-current assets	—	(11)	(5)
Net cash used in investing activities - continuing operations	(497,946)	(254,678)	(112,350)
Net cash provided by (used in) investing activities - discontinued operations	997	3,405	(40)
Net cash used in investing activities	(496,949)	(251,273)	(112,390)
<b>Financing activities:</b>			
Principal payments on lease financing obligations	(3,282)	(4,000)	(3,518)
Proceeds from issuance of common stock	13,147	389,031	248,805
Net cash provided by financing activities	9,865	385,031	245,287
Effect of exchange rate changes on cash	(10)	654	1,870
Net increase in cash, cash equivalents and restricted cash	81,600	2,200	68,125
Cash, cash equivalents and restricted cash at beginning of year	161,900	159,700	91,575
Cash, cash equivalents and restricted cash at end of year	<u>\$ 243,500</u>	<u>\$ 161,900</u>	<u>\$ 159,700</u>

**Supplemental disclosure of cash flow information:**

Interest paid	<u>\$ 4,787</u>	<u>\$ 5,696</u>	<u>\$ 5,967</u>
---------------	-----------------	-----------------	-----------------

**Supplemental disclosure of non-cash investing and financing information:**

Disposition of property and land upon lease expiration	<u>\$ —</u>	<u>\$ 3,944</u>	<u>\$ —</u>
Reduction in lease financing obligation from release of residual value upon lease expiration	<u>\$ —</u>	<u>\$ 5,039</u>	<u>\$ —</u>

See accompanying notes to consolidated financial statements.

## **1. The Company and Summary of Significant Accounting Policies**

### **The Company**

Arena Pharmaceuticals, Inc., or Arena, was incorporated on April 14, 1997, and commenced operations in July 1997. We are a biopharmaceutical company focused on delivering novel, transformational medicines with optimized pharmacology and pharmacokinetics to patients globally. Our proprietary, internally-developed pipeline includes multiple potentially first- or best-in-class assets with broad clinical utility.

Our most advanced investigational clinical programs include: etrasimod, which is being evaluated in a Phase 3 program for ulcerative colitis, a Phase 2b/3 program for Crohn's disease, and a Phase 2b program in atopic dermatitis. We also plan to evaluate etrasimod in a Phase 2b program for eosinophilic esophagitis, and a Phase 2 program in alopecia areata. Olorinab is being evaluated for a broad range of visceral pain conditions associated with gastrointestinal diseases, currently in a Phase 2b trial for treatment of abdominal pain associated with irritable bowel syndrome. APD418 is being evaluated in a Phase 1 trial for acute heart failure. Additionally, we have collaboration or license agreements with various companies.

We operate in one business segment. Our primary clinical operations are conducted in San Diego, California and Boston, Massachusetts; and in Zug, Switzerland by Arena Pharmaceuticals Development GmbH, or APD GmbH, our wholly-owned subsidiary.

### **Basis of Presentation**

The accompanying consolidated financial statements have been prepared in accordance with the US generally accepted accounting principles, or GAAP, and reflect all of our activities, including those of our wholly owned subsidiaries. All material intercompany accounts and transactions have been eliminated in consolidation. Certain prior period amounts in the consolidated financial statements have been reclassified to conform to the current period presentation. As a result of the sale of our Manufacturing Operations (see Note 5), the operations and cash flows of the Manufacturing Operations are reflected as discontinued operations for the years ended December 31, 2018, and 2017.

The accompanying consolidated financial statements also include the activity of Beacon Discovery, Inc., or Beacon, a variable interest entity in which we had a controlling financial interest until December 2017 at which point we deconsolidated Beacon (see Note 12). The results of operations and comprehensive loss attributable to the noncontrolling interest in Beacon are presented as separate components from the results of operations and comprehensive loss attributable to the stockholders of Arena in the consolidated statements of operations and comprehensive loss.

### **Liquidity**

As of December 31, 2019, we had cash, cash equivalents and available-for-sale investments of approximately \$1.1 billion. We believe our cash, cash equivalents and available-for-sale investments will be sufficient to fund our operations for at least the next 12 months from the date these consolidated financial statements are issued.

We will require substantial cash to achieve our objectives of discovering, developing and commercializing drugs, as this process typically takes many years and potentially 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 and license agreements, under new collaboration, licensing or other commercial agreements for one or more of our drug candidates and programs or patent portfolios, or from other potential sources of liquidity, which may include the sale of equity, issuance of debt or other transactions.

## Changes in Accounting Policies - Leases.

Effective January 1, 2019, we adopted Accounting Standard Codification Topic 842, *Leases*, or ASC 842, issued by the Financial Accounting Standards Board, or FASB. ASC 842 requires lessees to recognize leases on the balance sheet and disclose key information about leasing arrangements. The new standard established a right-of-use model that requires a lessee to recognize a right-of-use asset and lease liability on the balance sheet for all leases with a term longer than 12 months. Leases are classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the statement of operations. As a result, we have changed our accounting policy for leases as detailed below.

We implemented ASC 842 using the modified retrospective transition approach by applying the new standard to leases existing at the date of initial application. We used the effective date as our date of initial application. Therefore, we did not update the financial information and did not provide the disclosures required under the new standard for dates and periods before January 1, 2019.

We applied ASC 842 using a package of practical expedients, which permitted us not to reassess under the new standard our prior conclusions about lease identification, lease classification and initial direct costs. We did not elect the use-of-hindsight or the practical expedient pertaining to land easements; the latter not being applicable to us.

Upon adoption of ASC 842, we recorded an operating lease liability of \$6.3 million based on the present value of the remaining minimum rental payments under the terms of our existing operating lease pertaining to one of our leased properties with a corresponding right-of-use asset of \$5.9 million. Adoption of this standard did not have a material impact on our consolidated statements of operations or cash flows.

The new standard also provides practical expedients for an entity's ongoing accounting. We elected the short-term lease recognition exemption for our office equipment leases and short-term office space leases. This means, for those leases that qualify, we do not recognize right-of-use assets or lease liabilities. See Note 6 for disclosures related to our leases.

## Recent Accounting Pronouncements

In November 2018, the FASB issued ASU No. 2018-18, *Collaborative Arrangements (Topic 808)—Clarifying the Interaction between Topic 808 and Topic 606*. The amendments in ASU No. 2018-18 make targeted improvements to generally accepted accounting principles for collaborative arrangements by clarifying that certain transactions between collaborative arrangement participants should be accounted for as revenue under Accounting Standard Codification Topic 606, *Revenue from Contracts with Customers*, or ASC 606, when the collaborative arrangement participant is a customer in the context of a unit of account. In those situations, all the guidance in ASC 606 should be applied, including recognition, measurement, presentation, and disclosure requirements. In addition, unit-of-account guidance in ASC 808 was aligned with the guidance in ASC 606 when an entity is assessing whether the collaborative arrangement or a part of the arrangement is within the scope of ASC 606. The amendments in ASU No. 2018-18 are applied retrospectively to the date of initial application of ASC 606, which for us was January 1, 2018. The adoption of this ASU did not have a material impact on our consolidated financial statements.

In December 2019, the FASB issued ASU No. 2019-12 which modifies ASC 740, *Income Taxes* to simplify the accounting for income taxes in various areas. The amendments in ASU 2019-12 are effective for us for fiscal years beginning after December 15, 2020, including interim periods therein. Early adoption of the standard is permitted, including adoption in interim or annual periods for which financial statements have not yet been issued. We are currently evaluating the impact of adoption on our consolidated financial statements.

## Use of Estimates

The preparation of financial statements in conformity with 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.

## 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. The following table provides a reconciliation of the components of cash, cash equivalents and restricted cash reported in our consolidated balance sheets to the total of the amount presented in the consolidated statements of cash flows, in thousands:

	December 31, 2019	December 31, 2018
Cash and cash equivalents	\$ 243,274	\$ 161,037
Restricted cash included in other non-current assets	226	863
Total cash, cash equivalents and restricted cash presented in the consolidated statement of cash flows	<u>\$ 243,500</u>	<u>\$ 161,900</u>

The restricted cash relates to our property leases. The restriction will lapse when the related leases expire.

### Available-for-Sale Investments

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

### Concentrations of Risk

Financial instruments, which potentially subject us to concentrations of credit risk, consist primarily of cash and cash equivalents and available-for-sale investments. We limit our exposure to credit loss by holding our cash primarily in US dollars or 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.

Our customers are typically other biopharmaceutical companies to which we license our intellectual property, or sell research and development services or other services under license or collaboration agreements. For the year ended December 31, 2019, more than 99% of our annual revenues was from United Therapeutics. For the year ended December 31, 2018, Eisai, Boehringer Ingelheim, Outpost Medicine, Axovant and Everest accounted for 36.6%, 24.8%, 15.3%, 12.1% and 11.1%, respectively, of our total revenues. For the year ended December 31, 2017, Everest, Boehringer Ingelheim and Axovant accounted for 56.2%, 23.8%, and 10.5%, respectively, of our total revenues.

We monitor our customers' financial credit worthiness in order to assess and respond to any changes in their credit profile. During the years ended December 31, 2019, 2018, and 2017, we did not record any write-offs or reserves against accounts receivable.

### 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 using the straight-line method. Capital improvements are stated at cost and amortized over the estimated useful lives of the underlying assets using the straight-line method.

### 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 to the carrying value of the asset.

### Foreign Currency

The functional currency of our wholly owned subsidiaries in Switzerland, APD GmbH and, until March 31, 2018, Arena Pharmaceuticals GmbH, or Arena GmbH, was the Swiss franc. Accordingly, all assets and liabilities of these subsidiaries are translated to US dollars based on the applicable exchange rate on the balance sheet date. Revenue and expense components are translated to US dollars at weighted-average exchange rates in effect during the period. Gains and losses resulting from foreign currency translation are reported as a separate component of accumulated other comprehensive income or loss in the equity section of our consolidated balance sheets.

Foreign currency transaction gains and losses are primarily the result of remeasuring US dollar-denominated receivables and payables of our foreign subsidiaries. Foreign currency transaction gains and losses recorded by Arena GmbH are included in net income (loss) from discontinued operations.

### 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 term, expected stock price volatility and expected risk-free interest rate. Expected volatility is computed using historical volatility for a period equal to the expected term. The expected term 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. We account for the forfeitures in the period they occur. 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.

### Revenue Recognition

Our revenues to date have been generated primarily through collaboration and license agreements. Our collaboration and license agreements frequently contain multiple types of promised goods or services including (i) intellectual property licenses, (ii) product research, development and regulatory services and (iii) product manufacturing. Consideration we receive under these arrangements may include upfront payments, research and development funding, cost reimbursements, milestone payments, payments for product sales and royalty payments.

Effective January 1, 2018, we adopted Accounting Standard Codification 606, *Revenue from Contracts with Customers*, or ASC 606, issued by the Financial Accounting Standards Board, or FASB. As a result, we have changed our accounting policy for revenue recognition as detailed below.

We implemented ASC 606 using the modified retrospective method by recognizing the cumulative effect of initially applying ASC 606 as an adjustment to the opening balance of our accumulated deficit at January 1, 2018. Therefore, the comparative period information has not been adjusted.

We applied ASC 606 using a practical expedient for contracts that were modified before the implementation date, which allowed us to determine an aggregate effect of all modifications that occurred before January 1, 2018, when determining the satisfied and unsatisfied performance obligations, the transaction price, and allocating that transaction price to the performance obligations instead of retrospectively restating the contracts for such contract modifications.

The cumulative impact to our accumulated deficit balance at January 1, 2018, as a result of the adoption of ASC 606 was a decrease of \$19.0 million. The decrease arose primarily from a reduction of deferred revenue balances related to upfront payments received from customers and recognition of contract assets due to a combination of (i) the effects of applying the practical expedient for contract modifications and our conclusions related to satisfied and unsatisfied performance obligations, which resulted in a relatively higher portion of the total transaction price recognized as revenue in periods prior to our adoption of ASC 606, (ii) the effect of the bill-and-hold accounting guidance for inventory in ASC 606 and (iii) the inclusion of estimated future royalty payments related to our intellectual property in the total transaction price to the extent such intellectual property was legally sold to our customer rather than licensed. The cumulative effect adjustment is net of an impairment loss of \$13.1 million which was a direct effect of the adoption of ASC 606 on the asset group of the Manufacturing Operations, which was classified as assets of disposal group held for sale since December 2017.

The following table summarizes the impacts of adopting ASC 606 on our consolidated financial statements, in thousands.

**Impact of Changes in Accounting Policies**

<b>Year ended December 31, 2018</b>	<b>Impact of Changes in Accounting Policies</b>		
	<b>As reported</b>	<b>Adjustments</b>	<b>Balances without adoption of ASC 606</b>
Collaboration and other revenue	\$ 11,402	\$ 105	\$ 11,507
Royalty revenue	6,568	(1,847)	4,721
Total revenues	17,970	(1,742)	16,228
Loss from operations	(144,783)	(1,742)	(146,525)
Loss from continuing operations	(28,569)	(594)	(29,163)
Income (loss) from discontinued operations	(830)	13,660	12,830
Net loss	(29,399)	13,066	(16,333)
Net loss attributable to stockholders of Arena	(29,399)	13,066	(16,333)
<b>As of December 31, 2018</b>			
Prepaid expenses and other current assets	\$ 10,008	\$ (1,484)	\$ 8,524
Total current assets	460,725	(1,484)	459,241
Other non-current assets	10,319	(4,471)	5,848
Total assets	686,903	(5,955)	680,948
Total current liabilities	29,918	10	29,928
Accumulated deficit	(1,500,552)	(5,965)	(1,506,517)
Total stockholders' equity	606,258	(5,965)	600,293
Total liabilities and stockholders' equity	686,903	(5,955)	680,948

Under ASC 606, revenue is recognized when a customer obtains control of promised goods or services. The amount of revenue recognized reflects the consideration that we expect to be entitled to receive in exchange for these services and excludes sales incentives and amounts collected on behalf of third parties. We analyze the nature of these performance obligations in the context of individual collaboration and license agreements in order to assess the distinct performance obligations. We apply the following five steps to recognize revenue:

*i) Identify the contract with a customer.* We consider the terms and conditions of our collaboration and license agreements to identify contracts within the scope of ASC 606. We consider that we have a contract with a customer when the contract is approved, we can identify each party's rights regarding the goods and services to be transferred, we can identify the payment terms for the goods and services, we have determined the customer has the ability and intent to pay and the contract has commercial substance. We use judgment in determining the customer's ability and intent to pay, which is based upon factors including the customer's historical payment experience or, for new customers, credit and financial information pertaining to the customers.

*ii) Identify the performance obligations in the contract.* Performance obligations in our collaboration and license agreements are identified based on the goods and services that will be transferred to the customer that are both capable of being distinct, whereby the customer can benefit from the service either on its own or together with other resources that are readily available from third parties or from us, and are distinct in the context of the contract, whereby the transfer of the services is separately identifiable from other promises in the contract. Our performance obligations generally consist of intellectual property licenses, research, development and/or regulatory services and manufacturing and supply commitments.

*iii) Determine the transaction price.* We determine the transaction price based on the consideration to which we expect to be entitled in exchange for transferring goods and services to the customer. In determining the transaction price, any variable consideration would be considered, to the extent applicable, if, in our judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. In accordance with the royalty exception under ASC 606 for licenses of intellectual property, the transaction price excludes future royalty payments to be received from our customers. None of our collaboration and license agreements contain consideration payable to our customer or a significant financing component.

*iv) Allocate the transaction price to performance obligations in the contract.* If the contract contains a single performance obligation, the entire transaction price is allocated to that performance obligation. Contracts that contain multiple performance obligations require an allocation of the transaction price to each performance obligation based on a relative standalone selling price.

*v) Recognize revenue when or as we satisfy a performance obligation.* Revenue is recognized at the time the related performance obligation is satisfied by transferring the promised goods or services to a customer. We recognize revenue when we transfer control of the goods or services to our customers for an amount that reflects the consideration that we expect to receive in exchange for those services.



## ***Performance Obligations***

The following is a description of principal goods and services from which we generate revenue.

### ***Intellectual property licenses***

We generate revenue from licensing our intellectual property including know-how and development and commercialization rights. These licenses provide customers with a term-based license to further research, develop and commercialize our internally-discovered drug candidates. The consideration we receive in the form of nonrefundable upfront consideration related to the functional intellectual property licenses is recognized when we transfer such license to the customer unless the license is combined with other goods or services into one performance obligation, in which case the revenue is recognized over a period of time based on our estimated pattern in which we satisfy the combined performance obligation. Our licensing agreements are generally cancelable. Customers have the right to terminate their contracts upon notice. We have the right to terminate the contracts generally only if the customer is in breach of the contract and fails to remedy the breach in accordance with the contractual terms.

### ***Intellectual property sales***

We generate royalty revenue from sales of our intellectual property. We estimate the future royalty payments and recognize revenue with a corresponding contract asset at a point in time when we transfer the intellectual property to the customer. We periodically reassess our estimate of the future royalty payments and recognize any estimate adjustments as revenue in the current period.

### ***Research, development and regulatory services***

We generate revenue from research, development and regulatory services we provide to our customers in connection with the licensed intellectual property. The services we provide to our customers primarily include scientific research activities, preparation for and management of clinical trials, and assistance during the regulatory approval application process. Revenue associated with these services is recognized based on our estimate of total consideration to be received for such services and the pattern in which we perform the services. The pattern of performance is generally determined to be the amount of incurred expenses reimbursed by the customer as a percentage of total expected reimbursable expenses associated with the contract.

### ***Product manufacturing***

In the past, we generated revenue from manufacturing and clinical supply promises to our customers in connection with securing a supply of drug products for development and clinical trial purposes. The drug products were generally manufactured by our contract manufacturing organizations. We used our product manufacturing facility in Zofingen, Switzerland for a portion of the product manufacturing requirements until we sold the Manufacturing Operations on March 31, 2018 (see Note 5). Revenue associated with product manufacturing obligations is recognized at a point in time as control of the related product is transferred to the customer.

## ***Contracts with Multiple Performance Obligations***

Most of our collaboration and license agreements with customers contain multiple promised goods or services. Based on the characteristics of the promised goods and services we analyze whether they are separate or combined performance obligations. The transaction price is allocated to the separate performance obligations on a relative standalone selling price basis. We determine standalone selling price based on our overall pricing and discounting objectives, taking into consideration the type of services, estimates of hourly market rates, and stage of the research, development or clinical trials.

### ***Variable Consideration***

Our contracts with customers primarily include two types of variable consideration: (i) development and regulatory milestone payments, which are due to us upon achievement of specific development and regulatory milestones and (ii) one-time sales-based payments and sales-based royalties associated with sold or licensed intellectual property.

Due to uncertainty associated with achievement of the development and regulatory milestones, the related milestone payments are excluded from the contract consideration and the corresponding revenue is not recognized until we conclude it is probable that reversal of such milestone revenue will not occur.

Product sales-based royalties under licensed intellectual property and one-time payments are accounted for under the royalty exception. We recognize revenue for sales-based royalties under licensed intellectual property and one-time payments at the later of when the sales occur or the performance obligation is satisfied or partially satisfied.

### ***Disaggregation of Revenue***

We operate in one reportable business segment. We provide goods and services to our customers in collaboration and license agreements pursuant to various geographical markets.

### ***Contract Assets***

We receive payments from customers based on contractual terms. Accounts receivable are recorded when the right to consideration becomes unconditional. For research and development services, we generally bill our customers monthly or quarterly as the services are performed. Product sales are generally billed as completed. Payment terms on invoiced amounts are typically 30 days. Contract assets include amounts related to our contractual right to consideration for both completed and partially completed performance obligations that have not been invoiced and for which we do not yet have the right to payment. The current portion of contract asset is included in prepaid expenses and other current assets in the consolidated balance sheet. The non-current portion of contract assets is included in other non-current assets in the consolidated balance sheet. We estimate the amount of the contract asset by applying the expected value method to our estimate of future royalty payments we will receive from this customer. Any changes to this estimate are recorded as an adjustment to revenue in the period in which the change in estimate is made.

### ***Cost to Obtain and Fulfill a Contract***

We generally do not incur costs to obtain new contracts. Costs to fulfill contracts are expensed as incurred.

### ***Remaining Performance Obligations***

The estimated revenue expected to be recognized in the future related to performance obligations that are unsatisfied (or partially unsatisfied) pursuant to our existing collaboration and license agreements as of December 31, 2019 is immaterial.

Under the royalty exception in ASC 606 for licensed intellectual property we do not recognize any revenue for the variable amounts related to sales-based royalties and milestones until the later of when the sales occur or the performance obligation is satisfied or partially satisfied. Accordingly, the revenue related to future sales-based royalties and milestones are excluded from the estimated revenue expected to be recognized in the future related to performance obligations that are unsatisfied.

### ***Previous Revenue Recognition Policy***

Prior to January 1, 2018, we recognized revenue when (i) persuasive evidence of an arrangement existed, (ii) delivery had occurred and title had passed, (iii) the price was fixed or determinable and (iv) collectability was reasonably assured. Any advance payments we received in excess of amounts earned were classified as deferred revenues.

We historically evaluated 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.

To determine the selling price of a separate deliverable, we used the hierarchy as prescribed in Accounting Standards Codification Topic 605-25 based on vendor-specific objective evidence, or VSOE, third-party evidence, or TPE, or best estimate of selling price, or BEBP. VSOE was based on the price charged when the element was sold separately and was the price actually charged for that deliverable. TPE was determined based on third-party evidence for a similar deliverable when sold separately. BEBP was the estimated selling price at which we would transact a sale if the elements of collaboration and license arrangements were sold on a stand-alone basis to the buyer.

Non-refundable upfront payments received under our collaboration and license agreements for commercialization rights were deferred if such rights were not deemed to have standalone value without ongoing services which may be required under the agreement. If deferred, such amounts were recognized as revenues on a straight-line basis over the period in which we expected to perform the services.

Amounts we received as reimbursement for our research and development expenditures were recognized as revenue as the services are performed.

Under the milestone method, we recognized revenue that was contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone was 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 considered 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 were recognized when earned.

### 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. In determining the amount to accrue, we rely on estimates of total costs incurred based on enrollment, 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 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. 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 Income (Loss)

Comprehensive income or loss is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. We report components of comprehensive income or loss in the period in which they are recognized. For the years ended December 31, 2019, 2018 and 2017, comprehensive income (loss) consisted of net income (loss), foreign currency translation gains and losses, and unrealized gains and losses related to available-for-sale investments.

### Income (Loss) Per Share

We calculate basic and diluted income (loss) from continuing operations, income (loss) from discontinued operations and net income (loss) per share using the weighted-average number of shares of common stock outstanding during the period.

Since we report a loss from continuing operations for the years ended December 31, 2018, and 2017, in addition to excluding potentially dilutive out-of-the-money securities, we have excluded from our calculation of income (loss) per share all potentially dilutive in-the-money (i) stock options, (ii) restricted stock unit awards, or RSUs, (iii) Performance-Based Restricted Stock Units, or PRSUs, (iv) Total Stockholder Return performance restricted stock unit awards, or TSR PRSUs, and (v) unvested restricted stock in our deferred compensation plan, and our diluted net loss per share is the same as our basic net loss per share. The table below presents the weighted-average number of potentially dilutive securities that were excluded from our calculation of diluted income (loss) per share for the years presented, in thousands.

	Years ended December 31,		
	2019	2018	2017
Stock options	3,962	5,835	3,664
RSUs and unvested restricted stock	—	20	3
Total	3,962	5,855	3,667

Because the market condition for the outstanding PRSUs was not satisfied at December 31, 2019, such securities are excluded from the table above. Because the market condition for the TSR PRSUs was not satisfied at December 31, 2017, 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.

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			
	Balance	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>December 31, 2019</b>				
<i>Assets:</i>				
Money market funds(1)	\$ 147,752	\$ 147,752	\$ —	\$ —
US government and government agency notes(2)	398,419	398,419	—	—
Corporate debt instruments(2)	483,788	—	483,788	—

	Fair Value Measurements			
	Balance	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>December 31, 2018</b>				
<i>Assets:</i>				
Money market funds(1)	\$ 62,438	\$ 62,438	\$ —	\$ —
US government and government agency notes(2)	171,278	171,278	—	—
Corporate debt instruments(2)	240,481	—	240,481	—

(1) Included in cash and cash equivalents in the accompanying consolidated balance sheets.

(2) Included in either cash and cash equivalents or available-for-sale investments in the accompanying consolidated balance sheet.

### 3. Investments, Available-for-Sale

Investments, available-for-sale, consisted of the following, in thousands:

December 31, 2019	Maturity in years	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
US government and government agency notes	Less than 1	\$ 201,046	\$ 292	\$ (5)	\$ 201,333
Corporate debt securities	Less than 1	294,481	495	(18)	294,958
Short-term investments, available-for-sale		<u>\$ 495,527</u>	<u>\$ 787</u>	<u>\$ (23)</u>	<u>\$ 496,291</u>
US government and government agency notes	1 - 5	\$ 197,157	\$ 85	\$ (155)	\$ 197,087
Corporate debt securities	1 - 5	173,322	603	(74)	173,851
Investments, available-for-sale		<u>\$ 370,479</u>	<u>\$ 688</u>	<u>\$ (229)</u>	<u>\$ 370,938</u>
December 31, 2018	Maturity in years	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
US government and government agency notes	Less than 1	\$ 139,274	\$ —	\$ (18)	\$ 139,256
Corporate debt securities	Less than 1	145,468	—	(130)	145,338
Short-term investments, available-for-sale		<u>\$ 284,742</u>	<u>\$ —</u>	<u>\$ (148)</u>	<u>\$ 284,594</u>
US government and government agency notes	1 - 5	\$ 16,998	\$ 6	\$ —	\$ 17,004
Corporate debt securities	1 - 5	65,512	—	(104)	65,408
Investments, available-for-sale		<u>\$ 82,510</u>	<u>\$ 6</u>	<u>\$ (104)</u>	<u>\$ 82,412</u>

### 4. Balance Sheet Details

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

	December 31,	
	2019	2018
Land	\$ 4,950	\$ 4,950
Building and capital improvements	45,246	45,246
Leasehold improvements	19,277	14,915
Machinery and equipment	169	173
Computers and software	2,749	3,083
Furniture and office equipment	1,531	1,175
	73,922	69,542
Less accumulated depreciation and amortization	(48,794)	(46,428)
Land, property and equipment, net	<u>\$ 25,128</u>	<u>\$ 23,114</u>

As of December 31, 2019, majority of our long-lived assets were located in the United States.

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

	December 31,	
	2019	2018
Accounts payable	\$ 6,043	\$ 6,192
Accrued compensation	14,329	8,622
Other accrued liabilities	5,127	1,367
Total accounts payable and other accrued liabilities	<u>\$ 25,499</u>	<u>\$ 16,181</u>

## 5. Sale of Manufacturing Operations

In order to further focus our efforts and resources on our strategic objectives of developing our pipeline drug candidates, in March 2018, we entered into an Asset Purchase Agreement, or Sale Agreement, with Siegfried Pharma AG and Siegfried AG, (collectively and individually, Siegfried). Under the Sale Agreement, we agreed to sell and assign to Siegfried, and Siegfried agreed to purchase and assume from Arena GmbH, certain drug product finishing facility assets and know-how, including fixtures, equipment, other personal property and real estate assets located in Zofingen, Switzerland and related contracts and certain related liabilities, or collectively, the Manufacturing Operations. We refer to this transaction as the Siegfried Transaction. The Siegfried Transaction was completed on March 31, 2018. In connection with the Siegfried Transaction, all of Arena GmbH's approximately 50 employees transferred to Siegfried. We have excluded from our continuing operations for all periods presented in this report revenues and expenses associated with the disposed Manufacturing Operations, which are reported as discontinued operations. The total sales price for the Manufacturing Operations was approximately CHF 4 million of which approximately CHF 3 million was received in cash in March 2018 and the remaining portion was received in March 2019.

The following table summarizes the results of discontinued operations for the periods presented in the consolidated statements of operations for the years ended December 31, 2018, and 2017, in thousands:

Revenues	Years ended December 31,	
	2018	2017
Net product sales	\$ 1,129	\$ 9,189
Other collaboration revenue	372	6,671
Toll manufacturing	1,006	3,179
Total revenues	2,507	19,039
<b>Operating costs and expenses</b>		
Cost of product sales	1,858	7,472
Cost of toll manufacturing	1,411	4,756
Research and development	—	643
General and administrative	329	1,672
Other (income) expense, net	464	1,374
Total costs and expenses	4,062	15,917
Income (loss) from operations of discontinued operations	(1,555)	3,122
Gain on sale of discontinued operations	725	—
Income (loss) from discontinued operations	<u>\$ (830)</u>	<u>\$ 3,122</u>

## 6. Leases

### San Diego, California

We have three properties in San Diego, California, under sale and leaseback agreements. The terms of these leases contain a purchase option and stipulate annual increases in monthly lease payments of 2.5%. We account for our sale and leaseback transactions using the financing method. Under the financing method, the book value of the properties and related accumulated depreciation remain on our balance sheet and no sale is recognized. The adoption of ASC 842 did not result in a change to our current accounting policy related to our sale and leaseback agreements. The sales price of the properties is recorded as a financing obligation, and a portion of each lease payment is recorded as interest expense. For the years ended December 31, 2019, 2018, and 2017, we recorded interest expense of \$4.8 million, \$5.7 million, and \$6.1 million respectively, related to these leases. We expect interest expense related to our facilities to total \$21.2 million from December 31, 2019, through the remaining terms of the leases in fiscal year 2027. At December 31, 2019, the total financing obligation associated with these sale and leaseback agreements was \$49.4 million. The aggregate residual value of the facilities at the end of the lease terms is \$5.0 million.

We lease an additional property in San Diego, California under an operating lease, which expires in May 2027, contains a purchase option and stipulates annual increases in monthly lease payments of 2.5%. Upon adoption of ASC 842, we recorded an operating lease liability of \$6.3 million based on the present value of the remaining minimum lease payments under the terms of our existing operating lease with a corresponding right-of-use asset of \$5.9 million. As this lease did not provide an implicit rate, we used our estimated incremental borrowing rate based on the information available at effective date of adoption in determining the present value of remaining minimum lease payments. The weighted-average discount rate we used was 7.25%.

### Boston, Massachusetts

In the third quarter of 2019, we entered into a new lease agreement for approximately 12,755 square feet of office space in Boston, Massachusetts with the lease inception date of September 1, 2019. This lease is classified as an operating lease and expires in December 2026. The lease stipulates annual increases in monthly lease payments of 2.0%. At the lease inception date, we recorded an

operating lease liability of \$5.2 million based on the present value of the remaining minimum lease payments under the terms of this lease with a corresponding right-of-use asset of \$5.2 million. As this lease did not provide an implicit rate, we used our estimated incremental borrowing rate based on the information available at effective date of adoption in determining the present value of remaining minimum lease payments. The weighted-average discount rate we used was also 7.25%.

### Zug, Switzerland

In the second quarter of 2019, we entered into a lease in Zug, Switzerland, for approximately 10,500 square feet of office space with the lease inception date of June 1, 2019. This lease expires in May 2024. At the lease inception, we recorded an operating lease liability of \$1.4 million based on the present value of the remaining minimum lease payments under the terms of this operating lease with a corresponding right-of-use asset of \$1.5 million. As this lease did not provide an implicit rate, we used our estimated incremental borrowing rate based on the information available as of the lease inception in determining the present value of remaining minimum lease payments. The weighted-average discount rate we used was 7.25%. In the third quarter of 2019, we entered into an addendum to this lease for approximately 4,050 square feet of additional office space in the same location with the same landlord and the lease inception date of January 1, 2020.

As of December 31, 2019, the balance of the right-of-use assets associated with the leases described above was \$11.8 million and is included in other non-current assets in the accompanying consolidated balance sheet. As of December 31, 2019, the current portion of the corresponding lease liabilities of \$1.3 million is included in accounts payable and other accrued liabilities and the non-current portion of the lease liabilities of \$11.4 million is included in other long-term liabilities in the accompanying consolidated balance sheet. The operating lease costs and cash paid for the amounts included in the measurement of lease liabilities are classified as operating activities in the accompanying consolidated cash flow statement. We recognize rent expense on a straight-line basis over the term of each lease. Rent expense of \$1.9 million, \$1.2 million and \$1.5 million was recognized for the years ended December 31, 2019, 2018, and 2017, respectively. The weighted-average remaining lease term for all operating leases as of December 31, 2019 was 6.8 years.

At December 31, 2019, the future lease payments under our existing financing and non-cancellable operating leases were as follows, in thousands:

Year ending December 31,	Financing Obligations	Operating Leases
2020	\$ 7,576	\$ 2,236
2021	8,461	2,497
2022	8,672	2,540
2023	8,889	2,584
2024	9,111	2,280
Thereafter	22,941	4,667
Total minimum lease payments	65,650	\$ 16,804
Less amounts representing interest	(21,173)	
Add amounts representing residual value	4,950	
Lease financing obligations	49,427	
Less current portion	(3,814)	
	\$ 45,613	

Under the prior lease guidance, at December 31, 2018, the future minimum lease payments under our existing financing and operating lease obligations were as follows, in thousands:

Year ending December 31,	Financing Obligations	Operating Leases
2019	\$ 7,391	\$ 1,050
2020	8,254	1,100
2021	8,461	976
2022	8,672	1,000
2023	8,889	1,025
Thereafter	32,052	3,698
Total minimum lease payments	73,719	<u>\$ 8,849</u>
Less amounts representing interest	(25,960)	
Add amounts representing residual value	4,950	
Lease financing obligations	52,709	
Less current portion	(3,283)	
	<u>\$ 49,426</u>	

### Subleases

In 2016 and 2017, we entered into agreements to sublease several of our California properties. All our subleases expire in May 2027. The terms of the subleases stipulate annual increases in monthly rental payments. For the years ended December 31, 2019, 2018 and 2017, we recognized rent income from our subleases of \$3.0 million, \$2.5 million and \$1.7 million, respectively

We recognize rent income on a straight-line basis over the term of the subleases. Expected minimum rental payments to be received under the sublease are as follows:

Year ending December 31,	
2020	\$ 1,873
2021	2,477
2022	3,487
2023	3,794
2024	3,896
Thereafter	9,839
Total	<u>\$ 25,366</u>

## 7. Stockholders' Equity

In March 2018, we completed the sale of an aggregate of 9,775,000 shares of our common stock under an underwritten public offering. Net proceeds from the offering were approximately \$383.1 million after deducting underwriting discounts and commissions and offering expenses payable by us.

In July 2017, we completed the sale of an additional 7,187,500 shares of our common stock under an underwritten public offering. Net proceeds from the offering were \$162.0 million after deducting underwriting discounts and commissions, and offering expenses payable by us.

In April 2017, we completed the sale of an aggregate of 6,900,000 shares of our common stock under an underwritten public offering. Net proceeds from the offering were approximately \$74.4 million after deducting underwriting discounts and commissions, and offering expenses payable by us.

In January 2017, we entered into an Equity Distribution Agreement, or ATM, with Citigroup Global Markets, Inc., or the Sales Agent, under which we could sell common stock through our Sales Agent. Sales of the shares under the ATM were made in transactions that are deemed to be "at-the-market" equity offerings as defined in Rule 415 under the Securities Act of 1933, as amended, including sales made by means of ordinary brokers' transactions, including on the Nasdaq Stock Market. During the period from February through April 2017, we sold 489,023 shares of our common stock at an average market price of \$15.05 per share under the ATM for aggregate net proceeds of approximately \$7.0 million after deducting commissions and expenses.



## Equity Compensation Plans

In June 2017, our stockholders approved our 2017 Long-Term Incentive Plan, or 2017 LTIP. Upon such approval, our 2013 Long-Term Incentive Plan, or 2013 LTIP, was terminated. Notwithstanding such termination or the previous termination of our 2012 Long-Term Incentive Plan, 2009 Long-Term Incentive Plan, and 2006 Long-Term Incentive Plan, as amended, or, together with the 2013 LTIP, the Prior Plans, all outstanding awards under the Prior Plans continue to be governed under the terms of the Prior Plans. In June 2018, our stockholders approved amendment and restatement of our 2017 Long-Term Incentive Plan, to, among other things, increase the number of shares authorized for issuance under the 2017 LTIP. The number of shares of common stock authorized for issuance under the 2017 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 2017 LTIP.

The aggregate number of shares of our common stock that initially may be issued pursuant to stock awards granted under the 2017 LTIP is 6,958,560 shares, less 1 share for every share that was subject to an option or stock appreciation right granted under the 2017 Plan and 1.9 shares for every 1 share that share that was subject to an award other than an option or stock appreciation right granted under the 2017 LTIP after March 31, 2018. Shares issued pursuant to the exercise of stock options and stock appreciation rights granted under the 2017 LTIP reduce the available number of shares by 1 share for every share issued while awards other than stock options and stock appreciation rights granted under the 2017 LTIP reduce the available number of shares by 1.9 shares for every share issued.

Shares under the 2017 LTIP may be granted as incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards and performance awards. Performance awards may be based on the achievement of operational, financial, research and development, collaboration and license arrangements and other performance metrics provided under the 2017 LTIP, such as total stockholder return, revenue, research, development and regulatory achievements and strategic and operational initiatives.

A total of 3,024,775 shares of our common stock were reserved for future issuance at December 31, 2019, pursuant to our Equity Compensation Plans.

Stock options granted under the 2017 LTIP generally vest over four years with 25% of the shares subject to each option vesting on the first anniversary of the grant date and the remainder of the shares vesting monthly over the following three years in equal installments and, to the extent vested, 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 2017 LTIP prohibits option and stock appreciation right repricings (other than to reflect stock splits, spin-offs or certain other corporate events) without stockholder approval.

The following table summarizes our stock option activity under the Prior Plans and the 2017 LTIP, or collectively, our Equity Compensation Plans, for the year ended December 31, 2019, 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, 2018	6,541	\$ 28.83		
Granted	3,070	\$ 44.53		
Exercised	(626)	\$ 24.27		
Forfeited/cancelled/expired	(450)	\$ 38.37		
Outstanding at December 31, 2019	<u>8,535</u>	\$ 34.31	5.08	\$ 104,380
Vested and expected to vest at December 31, 2019	<u>8,535</u>	\$ 34.31	5.08	\$ 104,380
Vested and exercisable at December 31, 2019	<u>3,194</u>	\$ 26.37	4.18	\$ 63,866

The aggregate intrinsic value in the above table is calculated as the difference between the closing price of our common stock at December 31, 2019, of \$45.42 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, 2019, 2018, and 2017, was \$17.2 million, \$7.1 million, and \$2.8 million, respectively. During the year ended December 31, 2019, cash of \$15.2 million was received from stock option exercises. 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 on our deferred tax assets.

In January 2019, a total of 297,000 target Performance-Based Restricted Stock Units, or PRSUs, were granted to employees in a company-wide grant. The PRSUs vest upon the closing price of our common stock, or the Closing Price, reaching certain price thresholds during the three-year performance period beginning January 4, 2019, and ending January 3, 2022, or the Performance Period, and the participant's subsequent satisfaction of a continuing service requirement of generally 90 calendar days. If, on five consecutive trading days or ten non-consecutive trading days during the Performance Period, the Closing Price equals or exceeds \$60.00, \$67.50 or \$75.00, and the participant thereafter satisfies a continuing service requirement, then the PRSUs are deemed vested at 50%, 100% or 200%, respectively, of the participant's respective target PRSU amount. The shares may be issued following achievement of each price threshold, and the maximum number of common shares that may be issued pursuant to each PRSU grant equals 200% of the number of PRSUs granted. As these awards contain a market condition, we used a Monte Carlo simulation model to estimate the grant-date fair value, which totaled \$18.1 million. The grant-date fair value is recognized as compensation expense over the requisite service period of approximately 1.2 years which was derived from the Monte Carlo simulation; no compensation expense is recognized for service not provided in case of separation from the Company. There is no adjustment of compensation expense recognized for service performed regardless of the number of PRSUs, if any, that ultimately vest. The \$60.00 market condition threshold was achieved in the third quarter of 2019. As a result, a total of 140,900 shares were issued to employees upon the satisfaction of the continuing service requirement.

In March 2015, we granted our executive officers TSR PRSU awards. The TSR PRSUs could be earned and converted into outstanding shares of our common stock based on the total stock return, or TSR, of our common stock relative to the TSR over a three-year performance period beginning March 1 of the year granted of the Nasdaq Biotechnology Index. In March 2018, 32,322 shares were issued to the holders of the remaining TSR PRSUs based on the TSR of our common stock relative to the TSR Nasdaq Biotechnology Index over the three-year performance period.

### Employee Stock Purchase Plan

In June 2015, our stockholders approved our 2009 Employee Stock Purchase Plan, as amended, or 2009 ESPP. Under the 2009 ESPP substantially all employees could choose to have up to 15% of their annual compensation withheld to purchase up to 625 shares of our common stock per purchase period, subject to certain limitations. The shares of our common stock could be purchased over an offering period with a maximum duration of 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. Under applicable accounting guidance, the 2009 ESPP was considered a compensatory plan. In June 2017, the 2009 ESPP was terminated.

In June 2019, our stockholders approved our 2019 Employee Stock Purchase Plan, or 2019 ESPP. Under the 2019 ESPP substantially all employees can elect to have up to 15% of their annual compensation withheld to purchase up to 2,000 shares of our common stock per purchase period, subject to certain limitations. The shares of our common stock can be purchased over an offering period with a maximum duration of 12 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 six-month purchase period. Under applicable accounting guidance, the 2019 ESPP is considered a compensatory plan.

During the years ended December 31, 2017, a total of 2,236 shares, respectively, were purchased by our employees under the 2009 ESPP. There were no purchases under the 2019 ESPP in 2019. The amount of compensation expense associated with the 2009 ESPP and 2019 ESPP for the years ended December 31, 2019, 2018, and 2017 was immaterial.

### 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 stock options, options to purchase stock granted under our employee stock purchase plan, RSUs, and 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 presented:

	Years ended December 31,		
	2019	2018	2017
Risk-free interest rate	2.3%	2.6%	1.9%
Dividend yield	—%	—%	—%
Expected volatility	64%	63%	69%
Expected life (years)	4.47	4.58	4.58
Weighted-average estimated fair value per share of stock options granted	\$ 23.47	\$ 20.01	\$ 9.17

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

	Years ended December 31,		
	2019	2018	2017
Research and development	\$ 27,361	\$ 8,385	\$ 1,945
General and administrative	25,686	11,158	5,925
Discontinued operations	—	11	120
Total share-based compensation expense	\$ 53,047	\$ 19,554	\$ 7,990
Impact on net loss per share, basic	\$ 1.07	\$ 0.42	\$ 0.24
Impact on net loss per share, diluted	\$ 1.03	\$ 0.42	\$ 0.24

The table below sets forth our total unrecognized estimated compensation expense at December 31, 2019, by type of award and the weighted-average remaining requisite service period over which such expense is expected to be recognized:

	Unrecognized Expense (in thousands)	Remaining Weighted-Average Recognition Period (in years)
Unvested stock options	\$ 95,703	2.62
PRSUs	1,750	0.21
RSUs	613	0.57

## 8. Collaborations and License Agreements

We have collaborations or license agreements with the following companies: United Therapeutics Corporation, or United Therapeutics, Everest Medicines Limited, Eisai Co., Ltd. and Eisai Inc., or collectively, Eisai, and Boehringer Ingelheim International GmbH, or Boehringer Ingelheim.

In the following table, revenue is disaggregated by major customers, timing of revenue recognition and revenue classification, in thousands:

Customers	Year ended December 31,	
	2019	2018
United Therapeutics	\$ 800,000	\$ —
Everest	5,000	2,000
Eisai	(1,077)	8,070
Other	2,508	10,407
Total	\$ 806,431	\$ 20,477
<b>Timing of revenue recognition</b>		
Revenue recognized at a point in time	\$ 803,580	\$ 14,092
Revenue recognized over time	2,851	6,385
Total	\$ 806,431	\$ 20,477
<b>Classification</b>		
Revenue from continuing operations	\$ 806,431	\$ 17,970
Revenue reported under discontinued operations	—	2,507
Total	\$ 806,431	\$ 20,477

### United Therapeutics Corporation

In November 2018, we entered into an exclusive license agreement with United Therapeutics. Under this agreement, we granted United Therapeutics an exclusive, worldwide, royalty-bearing license to develop, manufacture and commercialize ralinepag in any formulation. This transaction was completed in January 2019. United Therapeutics is responsible for all development, manufacturing and commercialization of the licensed products globally. In connection with this transaction we incurred transaction fees of

approximately \$17.0 million, of which \$14.6 million was incurred in 2019 and \$2.4 million was incurred in 2018, and are presented as transaction costs in the accompanying consolidated statement of operations.

We received an upfront payment of \$800.0 million under the agreement in the first quarter of 2019. We are also eligible to receive up to an aggregate of \$400.0 million in regulatory milestone payments related to ralinepag, consisting of a payment of \$150.0 million upon first marketing approval of an oral formulation of ralinepag in a major non-U.S. market, and a payment of \$250.0 million upon U.S. marketing approval of an inhaled formulation of ralinepag to treat pulmonary arterial hypertension, as well as low double-digit, tiered royalties on net sales of ralinepag products, subject to certain adjustments for third party license payments.

The promised goods and services under this agreement are accounted for as a single performance obligation consisting of a research, development and commercialization license. Our performance obligation under this agreement was satisfied upon the closing of the transaction in January 2019, and accordingly, the estimated total transaction price of the agreement of \$800.0 million was recognized as revenue at the commencement of this agreement in 2019. The future potential milestone payments were excluded from the estimated total transaction price as they are considered constrained. Under the royalty exception in ASC 606 for licensed intellectual property, we do not include any variable amounts related to sales-based royalties in the transaction price until the later of when the sales occur or the performance obligation is satisfied or partially satisfied.

### **Everest**

In December 2017, we and Everest entered into an exclusive agreement, or the Everest Agreement, to conduct joint development for the ralinepag and etrasimod programs. Under the Everest Agreement, we granted Everest an exclusive, royalty-bearing license to develop and commercialize ralinepag (in any formulation) and etrasimod (in oral formulations), in mainland China, Taiwan, Hong Kong, Macau and South Korea, or collectively, the Territories. Everest is generally responsible for development and commercialization of the licensed products in the Territories, and may participate in the portion of our global clinical trials that is conducted in the Territories. In January 2019, we and Everest amended the Everest Agreement by entering into two separate agreements, one for each development program with the terms identical to the original Everest Agreement. Under the agreement with United Therapeutics described above, we assigned all our rights and obligations with respect to the ralinepag program under the Everest Agreement, to United Therapeutics.

In connection with entering into the Everest Agreement, we received from Everest an upfront payment of \$12.0 million in December 2017.

In the fourth quarter of 2018, the Chinese National Medical Products Administration accepted the initial clinical trial applications for etrasimod and the oral formulation of ralinepag. Under the terms of the Everest Agreement, we recognized revenue of \$2.0 million from the achievement of these milestones.

In October 2019, Everest announced that the first subject has been dosed in a Phase 3 trial evaluating etrasimod in development for the treatment of UC in Greater China and South Korea. Everest paid us a \$5.0 million milestone payment due from this achievement, which we recognized as revenue in the fourth quarter of 2019.

We are also eligible to receive up to an aggregate of \$110.0 million in success milestones in case of full commercial success of etrasimod products. We are also eligible to receive tiered royalties on net sales of etrasimod products in the Territories.

The promised goods and services under the Everest Agreement are accounted for as a single performance obligation consisting of a development and commercialization license. The amount of the upfront payment was recognized as revenue in December 2017 as we determined (i) that the license is a deliverable with standalone value to Everest and (ii) the upfront payment represents consideration to be allocated to the delivered license. As of December 31, 2019, all remaining future potential milestone payments were excluded from the estimated total transaction price as they are considered constrained.

For the years ended December 31, 2019, 2018, and 2017, we recognized revenues of \$5.0 million, \$2.0 million and \$12.0 million, respectively from the Everest Agreement.

### **Eisai**

In July 2010, we granted Eisai exclusive commercialization rights for lorcaserin (marketed as BELVIQ/BELVIQ XR) solely in the United States and its territories and possessions. In May 2012, we and Eisai entered into the first amended and restated agreement, which expanded Eisai's exclusive commercialization rights to include most of North and South America. In November 2013, we and Eisai entered into the second amended and restated agreement, or Second Amended Agreement, which expanded Eisai's exclusive

commercialization rights for lorcaserin to all countries in the world, except for South Korea, Taiwan, Australia, New Zealand and Israel.

In December 2016, we and Eisai amended and restated the terms of marketing and supply agreement for lorcaserin with Eisai by entering into a Transaction Agreement and a Supply Agreement (collectively, the Eisai Agreement) with Eisai. Under the Transaction Agreement, Eisai acquired an exclusive royalty-bearing license or transfer of intellectual property to global commercialization and manufacturing rights to lorcaserin, including in the territories retained by us under the prior agreement, with control over global development and commercialization decisions. Eisai is responsible for all lorcaserin development expenses in the future. We also assigned to Eisai our rights under the commercial lorcaserin distribution agreements with Ildong Pharmaceutical Co., Ltd., or Ildong, for South Korea; CY Biotech Company Limited, or CYB, for Taiwan; and Teva Pharmaceuticals Ltd.'s Israeli subsidiary, Abic Marketing Limited, or Teva, for Israel.

Under the Supply Agreement, Eisai paid us for finished drug product plus monthly manufacturing support payments through March 2018 totaling CHF 8.7 million.

Until March 31, 2018, when we sold the Manufacturing Operations, including the assignment of the Supply Agreement, to Siegfried (see Note 5), we manufactured lorcaserin at our manufacturing facility in Zofingen, Switzerland. Revenues earned for (i) lorcaserin sold by us to Eisai under the manufacturing and supply commitment within the Supply Agreement and (ii) the manufacturing support payments are classified within discontinued operations as part of the Manufacturing Operations in the consolidated statements of operations (see Note 5). All other revenues earned under the Transaction Agreement, such as royalties, are classified within continuing operations in the consolidated statements of operations.

#### *Royalty payments.*

Pursuant to the Transaction Agreement, we are eligible to receive tiered royalty payments from Eisai starting at 9.5% on the global net sales of lorcaserin.

#### *Upfront payments.*

Prior to the Transaction Agreement, we received from Eisai total upfront payments of \$115.0 million under prior lorcaserin collaboration agreements and \$7.5 million from the prior commercial lorcaserin distribution agreements with Ildong and CYB described below, and Teva. Revenues from these upfront payments were previously deferred, as we determined that the exclusive rights did not have standalone value without our ongoing development and regulatory activities. Accordingly, these payments were recognized ratably as revenue over the periods in which we expected the services to be rendered. The Transaction Agreement effectively eliminated our obligation to continue performing the development and regulatory activities required in the original agreement.

In total, prior to the Transaction Agreement, we received a total of \$102.1 million in milestone payments from Eisai, and other lorcaserin distributors. These payments were recognized as revenue upon the achievement of the milestones.

#### *Accounting for Eisai Agreement under ASC 606.*

Upon implementation of ASC 606 on January 1, 2018, we applied a practical expedient for contract modifications applicable to contracts that were modified before the implementation date. The promised goods and services under the Eisai Agreement were assessed in combination with promised goods and services under our previous agreements with Eisai and commercial lorcaserin distribution agreements with Ildong, CYB, and Teva. The total estimated transaction price of these contracts at the implementation date was \$344.4 million, which included previously received upfront payments, milestone payments, proceeds from net products sales, reimbursement of development expenses, reimbursement of patent expenses, manufacturing support payments received and expected to be received under the Supply Agreement, proceeds from the sale of on-hand inventory of bulk lorcaserin and the precursor material, royalty payments received through December 31, 2017, and estimated future royalty payments related to intellectual property sold to Eisai. The future potential milestone payments were excluded from the estimated total transaction price as they are considered constrained due to our assessment of the probability of a significant revenue reversal. The future royalties related to licensed intellectual property were excluded from the estimated total transaction price under the royalty exception in ASC 606. The estimated future royalties that relate to intellectual property sold to Eisai do not qualify for the royalty exception in ASC 606 and were included in the estimated total transaction price.

The estimated total transaction price was allocated between satisfied and unsatisfied performance obligations based on the relative standalone selling prices of the identified performance obligations. The remaining manufacturing and supply obligations under the Supply Agreement was the only unsatisfied performance obligation. As a result of this allocation, on January 1, 2018, we reduced the balance of deferred revenues associated with the Eisai Agreement at the implementation date by \$25.5 million, recognized a contract asset of \$6.1 million related to future manufacturing support payments under the Supply Agreement and recognized a contract

asset of \$4.1 million related to estimated future royalty payments from intellectual property sold to Eisai under the Transaction Agreement. In connection with the sale of the Manufacturing Operations on March 31, 2018, we derecognized the remaining portion of the contract asset associated with the Supply Agreement. During 2018, we adjusted our estimate of future royalty payments from intellectual property sold to Eisai under the Transaction Agreement based on the CVOT study results reported by Eisai and our estimate of the qualifying sales of BELVIQ in the future years and recorded associated royalty revenue and an increase to the contract asset of \$3.3 million. As of December 31, 2018, the contract asset balance was \$6.0 million. Subsequent to year end, Eisai agreed to voluntarily withdraw BELVIQ products from the U.S. market based on a change in the FDA's risk-benefit assessment of BELVIQ, and as requested by the FDA. As a result, we revised our estimate of future royalties and recorded a \$3.7 million reduction to our contract asset as of December 31, 2019.

Based on the bill-and-hold accounting guidance in ASC 606, effective January 1, 2018, we derecognized \$3.6 million of inventory of bulk lorcaseerin and the precursor material previously sold to Eisai for which the revenue recognition criteria were met on the implementation date under ASC 606.

For the years ended December 31, 2019, 2018 and 2017, we recorded royalty revenues of \$(1.1) million, \$6.6 million and \$1.7 million, respectively related to the Transaction Agreement. For the year ended December 31, 2018 and 2017, we recognized revenue of \$1.5 million and \$15.9 million, respectively, related to the Supply Agreement (classified under discontinued operations), all of which was recorded during the first quarter of 2018 and primarily consisting of net product sales and other collaboration revenue.

*Accounting for Eisai Agreement under previous revenue recognition policy.*

The total arrangement consideration of \$115.6 million primarily consists of (i) the December 28, 2016, balances of deferred revenues from the upfront payments received under the prior Eisai agreements and the distribution agreements with other distributors; (ii) the \$10.0 million payment received from Eisai on December 28, 2016; and (iii) the product purchase payments and manufacturing support payments we expect to receive from Eisai for the initial two-year manufacturing and supply commitment period.

All of the deliverables were determined to have standalone value and to meet the criteria to be accounted for as separate units of accounting. Factors considered in the determination included, among other things, for the license, the manufacturing experience and capabilities of Eisai and their sublicense rights, and for the remaining deliverables the fact that they are not proprietary and can be provided by other vendors. The total arrangement consideration was allocated to the units of accounting, consisting of the License Deliverable, the Inventory Deliverable the Manufacturing and Supply Commitment Deliverable, and on the basis of their relative estimated selling prices.

For the year ended December 31, 2017, we recognized \$6.4 million as revenue of discontinued operations related to this deliverable and \$0.9 million of the carrying value of this inventory as cost of product sales of discontinued operations.

The Manufacturing and Supply Commitment Deliverable was provided over 2017 and 2018 as product was shipped to Eisai until March 31, 2018. For the year ended December 31, 2017, we recognized \$9.5 million as revenue of discontinued operations related to this deliverable.

Under the Eisai Agreement, Eisai is solely responsible for all costs and expenses in connection with further development of lorcaseerin.

**Boehringer Ingelheim International GmbH**

In December 2015, we and Boehringer Ingelheim entered into a collaboration and license agreement, or Boehringer Ingelheim Agreement, under which we and Boehringer Ingelheim conduct joint research to identify drug candidates targeting an undisclosed G-protein-coupled receptor, or GPCR, that belongs to the group of orphan central nervous system receptors. Under Boehringer Ingelheim Agreement, we granted Boehringer Ingelheim exclusive rights to our internally discovered, novel compounds and intellectual property for an orphan CNS receptor. The agreement grants Boehringer Ingelheim exclusive worldwide rights to develop, manufacture and commercialize products resulting from the collaboration.

In December 2018 and October 2019, we earned a milestone payment of \$3.5 million and \$1.5 million, respectively upon Boehringer Ingelheim's initiation of preclinical development of a first and an additional compound.

We are also eligible to receive up to an aggregate of \$246.0 million (of which the first \$7.0 million is also payable to Beacon – see Note 12) in additional success milestone payments in case of full commercial success of multiple drug products.

The promised goods and services under the Boehringer Ingelheim Agreement are accounted for as a single combined performance obligation consisting of a research license, a development and commercialization license and research services. Our research services performance obligation under the original term of the Boehringer Ingelheim Agreement was completely satisfied as of January 2018, and accordingly the estimated total transaction price of the Boehringer Ingelheim Agreement under the original contractual term was fully recognized as revenue over the period from January 2016 through January 2018. We recognize revenue for the combined performance obligation based on the amount of incurred development expenses reimbursed by the customer as a percentage of total expected reimbursable expenses associated with the contract. As of December 31, 2019, all future potential milestone payments were excluded from the estimated total transaction price as they are considered constrained.

For the years ended December 31, 2019, 2018, and 2017, we recognized revenues of \$1.7 million, \$4.4 million and \$5.1 million, respectively from the Boehringer Ingelheim Agreement.

#### **Outpost Medicine LLC**

In April 2018, we and Outpost Medicine entered into a license agreement, or Outpost Agreement, under which Outpost Medicine has an exclusive right to advance an undisclosed, preclinical compound with potential utility in treating genitourinary disorders.

Under the Outpost Agreement, we received an upfront payment of \$3.0 million, of which \$1.5 million was in the form of an equity interest in Outpost Medicine. In September 2019, we earned a milestone payment of \$0.5 million upon Outpost's initiation of Phase 1 clinical trials.

The promised goods and services under the Outpost Agreement are accounted for as a single performance obligation consisting of a research, development and commercialization license. Our performance obligation under the Outpost Agreement was fully satisfied at the inception of the Outpost Agreement and, accordingly, the estimated total transaction price of the Outpost Agreement was fully recognized as revenue in the second quarter of 2018. As of December 31, 2019, all future potential milestone payments were excluded from the estimated total transaction price as they are considered constrained.

For the years ended December 31, 2019, 2018 and 2017, we recognized revenues of \$0.5 million, \$2.8 million and \$0.2 million, respectively from the Outpost Agreement. Subsequent to year end, the Outpost Agreement was terminated.

#### **Axovant Sciences GmbH**

In 2015, we entered into a development, marketing and supply agreement with Roivant Sciences Ltd., which subsequently assigned the exclusive rights to develop and commercialize nelotanserin to its subsidiary, Axovant. Under this agreement, Axovant had exclusive worldwide rights to develop and commercialize nelotanserin, subject to regulatory approval. We also provided certain services and manufactured and sold nelotanserin to Axovant. We refer to this agreement as the Axovant Agreement.

The promised goods and services under the Axovant Agreement were accounted for as two separate performance obligations: (i) a combined performance obligation consisting of commercialization rights and development and regulatory services and (ii) a manufacturing and supply commitment. We recognized revenue for the combined performance obligation consisting of commercialization rights and development and regulatory services based on the amount of incurred development expenses reimbursed by the customer as a percentage of total expected reimbursable expenses associated with the contract. In December 2018, Axovant announced negative results of an exploratory Phase 2 clinical study and a discontinuation of further clinical development activities under the nelotanserin program. As a result, we revised our estimate of the total transaction price as of December 31, 2018, based on our assessment that we will not perform any research and development services for Axovant in the future and concluded that all our performance obligations have been satisfied. As of December 31, 2018, all future potential purchase price adjustment payments and milestone payments were excluded from the estimated total transaction price as they were considered constrained.

For the years ended December 31, 2018, and 2017, and we recognized revenues of \$2.2 million, and \$2.2 million, respectively, from the Axovant Agreement. No revenue was recognized under this agreement for the year ended December 31, 2019. In the fourth quarter of 2019, the Axovant Agreement was terminated.

## 9. Income Taxes

The following table summarizes our income (loss) attributable to stockholders of Arena before provision (benefit) for income taxes by region for the years presented, in thousands:

	Years ended December 31,		
	2019	2018	2017
United States	\$ 298,315	\$ (138,522)	\$ (62,109)
Foreign	209,573	(1,142)	(29,298)
Total income (loss) attributable to stockholders of Arena before income taxes	\$ 507,888	\$ (139,664)	\$ (91,407)

For the year ended December 31, 2019, we have recorded an expense for income taxes for the usage of the deferred tax assets that were set up in 2018 related to the taxable gain pursuant to the United Therapeutics transaction. We recorded a benefit for income taxes for the year ended December 31, 2018, due to the estimated taxable gain pursuant to the United Therapeutics transaction. We did not record a benefit for income taxes for the year ended December 31, 2017, because we had a full valuation allowance.

Our effective income tax rate differs from the statutory federal rate of 21% for 2019 and 2018, and 34% for 2017 due to the following, in thousands:

	Years ended December 31,		
	2019	2018	2017
Benefit for income taxes at statutory federal rate	\$ 106,657	\$ (29,090)	\$ (32,140)
Change in valuation allowance due to tax reform	—	—	96,333
Change in federal and foreign valuation allowance	34,712	(76,336)	(68,604)
Permanent differences and other	601	1,963	(782)
Deferred adjustment related to foreign net operating losses	15,133	—	—
Capital loss on foreign subsidiary liquidation	(43,685)	—	—
Share-based compensation expense	1,624	889	7,071
Foreign losses at lower effective rates	21	257	1,428
Research and development and Orphan Drug credits	(4,730)	(7,948)	(3,306)
Benefit for income taxes	\$ 110,333	\$ (110,265)	\$ —

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

	December 31,	
	2019	2018
Deferred tax assets:		
Federal and California NOL carryforwards	\$ 140,762	\$ 210,853
Federal and California research and development credit carryforwards	73,956	69,221
Foreign NOL carryforwards	—	15,131
Share-based compensation expense	11,010	6,124
Depreciation	3,183	2,914
Lease liability	2,359	—
Other, net	354	784
Total deferred tax assets	231,624	305,027
Deferred tax liabilities:		
Right-of-use assets	(2,218)	—
Total deferred tax liabilities	(2,218)	—
Net deferred tax assets	229,406	305,027
Valuation allowance	(229,406)	(194,694)
Net deferred tax assets	\$ —	\$ 110,333

A valuation allowance is recorded against a portion of our deferred tax assets, as realization of a portion of these assets is not more-likely-than-not. The realization of our deferred tax assets is dependent upon future taxable income. In January 2019, a taxable income generating event, the transaction pursuant to the United Therapeutics Agreement created taxable income, resulting in the realization of a portion of our deferred tax assets. A portion of the valuation allowance in 2018 was released for the anticipated taxable



income generating event. We utilized net operating losses to offset taxable income in 2019. 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 further reduce or remove the valuation allowance. The valuation allowance increased by \$34.7 million from December 31, 2018, to December 31, 2019.

At December 31, 2019, we had federal NOL carryforwards of \$539.3 million that will begin to expire in 2029 unless previously utilized. At the same date, we had California NOL carryforwards of \$393.9 million, which begin expiring in 2028. Net operating losses generated after December 31, 2017 carry forward indefinitely. At December 31, 2019, we had \$151.4 million of net operating losses with no expiration. Net operating losses generated in 2018 are subject to an 80% limitation. At December 31, 2019, we also had federal and California research and development tax credit carryforwards, net of reserves, of \$38.7 million and \$25.1 million, respectively. At December 31, 2019, we had a Federal Orphan Drug Credit carryforward, net of reserves, of \$15.0 million. Federal credit carryforwards will begin to expire after 2026 unless previously utilized. The California research and development credit carries forward indefinitely.

Sections 382 and 383 of the 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 2019 and did not identify any ownership changes that limit our utilization of tax attribute carryforwards since 2010. Pursuant to IRC Section 382 and 383, use of our net operating loss and research and development income tax credit carryforwards may be limited in the event of cumulative changes in ownership subsequent to 2019 of more than 50% within a three-year period.

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.

The following table reconciles the beginning and ending amount of unrecognized tax benefits for the years presented, in thousands:

	Years ended December 31,		
	2019	2018	2017
Gross unrecognized tax benefits at the beginning of the year	\$ 9,033	\$ 7,762	\$ 5,906
Additions from tax positions taken in the current year	1,017	1,269	1,133
Additions from tax positions taken in prior years	—	2	723
Reductions from tax positions taken in prior years	(96)	—	—
Tax settlements	—	—	—
Gross unrecognized tax benefits at end of the year	<u>\$ 9,954</u>	<u>\$ 9,033</u>	<u>\$ 7,762</u>

Of our total unrecognized tax benefits at December 31, 2019, \$8.6 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.

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, 2019, or 2018, and did not recognize any interest and/or penalties in our consolidated statements of operations and comprehensive income (loss) for the years ended December 31, 2019, 2018, and 2017.

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.

## 10. Legal Proceedings

Beginning in September 2010, a number of complaints were filed in the US District Court for the Southern District of California, or District Court, against us and certain of our current and former employees and directors on behalf of certain purchasers of our common stock. The complaints were 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 sought unspecified monetary damages and other relief. In August 2011, the District Court consolidated the actions and appointed a lead plaintiff and lead counsel. In November 2017, we and the Lead Plaintiff signed a stipulation and agreement of settlement, or Stipulation, to resolve the consolidated class action. Under the terms of the Stipulation, and in exchange for a release of all claims

by class members and a dismissal of the consolidated class action with prejudice, we have agreed that (i) our insurers would pay class members and their attorneys a total of approximately \$12.025 million and (ii) Arena would pay class members and their attorneys approximately \$11.975 million in either shares of our common stock or cash at our election. On November 30, 2017, the District Court preliminary approved the settlement and the form of notice to potential class members of the proposed settlement and the procedure by which they can become class members. On March 8, 2018, the lead plaintiff filed motions for final approval of the settlement, the plan of allocation and award of attorney fees. On April 12, 2018, the District Court entered its final approval order approving the settlement and the plan of allocation and request for attorneys' fees and expense. We recognized \$11.975 million of net expense for the portion of the settlement that we agreed to pay in either common stock or cash in the consolidated statements of operations for the year ended December 31, 2017, and \$24.0 million as a current liability in the consolidated balance sheet as of December 31, 2017 for the gross settlement liability, with a corresponding \$12.025 million insurance recovery receivable. In the second quarter of 2018, we and our insurer made settlement payments in cash to the class members and their attorneys to settle our liability under the Stipulation.

We are not currently subject to any material legal proceedings

## 11. Quarterly Financial Data (Unaudited)

The following tables present selected quarterly financial data for the years presented, in thousands, except per share data:

2019	Quarter ended December 31	Quarter ended September 30	Quarter ended June 30	Quarter ended March 31
Revenues	\$ 3,002	\$ 1,350	\$ 1,022	\$ 801,057
Operating costs and expenses	96,875	80,685	69,578	76,547
Net income (loss)	(88,311)	(72,865)	(61,403)	620,134
Net income (loss) per share, basic	(1.76)	(1.46)	(1.24)	12.53
Net income (loss) per share, diluted	(1.76)	(1.46)	(1.24)	12.10

2018	Quarter ended December 31	Quarter ended September 30	Quarter ended June 30	Quarter ended March 31
Revenues	\$ 8,648	\$ 3,573	\$ 3,994	\$ 1,755
Operating costs and expenses	53,292	39,577	37,160	32,724
Income (loss) from continuing operations	68,711	(34,314)	(31,833)	(31,133)
Loss from discontinued operations	—	—	—	(830)
Net income (loss)	68,711	(34,314)	(31,833)	(31,963)
Net income (loss) per share, basic				
Continuing operations	\$ 1.39	\$ (0.70)	\$ (0.65)	\$ (0.78)
Discontinued operations	—	—	—	(0.02)
	<u>\$ 1.39</u>	<u>\$ (0.70)</u>	<u>\$ (0.65)</u>	<u>\$ (0.80)</u>
Net income (loss) per share, diluted				
Continuing operations	\$ 1.35	\$ (0.70)	\$ (0.65)	\$ (0.78)
Discontinued operations	—	—	—	(0.02)
	<u>\$ 1.35</u>	<u>\$ (0.70)</u>	<u>\$ (0.65)</u>	<u>\$ (0.80)</u>

## 12. Beacon Discovery, Inc.

In September 2016, we entered into a series of agreements with Beacon, a privately held drug discovery incubator which focuses on identifying and advancing molecules targeting GPCRs. Beacon was founded in 2016 by several of our former employees.

We entered into an agreement, or License and Collaboration Agreement, with Beacon, pursuant to which we transferred certain equipment to Beacon and granted Beacon a non-exclusive, non-assignable and non-sublicensable license to certain database information relating to compounds, receptors and pharmacology, and transferred certain equipment to Beacon. Beacon will seek to engage global partners to facilitate discovery and development. Beacon has agreed to assign to us any intellectual property relating to our existing research and development programs developed in the course of performing research for us, and grant us a non-exclusive license to any intellectual property developed outside the course of performing work for us that is reasonably necessary or useful for developing or commercializing the products under our research and development programs. We are also entitled to rights of negotiation and rights of first refusal to potentially obtain licenses to compounds discovered and developed by Beacon. In addition, we are entitled to receive (i) a percentage of any revenue received by Beacon on or after the second anniversary of the effective date of

the agreement from any third party pursuant to a third-party license, including upfront payments, milestone payments and royalties; (ii) single-digit royalties on the aggregate net sales of any related products sold by Beacon and its affiliates; and (iii) in the event that Beacon is sold, a percentage of the consideration for such sale transaction.

We entered a services agreement with Beacon, or Master Services Agreement, pursuant to which Beacon performs certain research services for us.

We also entered into a separate services agreement with Beacon, or Beacon Services Agreement, pursuant to which Beacon performed our research obligations under our agreement with Boehringer Ingelheim. In consideration for performing these research obligations, Beacon is entitled to receive the applicable FTE payments that are paid to us by Boehringer Ingelheim for the research services and certain milestone payments.

We also entered into a sublease agreement, or Sublease, with Beacon, pursuant to which we sublease approximately 30,000 square feet of laboratory, office and meeting room space to Beacon until May 2027.

As Beacon's equity investment at risk in September 2016 was not sufficient to permit Beacon to finance its activities without subordinated financial support, Beacon was considered a variable interest entity in which we held a significant variable interest pursuant to the License and Collaboration Agreement. We do not own any equity interest in Beacon; however, as the agreements described above provided us the controlling financial interest in Beacon until December 2017, we consolidated Beacon's balances and activity within our consolidated financial statements until December 2017 as we were determined to be the primary beneficiary of Beacon. Pursuant to a contract Beacon entered into with a third party in December 2017, we determined we no longer held the controlling financial interest as of that date and, therefore, deconsolidated Beacon from our consolidated financial statements as we were no longer deemed to be the primary beneficiary. Our consolidated financial statements for the year ended December 31, 2017, include Beacon's results of operations and cash flows until the December 2017 deconsolidation. Beacon's net and comprehensive loss of \$1.3 million for the year ended December 31, 2017 is presented as net loss attributable to noncontrolling interest in consolidated variable interest entity in our consolidated statement of operations and comprehensive loss as we do not own any equity interest in Beacon.

In January 2020, we entered into a new multi-year strategic Collaboration and License Agreement with Beacon, aimed at building novel medicines across a range of GPCR targets believed to play a role in immune and inflammatory diseases. Under the terms of this agreement Beacon is responsible for early drug discovery activities and we will be responsible for any potential future development and, ultimately, commercialization activities. We are required to pay to Beacon research initiation fees, make quarterly research funding payments for the duration of Beacon's research activities as well as research, development and regulatory milestone payments depending on the future research and development progress. We are also obligated to pay Beacon tiered royalties on net sales of low single digits levels.

### **13. Subsequent Events**

See Note 12 regarding the collaboration and license agreement with Beacon, which was executed in January 2020.

### **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**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

As of December 31, 2019, we conducted an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, 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 Chief Executive Officer and Chief 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.

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

Our management is also 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 Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the *Internal Control—Integrated Framework* (2013 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, 2019.

The registered public accounting firm that audited our financial statements as of and for the year ended December 31, 2019, 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**

An evaluation was also performed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of any changes in our internal control over financial reporting that occurred during our last fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. That evaluation did not identify any change in our internal control over financial reporting during the fourth quarter of the year ended December 31, 2019 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

To the Stockholders and Board of Directors  
Arena Pharmaceuticals, Inc.:

*Opinion on Internal Control Over Financial Reporting*

We have audited Arena Pharmaceuticals, Inc. and subsidiaries' (the Company) internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2019 and 2018, the related consolidated statements of operations and comprehensive income (loss), equity, and cash flows for each of the years in the three-year period ended December 31, 2019, and the related notes (collectively, the consolidated financial statements), and our report dated February 27, 2020 expressed an unqualified opinion on those consolidated financial statements.

*Basis for Opinion*

The Company'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 the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. 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 of internal control over financial reporting 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.

*Definition and Limitations of Internal Control Over Financial Reporting*

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.

/s/ KPMG LLP

San Diego, California  
February 27, 2020

## Item 9B. Other Information.

### *Sales Agreement*

On February 27, 2020, we entered into a Sales Agreement (the “Sales Agreement”) with Credit Suisse Securities (USA) LLC, SVB Leerink LLC and Cantor Fitzgerald & Co., as sales agents (collectively, the “Sales Agents”), pursuant to which we may offer and sell up to \$250.0 million of shares of our common stock from time to time through the Sales Agents. Sales of shares of our common stock may be made at market prices by any method deemed to be an “at the market offering” as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended, including, without limitation, sales made directly on or through The Nasdaq Global Select Market or any other existing trading market for our common stock. The shares will be offered and sold only pursuant to an effective shelf registration statement on Form S-3.

We are not obligated to sell any shares under the Sales Agreement. Each of the Sales Agents has agreed to use its commercially reasonable efforts to sell on our behalf all of the shares of common stock requested to be sold by us, consistent with its normal trading and sales practices, on mutually agreed terms among the Sales Agents and us. We will pay the Sales Agents commissions of up to 3.0% of the gross sales price per share sold under the Sales Agreement.

We and the Sales Agents may each terminate the Sales Agreement at any time upon five days’ prior notice.

This summary of the material provisions of the Sales Agreement does not purport to be a complete statement of its terms and conditions.

### *Management Transition*

On February 26, 2020, we announced that Kevin R. Lind, our Executive Vice President and Chief Financial Officer, has been appointed the President and Chief Executive Officer of our wholly owned subsidiary, Arena Neuroscience, Inc. Arena Neuroscience, Inc. was formed in January 2020 to focus on programs and platforms in the area of neuroscience.

On February 26, 2020, we appointed Laurie D. Stelzer as our Executive Vice President and Chief Financial Officer, effective upon her commencing employment with us (the “Commencement Date”), which is expected to occur in March 2020, replacing Mr. Lind in that capacity.

Ms. Stelzer, age 52, currently serves as the Senior Vice President, Chief Financial Officer of Halozyme Therapeutics, Inc. (Nasdaq: HALO). Ms. Stelzer joined Halozyme in June 2015 as Senior Vice President, Chief Financial Officer. Prior to joining Halozyme, Ms. Stelzer served from April 2014 to January 2015 as the Senior Vice President of Finance supporting R&D, Technical Operations and M&A at Shire, Inc., a biopharmaceutical company. Prior to that, she was the Division CFO for the Regenerative Medicine Division and the Head of Investor Relations at Shire from March 2012 to April 2014. Prior to Shire, Ms. Stelzer held positions of increasing responsibility for 15 years at Amgen, Inc., a biopharmaceutical company, including Interim Treasurer, Head of Emerging Markets Expansion, Executive Director of Global Commercial Finance and Head of Global Accounting. Early in her career, Ms. Stelzer held various finance and accounting positions in the real estate and banking industries. Ms. Stelzer serves on the board of directors of Surface Oncology, Inc., an immuno-oncology company. Ms. Stelzer received her MBA from the Anderson School at the University of California, Los Angeles, and a Bachelor of Science in Accounting from Arizona State University.

In connection with her appointment as our Executive Vice President and Chief Financial Officer, we entered into an offer letter agreement with Ms. Stelzer. Pursuant to her offer letter, Ms. Stelzer will be entitled to: (i) an annual base salary of \$480,000; (ii) participation under our Annual Incentive Plan with a target bonus of up to 50% of her then-current base salary; (iii) an option to purchase up to 132,000 shares of our common stock under our Amended and Restated 2017 Long-Term Incentive Plan, as amended, subject to a four-year vesting period; and (iv) PRSUs under our Amended and Restated 2017 Long-Term Incentive Plan, as amended, pursuant to which 6,300 shares will vest if our stock price closes at or above \$67.50 for five consecutive trading days or ten non-consecutive trading days during the performance period, and an aggregate of 12,600 shares will vest if our stock price closes at or above \$75.00 for five consecutive trading days or ten non-consecutive trading days during the performance period, subject to her continuous service with us and the other terms and conditions of the PRSUs. In addition, Ms. Stelzer’s position as Executive Vice President will entitle her to participate under our Amended and Restated Severance Benefit Plan, which is filed as Exhibit 10.20 to this Annual Report on Form 10-K. Ms. Stelzer’s severance period under our Amended and Restated Severance Benefit Plan will be 18 months.

## 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 that person who is granted the waiver and the date of the waiver.

The other information required by this item will be included under the captions “Election of Directors,” “Compensation and Other Information Concerning Executive Officers, Directors and Certain Stockholders” and “Delinquent Section 16(a) Reports” in our definitive proxy statement for the annual meeting of stockholders to be held in June 2020 to be filed with the SEC on or before April 29, 2020, or the Proxy Statement, and is incorporated herein by reference.

### Item 11. Executive Compensation.

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

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

The information required by this item will be included under the captions “Security Ownership of Certain Beneficial Owners and Management” and “Securities Authorized for Issuance Under Equity Compensation Plans” in the Proxy Statement and is incorporated herein by reference.

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

The information required by this item will be included under the captions “Certain Relationships and Related Transactions” and “Election of Directors” in the Proxy Statement and is incorporated herein by reference.

### Item 14. Principal Accounting Fees and Services.

The information required by this item will be included under the captions “Independent Auditors’ Fees” and “Pre-approval Policies and Procedures” in the Proxy Statement and is incorporated herein by reference.

## 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 consolidated financial statements or the notes thereto included in this annual report.

### 3. EXHIBITS

<b>Exhibit No.</b>	<b>Exhibit Description</b>
2.1*	<a href="#">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 current report on Form 8-K filed with the Securities and Exchange Commission on May 8, 2007, Commission File No. 000-31161).</a>
2.2+*	<a href="#">Exclusive License Agreement, dated as of November 15, 2018, by and between Arena and United Therapeutics Corporation (incorporated by reference to Exhibit 2.1 to Arena's current report on Form 8-K filed with the Securities and Exchange Commission on January 25, 2019, Commission File No. 000-31161).</a>
3.1	<a href="#">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).</a>
3.2	<a href="#">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).</a>
3.3	<a href="#">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).</a>
3.4	<a href="#">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).</a>
3.5	<a href="#">Certificate of Amendment No. 4 of the Fifth Amended and Restated Certificate of Incorporation of Arena, as amended (incorporated by reference to Exhibit 3.1 to Arena's current report on Form 8-K filed with the Securities and Exchange Commission on June 15, 2017, Commission File No. 000-31161).</a>
3.6	<a href="#">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 9, 2014, Commission File No. 000-31161).</a>
4.1	Reference is made to Exhibits <a href="#">3.1</a> , <a href="#">3.2</a> , <a href="#">3.3</a> , <a href="#">3.4</a> , <a href="#">3.5</a> and <a href="#">3.6</a>
4.2	<a href="#">Form of common stock certificate (incorporated by reference to Exhibit 4.7 to Arena's registration statement on Form S-8, filed with the Securities and Exchange Commission on June 22, 2017, Commission File No. 333-218905).</a>
4.3	<a href="#">Description of Arena's common stock</a>
10.1**	<a href="#">Form of Indemnification Agreement between Arena and its directors (incorporated by reference to Exhibit 10.1 to Arena's current report on Form 8-K filed with the Securities and Exchange Commission on June 18, 2007, Commission File No. 000-31161).</a>
10.2**	<a href="#">Form of Indemnification Agreement between Arena and its executive officers (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 18, 2007, Commission File No. 000-31161).</a>
10.3**	<a href="#">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 current report on Form 8-K filed with the Securities and Exchange Commission on June 18, 2007, Commission File No. 000-31161).</a>
10.4	<a href="#">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).</a>
10.5	<a href="#">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).</a>



Exhibit No.	Exhibit Description
10.6	<a href="#">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)</a>
10.7	<a href="#">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)</a>
10.8**	<a href="#">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)</a>
10.9**	<a href="#">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)</a>
10.10**	<a href="#">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)</a>
10.11**	<a href="#">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)</a>
10.12**	<a href="#">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 current report on Form 8-K filed with the Securities and Exchange Commission on June 20, 2012, Commission File No. 000-31161)</a>
10.13**	<a href="#">Arena's 2013 Long-Term Incentive Plan, as amended (incorporated by reference to Exhibit 10.3 to Arena's quarterly report on Form 10-Q for the quarter ended March 31, 2017, filed with the Securities and Exchange Commission on May 9, 2017, Commission File No. 000-31161)</a>
10.14**	<a href="#">Form of Stock Option Grant Agreement for Employees or Consultants under the Arena 2013 Long-Term Incentive Plan, as amended (incorporated by reference to Exhibit 10.3 to Arena's quarterly report on Form 10-Q for the quarter ended June 30, 2016, filed with the Securities and Exchange Commission on August 9, 2016, Commission File No. 000-31161)</a>
10.15**	<a href="#">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)</a>
10.16**	<a href="#">Executive Employment Agreement, dated as of May 6, 2016, by and between Arena and Amit D. Munshi (incorporated by reference to Exhibit 10.1 to Arena's current report on Form 8-K filed with the Securities and Exchange Commission on May 9, 2016, Commission File No. 000-31161)</a>
10.17**	<a href="#">Amended and Restated Severance Agreement, dated as of January 4, 2019, by and between Arena and Amit D. Munshi (incorporated by reference to Exhibit 10.1 to Arena's quarterly report on Form 10-Q for the quarter ended March 31, 2019, filed with the Securities and Exchange Commission on May 9, 2019, Commission File No. 000-31161)</a>
10.18**	<a href="#">Form of Amended and Restated Termination Protection Agreement, dated December 30, 2008, by and between Arena and Mr. Spector (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)</a>
10.19**	<a href="#">Form of Amendment to Amended and Restated Termination Protection Agreement, dated May 9, 2016, by and between Arena and Steven W. Spector (incorporated by reference to Exhibit 10.3 to Arena's current report on Form 8-K filed with the Securities and Exchange Commission on May 9, 2016, Commission File No. 000-31161)</a>
10.20**	<a href="#">Amended and Restated Severance Benefit Plan, effective January 4, 2019, and providing benefits for certain of Arena's executive officers (incorporated by reference to Exhibit 10.2 to Arena's quarterly report on Form 10-Q for the quarter ended March 31, 2019, filed with the Securities and Exchange Commission on May 9, 2019, Commission File No. 000-31161)</a>
10.21**	<a href="#">Annual Incentive Plan for Arena's executive officers, approved February 11, 2019 (incorporated by reference to Exhibit 10.28 to Arena's annual report on Form 10-K for the year ended December 31, 2018, filed with the Securities and Exchange Commission on February 28, 2019, Commission File No. 000-31161)</a>

<b>Exhibit No.</b>	<b>Exhibit Description</b>
10.22**	<a href="#">Employment Agreement, dated as of June 14, 2016, by and between Arena and Kevin R. Lind (incorporated by reference to Exhibit 10.1 to Arena's current report on Form 8-K filed with the Securities and Exchange Commission on June 16, 2016, Commission File No. 000-31161)</a>
10.23**	<a href="#">Summary of compensation for Arena's non-employee directors, approved June 13, 2019 (incorporated by reference to Exhibit 10.4 to Arena's quarterly report on Form 10-Q for the quarter ended June 30, 2019, filed with the Securities and Exchange Commission on August 9, 2019, Commission File No. 000-31161)</a>
10.24**	<a href="#">Employment Agreement, dated as of August 9, 2016, by and between Arena and Vincent E. Aurentz (incorporated by reference to Exhibit 10.3 to Arena's quarterly report on Form 10-Q for the quarter ended September 30, 2016, filed with the Securities and Exchange Commission on November 9, 2016, Commission File No. 000-31161)</a>
10.25**	<a href="#">Employment Agreement, dated as of February 15, 2017, by and between Arena and Preston Klassen, M.D. (incorporated by reference to Exhibit 10.1 to Arena's quarterly report on Form 10-Q for the quarter ended March 31, 2017, filed with the Securities and Exchange Commission on May 9, 2017, Commission File No. 000-31161)</a>
10.26**	<a href="#">Employment Agreement, dated as of October 30, 2018, by and between Arena and Robert Lisicki (incorporated by reference to Exhibit 10.3 to Arena's quarterly report on Form 10-Q for the quarter ended June 30, 2019, filed with the Securities and Exchange Commission on August 9, 2019, Commission File No. 000-31161)</a>
10.27+	<a href="#">Transaction Agreement, dated as of December 28, 2016, by and among 356 Royalty Inc., Eisai Inc. and Eisai Co., Ltd. (incorporated by reference to Exhibit 10.52 to Arena's annual report on Form 10-K for the year ended December 31, 2016, filed with the Securities and Exchange Commission on March 15, 2017, Commission File No. 000-31161)</a>
10.28	<a href="#">Amendment No. 1 dated as of March 9, 2018, to Transaction Agreement, dated as of December 28, 2016, by and among 356 Royalty Inc., Eisai Inc. and Eisai Co. Ltd. (incorporated by reference to Exhibit 10.46 to Arena's annual report on Form 10-K for the year ended December 31, 2017, filed with the Securities and Exchange Commission on March 14, 2018, Commission File No. 000-31161)</a>
10.29	<a href="#">Amendment, dated October 5, 2018, to Transaction Agreement, dated as of December 28, 2016 and amended as of March 9, 2018, by and among 356 Royalty Inc., Eisai Inc. and Eisai Co. Ltd. (incorporated by reference to Exhibit 10.33 to Arena's annual report on Form 10-K for the year ended December 31, 2018, filed with the Securities and Exchange Commission on February 28, 2019, Commission File No. 000-31161)</a>
10.30+	<a href="#">Supply Agreement, dated as of December 28, 2016, by and among Arena Pharmaceuticals GmbH, Eisai Inc. and Eisai Co., Ltd. (incorporated by reference to Exhibit 10.53 to Arena's annual report on Form 10-K for the year ended December 31, 2016, filed with the Securities and Exchange Commission on March 15, 2017, Commission File No. 000-31161)</a>
10.31	<a href="#">Amendment No. 1 dated as of March 9, 2018, to Supply Agreement, dated as of December 28, 2016, by and among Arena Pharmaceuticals GmbH, Eisai Inc. and Eisai Co., Ltd. (incorporated by reference to Exhibit 10.48 to Arena's annual report on Form 10-K for the year ended December 31, 2017, filed with the Securities and Exchange Commission on March 14, 2018, Commission File No. 000-31161)</a>
10.32**	<a href="#">Arena's 2017 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 22, 2017, Commission File No. 333-218905)</a>
10.33**	<a href="#">Arena's Amended and Restated 2017 Long-Term Incentive Plan, effective June 13, 2018 (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 14, 2018, Commission File No. 333-225608)</a>
10.34**	<a href="#">Arena's Amended and Restated 2017 Long-Term Incentive Plan, effective June 13, 2019 (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 14, 2019, Commission File No. 333-232142)</a>
10.35**	<a href="#">Form of Nonqualified Stock Option Grant Agreement for Employees and Consultants under the Arena 2017 Long-Term Incentive Plan (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 22, 2017, Commission File No. 333-218905)</a>
10.36**	<a href="#">Form of Incentive Stock Option Grant Agreement under the Arena 2017 Long-Term Incentive Plan (incorporated by reference to Exhibit 99.3 to Arena's registration statement on Form S-8 filed with the Securities and Exchange Commission on June 22, 2017, Commission File No. 333-218905)</a>

Exhibit No.	Exhibit Description
10.37**	<a href="#">Form of Restricted Stock Unit Grant Agreement (other than for non-employee directors) under the Arena 2017 Long-Term Incentive Plan (incorporated by reference to Exhibit 99.4 to Arena's registration statement on Form S-8 filed with the Securities and Exchange Commission on June 22, 2017, Commission File No. 333-218905)</a>
10.38**	<a href="#">Form of Performance Restricted Stock Unit Grant Agreement under the Arena 2017 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, 2018, filed with the Securities and Exchange Commission on February 28, 2019, Commission File No. 000-31161)</a>
10.39**	<a href="#">Form of Restricted Stock Unit Grant Agreement for Non-Employee Directors under the Arena 2017 Long-Term Incentive Plan (incorporated by reference to Exhibit 99.5 to Arena's registration statement on Form S-8 filed with the Securities and Exchange Commission on June 22, 2017, Commission File No. 333-218905)</a>
10.40**	<a href="#">Form of Nonqualified Stock Option Grant Agreement for Non-Employee Directors under the Arena 2017 Long-Term Incentive Plan (incorporated by reference to Exhibit 99.6 to Arena's registration statement on Form S-8 filed with the Securities and Exchange Commission on June 22, 2017, Commission File No. 333-218905)</a>
10.41**	<a href="#">Arena's 2019 Employee Stock Purchase Plan (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 14, 2019, Commission File No. 333-232142)</a>
21.1	<a href="#">Subsidiaries of the Registrant</a>
23.1	<a href="#">Consent of Independent Registered Public Accounting Firm</a>
31.1	<a href="#">Certification of principal executive officer pursuant to Rule 13a-14(A) promulgated under the Securities Exchange Act of 1934</a>
31.2	<a href="#">Certification of principal financial and accounting officer pursuant to 18 U.S.C. Section 1350 and Rule 13a-14(B) promulgated under the Securities Exchange Act of 1934</a>
32.1	<a href="#">Certification of principal executive officer and principal financial and accounting officer pursuant to 18 U.S.C. Section 1350 and Rule 13a-14(B) promulgated under the Securities Exchange Act of 1934</a>
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibit 101.INS)

+ Confidential treatment has been requested or granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

\* 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.

**Item 16. Form 10-K Summary.**

None.



## DESCRIPTION OF THE REGISTRANT'S COMMON STOCK

The following summary describes the material terms of the common stock, par value \$0.0001 per share, of Arena Pharmaceuticals, Inc. (“we,” “us” and “our”). The description of common stock is qualified by reference to our amended and restated certificate of incorporation and our amended and restated bylaws, which are incorporated by reference as exhibits to the Annual Report on Form 10-K of which this exhibit is a part.

### General

Our amended and restated certificate of incorporation, as amended, authorizes us to issue 73,500,000 shares of common stock. In addition, under our amended and restated certificate of incorporation, as amended, our board of directors has the authority, without further action by stockholders, to designate up to 7,500,000 shares of preferred stock, par value \$0.0001 per share, in one or more series and to fix the rights, preferences, privileges, qualifications and restrictions granted to or imposed upon the preferred stock, including dividend rights, conversion rights, voting rights, rights and terms of redemption, liquidation preference and sinking fund terms, any or all of which may be greater than the rights of our common stock. The issuance of preferred stock could adversely affect the voting power of holders of common stock and reduce the likelihood that common stockholders will receive dividend payments and payments upon liquidation. The issuance could also have the effect of decreasing the market price of the common stock. The issuance of preferred stock also could have the effect of delaying, deterring or prevent a change in control of us. All of our authorized shares of preferred stock are currently undesignated and no shares of preferred stock are issued and outstanding.

Our common stock is listed on the Nasdaq Global Select Market under the symbol “ARNA.”

### Voting

Common stockholders are entitled to one vote per share for the election of directors and on all other matters that require common stockholder approval.

### Dividends and Other Distributions

Holders of our common stock are entitled to share in an equal amount per share in any dividends declared by our board of directors on the common stock and paid out of legally available assets.

### Distribution on Dissolution

Subject to any preferential rights of any outstanding preferred stock, in the event of our liquidation, dissolution or winding up, holders of our common stock are entitled to share ratably in the assets remaining after payment of liabilities and the liquidation preferences of any outstanding preferred stock.

### Other Rights

Our common stock does not carry any preemptive rights enabling a holder to subscribe for, or receive shares of, any class of our common stock or any other securities convertible into shares of any class of our common stock, or any redemption rights.

### Anti-Takeover Provisions

*Delaware Law.* We are governed by the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a “business combination” with an “interested stockholder” for a period of three years after the date of the transaction in which the person became an interested stockholder, unless (i) before the date that the person became an “interested stockholder,” our board of directors approved either the “business combination” or the transaction which makes the person an “interested stockholder,” (ii) the “interested stockholder” owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares

---

outstanding (a) shares owned by persons who are directors and also officers and (b) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer, or (iii) after the date that the person became an “interested stockholder,” the business combination is approved by our board of directors and the vote of at least 66 2/3% of our outstanding voting stock that is not owned by the “interested stockholder.” Generally, a “business combination” includes (A) any merger or consolidation involving the corporation and the interested stockholder, (B) any sale, transfer, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation, (C) subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder, (D) any transaction involving the corporation that has the effect of increasing the proportionate share of its stock owned by the interested stockholder, or (E) the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation. An “interested stockholder” is a person who either owns 15% or more of our outstanding voting stock or, together with affiliates and associates, owns or, within three prior years, did own, 15% or more of our outstanding voting stock. The statute could have the effect of delaying, deferring or preventing a change in our control.

*Bylaw and Certificate of Incorporation Provisions.* Our amended and restated bylaws provide that special meetings of our stockholders may be called by our board of directors or President. Our amended and restated certificate of incorporation (i) specifies that the authorized number of directors shall be fixed by our board of directors in the manner provided by our amended and restated bylaws, which provide that the number of directors constituting our board of directors shall be fixed from time to time by resolution passed by a majority of our board of directors and (ii) does not include a provision for cumulative voting for directors. Under cumulative voting, a minority stockholder holding a sufficient percentage of a class of shares may be able to ensure the election of one or more directors. These and other provisions contained in our amended and restated certificate of incorporation and amended and restated bylaws could delay or discourage transactions involving an actual or potential change in control of us or our management, including transactions in which stockholders might otherwise receive a premium for their shares over then current prices. Such provisions could also limit the ability of stockholders to remove current management or approve transactions that stockholders may deem to be in their best interests and could adversely affect the price of our common stock.

### **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A.

**Subsidiaries of Arena Pharmaceuticals, Inc.**

*As of December 31, 2019*

125 Royalty Inc., a Delaware corporation

356 Royalty Inc., a Delaware corporation

Arena Pharmaceuticals Development GmbH, a limited liability company organized under the laws of Switzerland and having its domicile in Zug

Arena Pharmaceuticals GmbH in Liquidation, a limited liability company organized under the laws of Switzerland and having its domicile in Zofingen

Arena Pharmaceuticals Limited, a limited liability company organized under the laws of Ireland and having its domicile in Dublin

API Development LTD, a company incorporated in the Cayman Islands with limited liability

**Consent of Independent Registered Public Accounting Firm**

The Board of Directors  
Arena Pharmaceuticals, Inc.:

We consent to the incorporation by reference in the registration statements (Nos. 333-160329, 333-182238, 333-189213, 333-204999, 333-212012, 333-214529, 333-217805, 333-218905, 333-225608, and 333-232142) on Form S-8 and (Nos. 333-112542, 333-136023, 333-160983, 333-167498, and 333-219237) on Form S-3 of Arena Pharmaceuticals, Inc. of our reports dated February 27, 2020, with respect to the consolidated balance sheets of Arena Pharmaceuticals, Inc. as of December 31, 2019 and 2018, the related consolidated statements of operations and comprehensive income (loss), equity, and cash flows for each of the years in the three-year period ended December 31, 2019, and the related notes, and the effectiveness of internal control over financial reporting as of December 31, 2019, which reports appear in the December 31, 2019 annual report on Form 10-K of Arena Pharmaceuticals, Inc. Our report refers to the adoption of Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers*, and Accounting Standards Codification Topic 842, *Leases*.

/s/ KPMG LLP

San Diego, California  
February 27, 2020



## CERTIFICATION

I, Amit D. Munshi, certify that:

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

Date: February 27, 2020

/s/ Amit D. Munshi

---

**Amit D. Munshi, President and Chief Executive Officer**  
**(principal executive officer)**

## CERTIFICATION

I, Kevin R. Lind, certify that:

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

Date: February 27, 2020

/s/ Kevin R. Lind

---

**Kevin R. Lind, Executive Vice President and Chief Financial Officer**  
**(principal financial and accounting officer)**

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

In connection with the Annual Report on Form 10-K of Arena Pharmaceuticals, Inc. (“the Company”) for the period ended December 31, 2019, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), Amit D. Munshi, as President and Chief Executive Officer (principal and financial officer) of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

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

/s/ Amit D. Munshi

\_\_\_\_\_  
Amit D. Munshi

President and Chief Executive Officer

(principal executive officer)

Date: February 27, 2020

In connection with the Annual Report on Form 10-K of Arena Pharmaceuticals, Inc. (“the Company”) for the period ended December 31, 2019, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), Kevin R. Lind, as Executive Vice President and Chief Financial Officer (principal financial and accounting officer) of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

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

/s/ Kevin R. Lind

\_\_\_\_\_  
Kevin R. Lind

Executive Vice President and Chief Financial Officer

(principal financial and accounting officer)

Date: February 27, 2020