UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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, 2018
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: 001-34962

Zogenix, Inc.

Delaware (State of Incorporation)	**20-5300780** (I.R.S. Employer Identification No.)
5858 Horton Street, Suite 455 Emeryville, California	**94608**

(510) 550-8300
Securities registered pursuant to Section 12(b) of the Act:

Common Stock, par value $0.001 per share	**The Nasdaq Global Market**

Securities registered pursuant to Section 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 15(d) of the Exchange 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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See 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 ☒	Accelerated filer ☐
Non-accelerated filer ☐	Smaller reporting company ☐
	Emerging growth company ☐

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 ☒

As of June 30, 2018, the aggregate market value of common stock held by non-affiliates of the Registrant, computed by reference to the closing price and shares outstanding, was approximately $1.4 billion.

As of February 15, 2019, there were 42,218,424 shares of the Registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive Proxy Statement to be filed for its 2019 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K. Such proxy statement will be filed with the Securities and Exchange Commission within 120 days of the Registrant's fiscal year ended December 31, 2018.

ZOGENIX, INC.

FORM 10-K

For the Year Ended December 31, 2018

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PART I

Forward-Looking Statements and Market Data

This Annual Report on Form 10-K and the information incorporated herein by reference contain forward-looking statements that involve substantial risks and uncertainties. These forward looking statements include, but are not limited to, statements about:

- the progress and timing of clinical trials of our lead product candidate Fintepla/ZX008;
- the safety and efficacy of our product candidates;
- the timing of submissions to, and decisions made by the U.S. Food and Drug Administration (FDA) and other regulatory agencies, including foreign regulatory agencies, with regards to the demonstration of the safety and efficacy of our product candidates and adequacy of the manufacturing processes related to our product candidates to the satisfaction of the FDA and such other regulatory agencies;
- our ability to obtain, maintain and successfully enforce adequate patent and other intellectual property or regulatory exclusivity protection of our product candidates and the ability to operate our business without infringing the intellectual property rights of others;
- the goals of our development activities and estimates of the potential markets for our product candidates, and our ability to compete within those markets;
- our ability to obtain and maintain adequate levels of coverage and reimbursement from third-party payors for any of our product candidates that may be approved for sale, the extent of such coverage and reimbursement and the willingness of third-party payors to pay for our products versus less expensive therapies;
- the impact of healthcare reform laws; and
- projected cash needs and our expected future revenues, operations and expenditures.

The forward-looking statements are contained principally in the sections entitled “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business.” In some cases, you can identify forward-looking statements by the following words: “may,” “will,” “could,” “would,” “should,” “expect,” “intend,” “plan,” “anticipate,” “believe,” “estimate,” “predict,” “project,” “potential,” “continue,” “ongoing” or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. These statements relate to future events or our future financial performance or condition and involve known and unknown risks, uncertainties and other factors that could cause our actual results, levels of activity, performance or achievement to differ materially from those expressed or implied by these forward-looking statements. We discuss many of these risks, uncertainties and other factors in this Annual Report on Form 10-K in greater detail under the heading “Item 1A — Risk Factors.”

Given these risks, uncertainties and other factors, we urge you not to place undue reliance on these forward-looking statements, which speak only as of the date of this report. You should read this Annual Report on Form 10-K completely and with the understanding that our actual future results may be materially different from what we expect. For all forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. We undertake no obligation to revise or update publicly any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law.

This Annual Report on Form 10-K also contains estimates, projections and other information concerning our industry, our business, and the markets for Fintepla and other product candidates, including data regarding the estimated size of those markets, their projected growth rates, the incidence of certain medical conditions, statements that certain drugs, classes of drugs or dosages are the most widely prescribed in the United States or other markets, the perceptions and preferences of patients and physicians regarding certain therapies and other prescription, prescriber and patient data, as well as data regarding market research, estimates and forecasts prepared by our management. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources. In particular, unless otherwise specified, all prescription, prescriber and patient data in this Annual Report on Form 10-K is from Source Healthcare Analytics, Source® Pharmaceutical Audit Suite (PHAST) Institution/Prescription, Source® PHAST Prescription, Source® Prescriber or Source® Dynamic Claims. In some cases, we do not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires.

Fintepla®, Zogenix™ and DosePro® are our trademarks. All other trademarks, trade names and service marks appearing in this Annual Report on Form 10-K are the property of their respective owners. Use or display by us of other parties' trademarks, trade dress or products is not intended to and does not imply a relationship with, or endorsements or sponsorship of, us by the trademark or trade dress owner.

Unless the context requires otherwise, references in this Annual Report on Form 10-K to "Zogenix," "we," "us" and "our" refer to Zogenix, Inc., a Delaware corporation, and its consolidated subsidiaries.

Item 1. Business

Company Overview

Zogenix, Inc. (Zogenix, We or the Company) is a pharmaceutical company developing and commercializing transformative central nervous system (CNS) therapies for people living with serious and life-threatening rare CNS disorders and medical conditions. We are currently focused on developing and commercializing CNS therapies to address rare, or "orphan" childhood-onset epilepsy disorders.

We currently own and control worldwide development and commercialization rights to Fintepla/ZX008, our lead product candidate. Fintepla is low-dose fenfluramine under development for the treatment of seizures associated with two rare and catastrophic forms of childhood-onset epilepsy: Dravet syndrome and Lennox-Gastaut syndrome (LGS).

Dravet syndrome is a rare form of pediatric-onset epilepsy with life threatening consequences for patients and for which current treatment options are very limited. Fintepla has received orphan drug designation in the United States and the European Union (EU) for the treatment of Dravet syndrome. In addition, Fintepla for the treatment of Dravet syndrome received Fast Track designation from the U.S. Food and Drug Administration (FDA) in January 2016. In February 2019, we completed our rolling submission of a New Drug Application (NDA) with the FDA and submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for Fintepla for the treatment of seizures associated with Dravet syndrome. The EMA has accepted the MAA and initiated its review.

We initiated our Phase 3 clinical trials for Fintepla for the treatment of seizures associated with Dravet syndrome in North America (Study 1501) in January 2016 and in Europe and Australia in June 2016 (Study 1502). Study 1501 and Study 1502 are each identical randomized, double-blind placebo-controlled studies of Fintepla as adjunctive therapy for patients with uncontrolled seizures who have Dravet syndrome. In January 2017, we announced our plan to report top-line results from Study 1501 and Study 1502 via a prospective merged study analysis approach whereby top-line results from the first approximately 120 subjects randomized into either Study 1501 or 1502 would have their study results analyzed and be reported initially as "Study 1". In April 2017, we completed enrollment of Study 1 and, in September 2017, we announced positive top-line results for the 119 patients included in the Study 1 Phase 3 trial. The Study 1 trial met its primary objective of demonstrating that Fintepla, at a dose of 0.8 mg/kg/day (30mg/day maximum), is superior to placebo as adjunctive therapy in the treatment of Dravet syndrome in children and young adults based on change in the frequency of convulsive seizures between the 6-week baseline observation period and the 14-week treatment period ($p<0.001$). In the trial, Fintepla at a dose of 0.8 mg/kg/day also demonstrated statistically significant improvements versus placebo in all key secondary measures, including the proportion of patients with clinically meaningful reductions in seizure frequency (50% or greater) and longest seizure-free interval. The same analyses comparing a 0.2 mg/kg/day Fintepla dose versus placebo also demonstrated statistically significant improvement compared with placebo. Fintepla was generally well tolerated without any signs or symptoms of valvulopathy or pulmonary hypertension.

In September 2016, we initiated Cohort 1 of Study 1504 that investigated the pharmacokinetic profile and safety of Fintepla when co-administered with the stiripentol regimen (stiripentol, valproate and/or clobazam). Based on the results of the Cohort 1 pharmacokinetic and safety portion of the trial, in February 2017 we initiated the Cohort 2 safety and efficacy portion of Study 1504 utilizing a dose of Fintepla 0.5mg/kg/day (20mg/day maximum). Study 1504 Cohort 2, a two-arm study, compared Fintepla versus placebo across the titration and 12-week maintenance periods at multiple sites located in France, the Netherlands, United States, Canada, Germany, the United Kingdom and Spain. In January 2018, we announced patient enrollment was complete at 87 patients, with 43 patients randomized into the Fintepla-arm and 44 patients randomized to the placebo arm. In July 2018, we reported positive top-line results from Cohort 2 of Study 1504. The study results, which are consistent with those reported in Study 1, successfully met the primary objective of demonstrating that Fintepla, at a dose of 0.5 mg/kg/day, when co-administered with stiripentol regimen (stiripentol, valproate and/or clobazam), was superior to placebo as adjunctive therapy in the treatment of Dravet syndrome in children and young adults based on change in the frequency of convulsive seizures between the 6-week baseline observation period and the 15-week treatment period ($p<0.001$). In the trial, Fintepla at a dose of 0.5 mg/kg/day also demonstrated statistically significant improvements versus placebo in all key secondary measures, the proportion of patients with clinically meaningful reductions in seizure frequency (50% or greater) and longest seizure-free interval. Fintepla was generally well-tolerated in this study, with the adverse events consistent with those observed in Study 1 and the known safety profile of fenfluramine without any signs or symptoms of valvular heart disease (valvulopathy) or pulmonary hypertension.

Upon completion of our Fintepla Phase 3 trials, eligible patients were permitted to enroll in an ongoing open-label extension (OLE) trial to study the long-term safety and effectiveness of Fintepla (Study 1503). In December 2018, we presented interim data from Study 1503 regarding the effectiveness and overall safety of Fintepla observed in the study, including the long-term cardiovascular assessments and findings at the 72nd Annual Meeting of the American Epilepsy Society (AES). A total of 232 patients from Study 1503 were included in the interim analysis of the OLE trial. As of March 13, 2018, the interim

cutoff date, the median duration of treatment with Fintepla was 256 days and the range was 58-634 days (equivalent to 161 patient-years of exposure to Fintepla). In this interim analysis population of 232 patients, a total of 22 (9.5%) patients had discontinued treatment for the following reasons: lack of efficacy (16), subject withdrawal (2), adverse event (1), Sudden Unexpected Death in Epilepsy (SUDEP) (1), physician decision (1), and withdrawal by caregiver (1). Approximately 90% of patients remained in the study at the time of the interim analysis. The median percent reduction in monthly convulsive seizure frequency over the entire OLE treatment period was 66.8% (compared with baseline frequency established in the core Phase 3 studies). Over the same period, 64.4% of children and young adults showed a >50% reduction in convulsive seizure frequency and 41.2% showed a >75% reduction. The occurrence of adverse events was consistent with the Phase 3 placebo-controlled studies. The most common adverse events occurring in more than 10% of children and young adults were pyrexia (22%), nasopharyngitis (20%), decreased appetite (16%), influenza (12%), diarrhea (11%), and upper respiratory tract infection (10%). A total of 13.4% of children lost >7% body weight at some point during the trial; in 42% of those children weight loss abated during the period covered by the interim analysis. Over the course of the OLE treatment period, one patient died from SUDEP that was deemed unrelated to Fintepla. A total of 703 color doppler echocardiograms were performed to assess cardiovascular health at baseline, week 4 or 6, and then every 3 months during the OLE trial. No patient developed valvular heart disease (valvulopathy) or pulmonary arterial hypertension at any time after daily treatment with Fintepla.

In February 2019, we completed our rolling submission of a NDA with the FDA and submitted a MAA to the EMA for Fintepla for the treatment of seizures associated with Dravet syndrome. Both applications were based on data from Study 1 and Study 1504 in Dravet syndrome and the interim analysis from Study 1503. The EMA has accepted the MAA and initiated its review.

LGS is another rare, refractory, debilitating pediatric-onset epilepsy with life threatening consequences for patients and for which current treatment options are limited and suboptimal. Beginning in first quarter of 2016, we funded an open-label, dose-finding, investigator-initiated study of the effectiveness and tolerability of Fintepla as an adjunctive therapy in patients with LGS. In December 2016, we presented initial data from an interim analysis of the first 13 patients to have completed at least 12 weeks of this Phase 2 clinical trial at the 70th Annual Meeting of the AES. In this interim analysis, Fintepla was observed to provide clinically meaningful improvement in major motor seizure frequency in patients with severe refractory LGS, with 7 out of 13 patients (54%) achieving at least a 50% reduction in the number of major motor seizures, at doses below the 0.8 mg/kg/day maximum allowed dose. In addition, Fintepla was generally well tolerated without any observed signs or symptoms of valvulopathy or pulmonary hypertension. We believe these data indicate that Fintepla has the potential to be a safe and effective adjunctive treatment of major motor seizures for patients with LGS. Based on the strength of the LGS data generated, in the first quarter of 2017, we submitted an Investigational New Drug Application (IND) to the FDA to initiate a Phase 3 program of Fintepla in LGS. Our IND for Fintepla as a potential treatment for LGS became effective in April 2017. In the first half of 2017, Fintepla received orphan drug designation for the treatment of LGS from the FDA in the United States and the EMA in the EU. In November 2017, we announced the initiation of our multicenter global Phase 3 clinical trial of Fintepla as an adjunctive treatment for seizures in patients with LGS (Study 1601) and are currently enrolling patients into the study. In December 2018, we announced that we expect to complete enrollment for Study 1601 in the second half of 2019 and be able to announce top-line results from the study in the first quarter of 2020.

Our Strategy

We are committed to developing and commercializing therapeutic solutions for people living with serious and life-threatening rare CNS disorders and medical conditions. Our strategy centers on developing and advancing our lead therapeutic product candidate, Fintepla, low-dose fenfluramine for the treatment of Dravet syndrome, LGS, and potentially other rare and catastrophic epilepsy disorders. In addition to Fintepla, we aim to identify, develop, and advance other transformative therapeutic product candidates with the potential to treat patients living with serious and life-threating rare CNS disorders. The key elements of our strategy are:

- **Seek regulatory approval and commence commercialization of Fintepla for the treatment of patients with Dravet syndrome.** In February 2019, we completed our rolling submission of a NDA with the FDA and submitted a MAA to the EMA for Fintepla for the treatment of seizures associated with Dravet syndrome. Also in February 2019, we entered into a master supply agreement with Aptuit (Oxford) Limited, an Evotec company, or Aptuit, pursuant to which Aptuit will be our commercial manufacturer and supplier of the fenfluramine active pharmaceutical ingredient (API) used in our product candidate Fintepla. We are continuing to build our internal commercial capabilities for potential commercialization.
- **Developing Fintepla for the treatment of Lennox-Gastaut syndrome.** In November 2017, we announced the initiation of Study 1601 for Fintepla as an adjunctive treatment of seizures associated with LGS with the enrollment of the first patient into the study. In December 2018, we announced that we expect to complete enrollment for Study 1601 in the second half of 2019 and be able to announce top-line results from the study in the first quarter of 2020. Fintepla received orphan drug designation for the treatment of LGS from the FDA and the EMA in the first half of 2017.

- **Evaluating Fintepla for potential treatment of other forms of orphan pediatric epilepsy.** In addition to Dravet syndrome and LGS, we believe that the unique mechanism of action of Fintepla has the potential to treat other epileptic encephalopathies where there is a significant unmet medical need. We expect to continue to evaluate its potential in additional orphan pediatric-onset epilepsy indications where there is a significant unmet medical need. For example, we are evaluating whether Fintepla has the potential to treat patients with Doose Syndrome, another rare pediatric epileptic encephalopathy that is often refractory to currently available anticonvulsant medication. There is currently no FDA approved medication for the treatment of seizures associated with Doose Syndrome. We plan to initiate a Phase 3 placebo-controlled trial in Doose Syndrome in the second half of 2019.
- **Identifying transformative, differentiated, promising product development candidates in the therapeutic area of rare CNS disorders for acquisition and further development**. Our business development team focuses on identifying and evaluating differentiated, high-value licensing and product acquisition opportunities that would build our CNS product candidate pipeline and effectively leverage our capabilities in the United States and Europe.

Our Clinical Product Candidate

We currently have one product candidate in clinical development being studied as a potential treatment for rare CNS disorders.

Fintepla (ZX008; Low-Dose Fenfluramine) for Patients with Dravet Syndrome

Dravet syndrome is a rare childhood-onset channelopathy in which intractable epilepsy is one of the most significant and devastating symptoms. Children and young adults with Dravet syndrome experience debilitating, persistent and potentially life-threatening seizures beginning in the first year of life. Seizures continue throughout their lifetime and are most often treatment resistant, meaning that currently available medications and therapies are not able to achieve complete or clinically meaningful seizure control and, in some cases, worsen the condition. Individuals with Dravet syndrome face a higher incidence of Status Epilepticus and SUDEP. These patients suffer from severe cognitive and other developmental impairment throughout life, as well as neurobehavioral disorders such as autistic-like behavior and attention deficit hyperactivity disorder, and motor abnormalities. The prognosis for patients with Dravet syndrome to become seizure free is poor. A recent study by Wu et. al. published by the American Academy of Pediatrics in 2015 reported an incidence rate for Dravet syndrome of approximately 1 per 16,000 live births.

Prior to 2018, there were no FDA-approved treatments indicated for the treatment of seizures associated with Dravet syndrome. In June 2018, the FDA approved the first treatment of seizures associated with Dravet syndrome, Epidiolex® (cannabidiol or CBD) liquid oral solution and in August 2018, the FDA approved a second treatment, Diacomit® (stiripentol), for the treatment of seizures associated with Dravet syndrome in patients who are also taking clobazam. Prior to 2018, the standard of care for the treatment of seizures in patients with Dravet syndrome usually involved a combination of the following anticonvulsant drugs: clobazam, clonazepam, levetiracetam, topiramate, valproic acid, ethosuximide and zonisamide. In addition to the United States, stiripentol is approved in Europe, Canada, Australia and Japan for the treatment of seizures associated with Dravet syndrome in conjunction with valproate and/or clobazam. In Europe, stiripentol was granted an orphan drug designation for the treatment of Dravet syndrome in 2001. Sodium channel blocking anticonvulsant drugs often used to treat most other epilepsy conditions increase seizure frequency in patients with Dravet syndrome. Management of this disease may also include a nonpharmacologic treatments, including ketogenic diet and vagal nerve stimulation.

Fenfluramine was originally developed and approved as an anorectic agent for the treatment of adult obesity. Pre-clinical and clinical evidence of the drug's ability to treat refractory pediatric epileptic seizures was first described in the 1980s. Fenfluramine was withdrawn from the market in 1997 because the risk outweighed the benefit in this adult obese population, after cases of heart valve defects and pulmonary hypertension were reported in adults who had taken fenfluramine, most often with phentermine. However, at this time, academic pediatric neurologists in Belgium continued to evaluate low doses of fenfluramine in a small number of refractory patients under a government approved compassionate use protocol. Their open-label study, which continues today, evaluated the safety and effectiveness of low-dose fenfluramine to reduce seizures in refractory Dravet syndrome patients.

In December 2016, we presented the most recent analyses of the original Dravet syndrome patients being treated in Belgium under this government approved protocol at the 70th AES Annual Meeting. At that time ten original patients who started treatment with fenfluramine prior to 2010 had been treated with low-dose fenfluramine for a mean of 17.5 years (range: 7-28 years) From the analysis, low-dose fenfluramine, as an adjunctive therapy to standard antiepileptic drugs, was providing these difficult to treat patients with long-term, durable seizure control. As reported at the meeting, for the most immediate past six years of treatment leading up to the analysis, three patients were seizure-free for the entire six years and four patients experienced seizure-free intervals of at least two years. None of these patients developed any clinically meaningful signs or symptoms of cardiac valvulopathy or pulmonary hypertension, while two patients had mild and stable cardiac valve thickening

on the most recent cardiac echocardiogram that was deemed to be clinically unimportant. After 2010, an additional 11 Dravet syndrome patients started adjuvant treatment with low-dose fenfluramine under the Belgium government approved protocol and data on this cohort was presented at the 71st AES Annual Meeting. The mean age at start of fenfluramine in this cohort was 12.5 years (range, 1- 30 years) and treatment with fenfluramine was for a median duration of 3.0 years (range, 1- 7 years). Ninety-one percent of these patients had a clinically meaningful reduction (≥50%) and 73% had substantial reductions (≥75%) in major motor seizure frequency at the prior visit. Fenfluramine was generally well tolerated with no clinical and/or echocardiographic signs of cardiac valvulopathy or pulmonary hypertension. In this ongoing Belgian study of low dose fenfluramine treating refractory Dravet syndrome patients, no patient has stopped treatment for any adverse event.

Because of the known cardiac side effects of fenfluramine reported when prescribed in higher doses for the treatment of adult obesity (without baseline cardiac data), the ongoing Belgian study requires ongoing periodic evaluations of the heart and, in particular, the heart valves and measures assessing for the presence of pulmonary hypertension using echocardiography. Overall, low-dose fenfluramine has been shown to be well tolerated and side-effects of treatment have been mild and transient over the entire 29-year study period. There have been no clinically significant findings related to cardiac valvulopathy and no reports of pulmonary hypertension in any Fintepla or low-dose fenfluramine studies to date.

We have participated in formal meetings with regulatory agencies in the United States and the EU to obtain concurrence on remaining pre-clinical and clinical requirements for regulatory approval. Based upon this information, we believe our two pivotal placebo-controlled Phase 3 studies in Dravet syndrome will be sufficient to support an application for regulatory approval of Fintepla in the United States and in Europe. The FDA accepted our IND for Fintepla for the treatment of Dravet syndrome in December 2015. We initiated our Phase 3 clinical trials in North America (Study 1501) in January 2016 and in Europe and Australia in June 2016 (Study 1502). Study 1501 and Study 1502 are each identical randomized, double-blind, placebo-controlled studies of Fintepla as adjunctive therapy for patients with uncontrolled seizures who have Dravet syndrome. In January 2017, we announced our plan to report top-line results from Study 1501 and Study 1502 via a prospective merged study analysis approach whereby top-line results from the first approximately 120 subjects randomized into either Study 1501 or 1502 would have their study results analyzed and be reported initially as "Study 1." In April 2017, we completed enrollment of Study 1 and, in September 2017, we announced positive top-line results for the 119 patients included in the Study 1 Phase 3 trial. The Study 1 trial met its primary objective of demonstrating that Fintepla, at a dose of 0.8 mg/kg/day, was superior to placebo as adjunctive therapy in the treatment of Dravet syndrome in children and young adults based on change in the frequency of convulsive seizures between the 6-week baseline observation period and the 14-week treatment period ($p<0.001$). In the trial Fintepla 0.8 mg/kg/day also demonstrated statistically significant improvements versus placebo in all key secondary measures, including the proportion of patients with clinically meaningful reductions (50% or greater) in convulsive seizure frequency and longest seizure-free interval. The same analyses comparing a 0.2 mg/kg/day Fintepla dose versus placebo also resulted in statistically significant improvement compared with placebo. Patients completing the Phase 3 trials are given the opportunity to enroll in an open label long-term extension safety study (Study 1503).

In September 2016, we initiated Part 1 of Study 1504, a two-part, double blind, randomized, two arm pivotal Phase 3 clinical trial of Fintepla in Dravet syndrome patients who are taking stiripentol, valproate and/or clobazam as part of their baseline standard care. Part 1 investigated the pharmacokinetic profile and safety of Fintepla when co-administered with the stiripentol regimen (stiripentol, valproate and/or clobazam). Based on the results of the pharmacokinetic and safety portion of the trial, in February 2017 we initiated the safety and efficacy portion of Study 1504 utilizing a dose of Fintepla 0.5mg/kg/day (20mg/day maximum). Study 1504, a two-arm study, compared Fintepla versus placebo across the titration and 12-week maintenance periods at multiple sites located the Netherlands, United States, Canada, Germany, the United Kingdom and Spain. In January 2018, we announced patient enrollment was complete at 87 patients, with 43 patients randomized into the Fintepla-arm and 44 patients randomized to the placebo arm.

In July 2018, we reported positive top-line results from Cohort 2 of Study 1504. The study results, which are consistent with those reported in Study 1, successfully met the primary objective of demonstrating that Fintepla, at a dose of 0.5 mg/kg/day, when co-administered with stiripentol regimen (stiripentol, valproate and/or clobazam), was superior to placebo as adjunctive therapy in the treatment of Dravet syndrome in children and young adults based on change in the frequency of convulsive seizures between the 6-week baseline observation period and the 15-week treatment period ($p<0.001$). In the trial, Fintepla at a dose of 0.5 mg/kg/day also demonstrated statistically significant improvements versus placebo in all key secondary measures, the proportion of patients with clinically meaningful reductions in seizure frequency (50% or greater) and longest seizure-free interval. Fintepla was generally well-tolerated in this study, with the adverse events consistent with those observed in Study 1 and the known safety profile of fenfluramine without any signs or symptoms of valvular heart disease (valvulopathy) or pulmonary hypertension.

Upon completion of our Fintepla Phase 3 trials, eligible patients were permitted to enroll in an ongoing OLE trial to study the long-term safety and effectiveness of Fintepla (Study 1503). In December 2018, we presented interim data from Study 1503 regarding the effectiveness and overall safety of Fintepla observed in the study, including the long-term cardiovascular

assessments and findings at the 72nd Annual Meeting of the AES. A total of 232 patients from Study 1503 were included in the interim analysis of the OLE trial. As of March 13, 2018, the interim cutoff date, the median duration of treatment with Fintepla was 256 days and the range was 58-634 days (equivalent to 161 patient-years of exposure to Fintepla). In this interim analysis population of 232 patients, a total of 22 (9.5%) patients had discontinued treatment for the following reasons: lack of efficacy (16), subject withdrawal (2), adverse event (1), SUDEP (1), physician decision (1), and withdrawal by caregiver (1). Approximately 90% of patients remained in the study at the time of the interim analysis. The median percent reduction in monthly convulsive seizure frequency over the entire OLE treatment period was 66.8% (compared with baseline frequency established in the core Phase 3 studies). Over the same period, 64.4% of children and young adults showed a >50% reduction in convulsive seizure frequency and 41.2% showed a >75% reduction.

The occurrence of adverse events was consistent with the Phase 3 placebo-controlled studies. The most common adverse events occurring in more than 10% of children and young adults were pyrexia (22%), nasopharyngitis (20%), decreased appetite (16%), influenza (12%), diarrhea (11%), and upper respiratory tract infection (10%). A total of 13.4% of children lost >7% body weight at some point during the trial; in 42% of those children weight loss abated during the period covered by the interim analysis. Over the course of the OLE treatment period included in the interim analysis, one patient died from SUDEP that was deemed unrelated to Fintepla. A total of 703 color doppler echocardiograms were performed to assess cardiovascular health at baseline, week 4 or 6, and then every 3 months during the OLE trial. No patient developed valvular heart disease (valvulopathy) or pulmonary arterial hypertension at any time after daily treatment with Fintepla.

In February 2019, we completed our rolling submission of a NDA with the FDA and submitted a MAA to the EMA for Fintepla for the treatment of seizures associated with Dravet syndrome. The EMA has accepted the MAA and initiated its review. In the event that the FDA requires a risk management plan (RMP) as a condition of approval to manage potential risks through education, labeling, and monitoring where appropriate, we are currently developing the appropriate elements of an RMP for Fintepla in the United States, as well as a similar RMP for Europe. This is consistent with other drugs with known safety issues that are approved for serious diseases with high unmet need.

Fintepla for Patients with LGS

LGS is a severe, refractory and debilitating form of epilepsy that typically becomes apparent during early childhood. Affected children experience generalized tonic-clonic seizures, tonic seizures, atonic seizures, and tonic/atonic seizures, all of which can result in “drop attacks.” Other seizure types that occur in some LGS patients include non-convulsive seizures, such as atypical absences, focal seizures, and myoclonic seizures. Children with LGS most often also develop cognitive dysfunction, delays in reaching developmental milestones and behavioral problems. LGS can be caused by a variety of underlying conditions, but in some cases no cause can be identified.

LGS makes up 1% to 4% of all pediatric epilepsies. There is no specific therapy for LGS that is effective in all cases and the disorder has proven particularly resistant to most currently available therapeutic options. The three main therapeutic options for the treatment of LGS are anti-epileptic drugs (AEDs), dietary therapy (typically the ketogenic diet) or surgery (VNS therapy or corpus callosotomy). AEDs are usually prescribed to individuals with LGS, but the individual response is highly variable. However, because individuals with LGS rarely respond successfully to one AED, they most often require polypharmacotherapy with multiple AEDs, and yet still most continue to have refractory seizures. Although a variety of specific drugs have been approved by the FDA and/or EMA for the treatment of LGS including Epidiolex (cannabidiol), topiramate, lamotrigine, clobazam, rufinamide, felbamate and clonazepam, these medications typically have limited success and in addition, are often associated with intolerable side effects, especially in individuals who receive multidrug, high-dose regimens. Furthermore, all current AEDs can also become less effective over time.

Beginning in first quarter of 2016, we funded an open-label, dose-finding, investigator-initiated study of the effectiveness and tolerability of Fintepla as an adjunctive therapy in patients with LGS. In December 2016, we presented initial data from an interim analysis of the first 13 patients to have completed at least 12 weeks of this Phase 2 clinical trial at the 70th Annual Meeting of the AES. In this interim analysis, Fintepla was observed to provide clinically meaningful improvement in major motor seizure frequency in patients with severe refractory LGS, with 7 out of 13 patients (54%) achieving at least a 50% reduction in the number of major motor seizures, at doses below the 0.8 mg/kg/day maximum allowed dose. In addition, Fintepla was generally well tolerated without any observed signs or symptoms of valvulopathy or pulmonary hypertension. We believe these data indicate that Fintepla has the potential to be a safe and effective adjunctive treatment of major motor seizures for patients with LGS. Based on the strength of the LGS data generated, in the first quarter of 2017, we submitted an Investigational New Drug Application (IND) to the FDA to initiate a Phase 3 program of Fintepla in LGS. Our IND for Fintepla as a potential treatment for LGS became effective in April 2017. In the first half of 2017, Fintepla received orphan drug designation for the treatment of LGS from the FDA in the United States and the EMA in the EU. In November 2017, we announced the initiation of our multicenter global Phase 3 clinical trial of Fintepla as an adjunctive treatment for seizures in patients with LGS (Study 1601) and are currently enrolling patients into the study. In December 2018, we announced that we

expect to complete enrollment for Study 1601 in the second half of 2019 and be able to announce top-line results from the study in the first quarter of 2020.

Beyond Dravet syndrome and LGS, we also intend to evaluate Fintepla's potential to treat additional indications in other rare pediatric-onset epileptic encephalopathies such as Doose Syndrome and related medical conditions in the future.

Competition

The pharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary and differentiated therapeutics. We face competition from a number of sources, some of which may target the same indications as our product candidates, including large pharmaceutical companies, smaller biopharmaceutical companies, biotechnology companies, academic institutions, government agencies and private and public research institutions, many of which have greater financial resources, research and development capabilities, sales and marketing capabilities, manufacturing capabilities, experience in obtaining regulatory approvals for product candidates and/or other resources than us. We will face competition not only in the commercialization of any product candidates for which we obtain marketing approval from the FDA or other regulatory authorities, but also for the in-licensing or acquisition of additional product candidates.

Fintepla

Prior to 2018, there were no FDA-approved treatments indicated for the treatment of seizures associated with Dravet syndrome. The standard of care for the treatment of seizures in patients with Dravet syndrome usually involved a combination of the following anticonvulsant drugs: clobazam, clonazepam, levetiracetam, topiramate, valproic acid, ethosuximide and zonisamide. In June 2018, the FDA approved the first treatment of seizures associated with Dravet syndrome, as well as LGS, GW Pharmaceuticals' Epidiolex® (cannabidiol or CBD). Epidiolex is a liquid drug formulation of plant-derived purified CBD, which is a chemical component of the Cannabis sativa plant, more commonly known as marijuana. In August 2018, the FDA approved a second treatment, Biocodex's Diacomit® (stiripentol), for the treatment of seizures associated with Dravet syndrome in patients who are also taking clobazam. Stiripentol is approved in Europe, Canada and Japan for the treatment of Dravet syndrome when used in conjunction with valproate and/or clobazam. GW Pharmaceuticals plc has filed a MAA in Europe for CBD in Dravet syndrome and LGS.

Fintepla has a novel mechanism of action (selective serotonin activity and possibly sigma-1 activity) that is different from the other antiepileptic drugs currently available and in clinical development in the United States and the EU for the treatment of epileptic encephalopathies like Dravet syndrome, including cannabidiol or stiripentol. Currently approved drugs have a different and distinct mechanism of action from Fintepla. As such, we do not expect the recent approvals of cannabidiol or stiripentol in the United States or Europe will block the FDA or EMA from granting approval of Fintepla.

Insys Therapeutics (Insys) is developing a synthetic CBD for the treatment of pediatric epilepsies, including Dravet syndrome. Insys previously advanced its synthetic CBD program, which has received orphan drug designation and Fast Track status by the FDA for use of CBD as a potential treatment for Dravet syndrome, into a Phase 1/2 clinical trial. Insys initiated Phase 2 development of its CBD product candidate for childhood absence epilepsy in December of 2017 and initiated a Phase 3 trial in infantile spasms, a pediatric epilepsy syndrome in the first quarter of 2018.

Ovid Therapeutics, Inc. is currently evaluating its product candidate OV935, a first-in-class inhibitor of the enzyme cholesterol 24-hydroxylase (CH24H), for the potential treatment of adult and pediatric patients with Dravet syndrome and LGS in Phase 2 clinical trials.

Several other companies, including Xenon Pharmaceuticals, Inc. and Stoke Therapeutics, Inc. have disclosed that they are developing preclinical drug candidates for the potential treatment of Dravet syndrome.

Manufacturing and Supply

We do not own or operate, and currently have no plans to establish or own any manufacturing facilities with respect to the manufacture of Fintepla or any future product candidates. In February 2019, we entered into a master supply agreement with Aptuit pursuant to which Aptuit will be our commercial manufacturer and supplier of the fenfluramine API used in Fintepla. The term of the master supply agreement is five years, which term shall be automatically extended for successive two year periods thereafter, unless terminated earlier. Aptuit has been providing the API to us for our clinical trial material supply needs and registration batches for the past several years.

We expect to continue to rely on third-party manufacturers to produce sufficient quantities of our product candidates and their component raw materials for use in our internal research efforts and clinical trials and in relation to any future commercialization of our product candidates. Our third-party manufacturers are responsible for obtaining the raw materials

necessary to manufacture our product candidates, which we believe are readily available from more than one source. Additional third-party manufacturers are and will be used to formulate, fill, label, package and distribute investigational drug products and eventually our products, if and when our product candidates receive approval. This approach allows us to maintain a more efficient infrastructure while enabling us to focus our expertise on developing and commercializing our product candidates. Although we believe we have multiple potential sources for the manufacture of our product candidates and their related raw materials, we currently rely on single manufacturers for different aspects of manufacturing Fintepla.

Strategic and License Agreements

In October 2014,we acquired Brabant Pharma Limited (Brabant) and obtained worldwide development and commercialization rights to Fintepla (ZX008; low-dose fenfluramine), its lead product candidate. Under the terms of the sale and purchase agreement, we agreed to make future milestone payments to the former owners of Brabant for up to $95.0 million in the event we achieve certain milestones with respect to Fintepla, consisting of $50.0 million in regulatory-related milestones and $45.0 million in sales-related milestones. In February 2019, we completed our rolling submission of a NDA with the FDA and submitted a MAA to the EMA for Fintepla for the treatment of seizures associated with Dravet syndrome. The EMA has accepted the MAA, which triggered a $10.0 million development milestone payment. An additional $10.0 million milestone payment shall become due and payable if our NDA is accepted by the FDA.

In addition, we have a collaboration and license agreement with the Universities of Antwerp and Leuven in Belgium (the Universities) that runs through September 2045. Under the terms of the agreement, the Universities granted us an exclusive worldwide license to use the data obtained from a study related to fenfluramine for the treatment of Dravet syndrome, as well as certain other intellectual property. We are required to pay a mid-single-digit percentage royalty on net sales of Fintepla for the treatment of Dravet syndrome or, in the case of a sublicense of Fintepla for the treatment of Dravet syndrome, a percentage in the mid-twenties of the sub-licensing revenues. The agreement may be terminated by the Universities if we: (a) do not use commercially reasonable efforts to (i) develop and commercialize Fintepla for the treatment of Dravet syndrome or related conditions stemming from infantile epilepsy, or (ii) seek approval of Fintepla for the treatment of Dravet syndrome in the United States; or (b) if we become insolvent or make an assignment for the benefit of creditors or should any petition in bankruptcy, or similar relief, be filed by or against us. We can terminate the agreement upon specified prior written notice to the Universities.

Intellectual Property

Our success will depend to a significant extent on our ability to obtain, expand and protect our intellectual property estate, enforce patents, maintain trade secret and trademark protection and operate without infringing the proprietary rights of other parties.

As of December 31, 2018, we have rights to four issued U.S. patents and two issued foreign patents, one of which is involved in an Opposition Proceeding in the European Patent Office. These patents, entitled “Method for the Treatment of Dravet Syndrome,” cover claims related to methods for treatment of seizures associated with Dravet syndrome with Fintepla and are expected to provide protection of the associated claims in the U.S. and other countries through 2033 and 2034, respectively. In addition, we also have 36 currently pending U.S. patent applications (which includes six provisional applications) and 74 pending foreign applications (which includes two allowed South Africa applications and seven Patent Cooperation Treaty applications) in the Fintepla series of patent cases. Our pending patent applications may not result in the issuance of any additional patents.

Government Regulation

FDA Approval Process

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act (FFDCA) and other federal and state statutes and regulations govern, among other things, the research, development, testing, manufacture, storage, record keeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling and import and export of pharmaceutical products. Failure to comply with applicable FDA or other requirements may subject a company to a variety of administrative or judicial sanctions, such as the FDA’s refusal to approve pending applications, a clinical hold, warning letters, recall or seizure of products, partial or total suspension of production, withdrawal of the product from the market, injunctions, fines, civil penalties or criminal prosecution.

FDA approval is required before any new drug or dosage form, including a new use of a previously approved drug, can be marketed in the United States. The process required by the FDA before a drug may be marketed in the United States generally involves:

- completion of pre-clinical laboratory and animal testing and formulation studies in compliance with the FDA's current good laboratory practice (GLP) regulations;
- submission to the FDA of an IND for human clinical testing which must become effective before human clinical trials may begin in the United States;
- performance of adequate and well-controlled human clinical trials in accordance with current good clinical practice (GCP) regulations, to establish the safety and efficacy of the proposed drug product for each intended use;
- submission, review and approval to the FDA of an NDA; and
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the product is produced to assess compliance with current Good Manufacturing Practice (cGMP) requirements.

The pre-clinical and clinical testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted by the FDA on a timely basis, if at all. Pre-clinical tests include laboratory evaluation of product chemistry, potency, biological activity, formulation, stability and toxicity, as well as animal studies to assess the characteristics and potential safety and efficacy of the product. The results of pre-clinical tests, together with manufacturing information, analytical data and a proposed clinical trial protocol and other information, are submitted as part of an IND to the FDA. Some pre-clinical testing may continue after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions relating to one or more proposed clinical trials, pre-clinical information or cGMP requirements and places a trial on clinical hold, 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. As a result, our submission of an IND may not result in FDA authorization to commence a clinical trial. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development.

Clinical trials involve the administration of an investigational drug to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. For purposes of an NDA submission and approval, human clinical trials are typically conducted in the following sequential phases, which may overlap or be combined:

- Phase 1: The drug is initially introduced into healthy human subjects or patients and tested for safety, dose tolerance, absorption, metabolism, distribution and excretion and, if possible, to gain an early indication of its effectiveness.
- Phase 2: The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted indications and to determine dose tolerance and optimal dosage.
- Phase 3: When Phase 2 evaluations demonstrate that a dose range of the product appears to be effective and has an acceptable safety profile, Phase 3 trials are undertaken in large patient populations to obtain additional evidence of clinical efficacy and safety in an expanded patient population at multiple, geographically-dispersed clinical trial sites.

In some cases, the FDA may condition the approval of the NDA on the sponsor's agreement to conduct additional pre-clinical and clinical studies to further assess the drug's safety and effectiveness after NDA approval. Such post-approval studies are typically referred to as Post-Marketing or Phase 4 studies.

The results of product development, pre-clinical studies and clinical trials are submitted to the FDA as part of an NDA. NDAs must also contain extensive information relating to the product's pharmacology, chemistry, manufacturing, and controls (CMC) and proposed labeling, among other things. In February 2019, we submitted a NDA to the FDA for Fintepla for the treatment of seizures associated with Dravet syndrome.

For some drugs, the FDA may determine that a Risk Evaluation and Mitigation Strategies (REMS) is necessary to ensure that the benefits of the drug outweigh the risks of the drug, and may require submission of a REMS as a condition of approval. In determining whether a REMS is necessary, the FDA considers the seriousness of known or potential adverse events, the expected benefit of the drug, the seriousness of the disease or condition to be treated, the size of the population likely to use the drug, , the duration of treatment, , and whether the drug is a new molecular entity. A REMS may be required to include various elements, such as a medication guide or patient package insert, a communication plan to educate health care 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 and other measures that the FDA deems necessary to assure the safe use of the drug. In addition, the REMS must include a timetable to assess the strategy, at a minimum, at 18 months, three years, and seven years after the strategy's approval. The submission of an NDA is additionally subject to a substantial application user fee, and the

manufacturer and/or sponsor under an approved NDA are also subject to annual program user fees. The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission has been accepted for filing, the FDA begins an in-depth substantive review.

During the FDA's review of an NDA the FDA may inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP, and if applicable, quality system regulation ("QSR") requirements (for medical device components), and are adequate to assure consistent production of the product within required specifications. Additionally, the FDA will typically inspect one or more clinical sites to assure compliance with GCP requirements before approving an NDA. The FDA may also refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it considers such recommendations carefully when making decisions.

Once the FDA's NDA review process is substantially complete, it may issue an approval letter, or it may issue a complete response letter (CRL) to indicate that the review cycle for an application is complete and that the application is not ready for approval. CRLs generally outline the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when the deficiencies have been addressed to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

The FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety problems are identified after the product reaches the market. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label, and, even if the FDA approves a product, it may limit the approved indications for use for the product or impose other conditions, including labeling or distribution restrictions or a post-market REMS requirement. Further, if there are any modifications to the drug, including changes in indications, labeling, or manufacturing processes or facilities, the sponsor is required to submit and obtain FDA approval of a new or supplemental NDA, which may require the development of additional data or conduct of additional pre-clinical studies and clinical trials.

Expedited Development and Review Programs

The FDA has a fast track designation program that is intended to expedite or facilitate the process for reviewing new drug products that meet certain criteria. Specifically, new drugs are eligible for Fast Track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Unique to a fast track product, the FDA may consider for review sections of the NDA 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 has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease 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 review applications with priority review designations within six months of the filing date as compared to ten months for review of new molecular entity NDAs under its current Prescription Drug User Fee Act (PDUFA) 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. 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. Fast track designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

The Food and Drug Administration Safety and Innovation Act established a category of drugs referred to as "breakthrough therapies" that may be eligible to receive breakthrough therapy designation. A sponsor may seek FDA designation of a product 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 work to expedite the development and review of such drug. In February 2018, granted breakthrough therapy designation for Fintepla in the United States for the treatment of Dravet syndrome.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. For example, the FDA may rescind breakthrough therapy designation for Fintepla based on an assessment of whether Fintepla continues to meet the criteria for breakthrough therapy designation in light of the FDA's approval in June 2018 of Epidiolex for the treatment of seizures associated with Dravet syndrome and the FDA's approval in August 2018 of Diacomit for the treatment of seizures associated with Dravet syndrome in patients who are also taking clobazam and neither Epidiolex nor Diacomit was approved as an existing therapy at the time the FDA granted breakthrough therapy designation for Fintepla.

Post-Approval Requirements

Once an NDA is approved, a product will be subject to continuing regulation by the FDA, including, among other things, requirements relating to drug/device listing, recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. There also are extensive U.S. Drug Enforcement Administration (DEA) regulations applicable to marketed controlled substances.

Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP or QSR requirements. Changes to the manufacturing process are strictly regulated and generally require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP or QSR and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP or QSR compliance.

The FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market, though the FDA must provide an application holder with notice and an opportunity for a hearing in order to withdraw its approval of an application. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates the marketing, labeling, advertising and promotion of drug and device products that are placed on the market. While physicians may prescribe drugs and devices for off label uses, manufacturers may only promote for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off label uses, and a company that is found to have improperly promoted off label uses may be subject to significant liability.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act (PDMA) and associated FDA regulations, which governs the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws

limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution, including a drug pedigree which tracks the distribution of prescription drugs. With the enactment of the Drug Quality and Security Act in November 2013, drug manufacturers will also be subject to requirements for identifying and tracking prescription drugs as they are distributed in the United States. The requirements of this law will be phased in over a ten-year period, including requirements for unique product identifiers and provision of product handling information to the FDA.

The FDA may require post-approval studies and clinical trials if the FDA finds they are appropriate based on available data, including information regarding related drugs. The purpose of such studies would be to assess a known serious risk or signals of serious risk related to the drug or to identify an unexpected serious risk when available data indicate the potential for a serious risk. The FDA may also require a labeling change if it becomes aware of new safety information that it believes should be included in the labeling of a drug. The FDA also has the authority to require a REMS to ensure that the benefits of a drug outweigh its risks. In determining whether a REMS is necessary, the FDA must consider the size of the population likely to use the drug, the seriousness of the disease or condition to be treated, the expected benefit of the drug, the duration of treatment, the seriousness of known or potential adverse events, and whether the drug is a new molecular entity. If the FDA determines a REMS is necessary for a new drug, the drug sponsor must submit a proposed REMS as part of its NDA prior to approval. The FDA may also impose a REMS requirement on a drug already on the market if the FDA determines, based on new safety information, that a REMS is necessary to ensure that the drug's benefits continue to 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 health care 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 and other measures that the FDA deems necessary to assure the safe use of the drug. In addition, the REMS must include a timetable to assess the strategy, at a minimum, at 18 months, three years, and seven years after the strategy's approval.

The FDA may require post-approval studies and clinical trials if the FDA finds they are appropriate based on available data, including information regarding related drugs. The purpose of such studies would be to assess a known serious risk or signals of serious risk related to the drug or to identify an unexpected serious risk when available data indicate the potential for a serious risk. The FDA may also require a labeling change if it becomes aware of new safety information that it believes should be included in the labeling of a drug. The FDA also has the authority to require a REMS to ensure that the benefits of a drug outweigh its risks. The FDA may impose a REMS requirement on a drug already on the market if the FDA determines, based on new safety information, that a REMS is necessary to ensure that the drug's benefits continue to outweigh its risks.

With respect to post-market product advertising and promotion, the FDA imposes a number of complex requirements on entities that advertise and promote pharmaceuticals, which include, among others, standards for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities, and promotional activities involving the internet and social media. The FDA has very broad enforcement authority under the FFDCA, and failure to abide by these regulations can result in penalties, including the issuance of a warning letter directing entities to correct deviations from FDA standards, a requirement that future advertising and promotional materials be pre-cleared by the FDA, and state and federal civil and criminal investigations and prosecutions.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000, there is no reasonable expectation that sales of the drug in the United States will be sufficient to offset the costs of developing and making the drug available in the United States. Orphan drug designation must be requested before submitting an NDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If the FDA approves a sponsor's marketing application for a designated orphan drug for use in the rare disease or condition for which it was designated, the sponsor is eligible for a seven-year period of marketing exclusivity, during which the FDA may not approve another sponsor's marketing application for a drug with the same active moiety and intended for the same use or indication as the approved orphan drug, except in limited circumstances, such as if a subsequent sponsor demonstrates its product is clinically superior. During a sponsor's orphan drug exclusivity period, competitors, however, may receive approval for drugs with different active moieties for the same indication as the approved orphan drug, or for drugs with the same active moiety as the approved orphan drug, but for different indications. Orphan drug exclusivity could block the approval of one of our products for seven years if a competitor obtains approval for a drug with the same active moiety intended for the same indication before we do, unless we are able to demonstrate that grounds for withdrawal of the orphan drug exclusivity exist, or that our product is clinically superior. Further, if a designated orphan drug receives marketing approval for

an indication broader than the rare disease or condition for which it received orphan drug designation, it may not be entitled to exclusivity.

Fintepla has received orphan drug designation in the United States and the EU for the treatment of Dravet syndrome and LGS. We may seek orphan drug designation for Fintepla for a different indication, or other product candidates, but the FDA may disagree with our analysis of the prevalence of the particular disease or condition or other criteria for designation and refuse to grant orphan status. We cannot guarantee that we will obtain orphan drug designation or approval for any product candidate, or that we will be able to secure orphan drug exclusivity if we do obtain approval.

Section 505(b)(2) New Drug Applications

An applicant may submit an NDA under Section 505(b)(2) of the FFDCA to seek approval for modifications or new uses of products previously approved by the FDA. Section 505(b)(2) was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Amendments, and permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely upon published literature and the FDA's previous findings of safety and effectiveness for an approved product based on the prior pre-clinical or clinical trials conducted for the approved product. The FDA may also require companies to perform new studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

To the extent that a Section 505(b)(2) NDA relies on studies conducted for a previously approved drug product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's current list of "Approved Drug Products with Therapeutic Equivalence Evaluations," known as the Orange Book. Specifically, the applicant must certify for each listed patent that (1) the required patent information has not been filed; (2) the listed patent has expired; (3) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patent is invalid, unenforceable or will not be infringed by the new product. A certification that the new product will not infringe the already approved product's listed patent or that such patent is invalid is known as a Paragraph IV certification. If the applicant does not challenge the listed patents through a Paragraph IV certification, the Section 505(b)(2) NDA application will not be approved until all the listed patents claiming the referenced product have expired. The Section 505(b)(2) NDA application also will not be accepted or approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a New Chemical Entity, listed in the Orange Book for the referenced product, has expired.

If the 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the referenced NDA and patent holders once the 505(b)(2) NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a legal challenge based on the Paragraph IV certification. Under the FFDCA, if a patent infringement lawsuit is filed against the 505(b)(2) NDA applicant within 45 days of receipt of the Paragraph IV certification notice, an automatic stay of approval is imposed, which prevents the FDA from approving the Section 505(b)(2) NDA for 30 months, or until a court decision or settlement finding that the patent is invalid, unenforceable or not infringed, whichever is earlier. The court also has the ability to shorten or lengthen the 30 month stay if either party is found not to be reasonably cooperating in expediting the litigation. Thus, the 505(b)(2) NDA applicant may invest a significant amount of time and expense in the development of its product only to be subject to significant delay and patent litigation before its product may be commercialized.

The 505(b)(2) NDA applicant may be eligible for its own regulatory exclusivity period, such as three-year new product exclusivity. The first approved 505(b)(2) applicant for a particular condition of approval, or change to a marketed product, such as a new extended-release formulation for a previously approved product, may be granted three-year Hatch-Waxman exclusivity if one or more clinical trials, other than bioavailability or bioequivalence studies, was essential to the approval of the application and was conducted/sponsored by the applicant. Should this occur, the FDA is precluded from making effective any other application for the same condition of use or for a change to the drug product that was granted exclusivity until after that three-year exclusivity period has expired. Additional exclusivities may also apply, such as an added six-month pediatric exclusivity period based on studies conducted in pediatric patients under a written request from the FDA.

Additionally, the 505(b)(2) NDA applicant may list its own relevant patents in the Orange Book, and if it does, it can initiate patent infringement litigation against subsequent applicants that challenge such patents, which could result in a 30-month stay delaying those applicants.

DEA Regulation

The Controlled Substances Act of 1970 (CSA) establishes registration, security, recordkeeping, reporting, storage, distribution and other requirements administered by the DEA. The DEA is concerned with the control of handlers of controlled substances, and with the equipment and raw materials used in their manufacture and packaging, in order to prevent loss and diversion into illicit channels of commerce.

The DEA regulates controlled substances as Schedule I, II, III, IV or V substances. Schedule I substances by definition have no established medicinal use, and may not be marketed or sold in the United States. A pharmaceutical product may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances.

Fenfluramine, the active ingredient in Fintepla, is currently regulated as a Schedule IV drug in the United States. Substances in Schedule IV are considered to have a low potential for abuse relative to substances in Schedule III. A prescription for controlled substances in Schedules III, IV, and V issued by a practitioner, may be communicated either orally, in writing, or by facsimile to the pharmacist, and may be refilled if so authorized on the prescription or by call-in. Many commonly prescribed sleep aids (e.g., Ambien®, Sonata®), most benzodiazepines (e.g., Ativan®, Valium®, Versed®, Diastat®, Onfi®) and some weight loss drugs (e.g., Belviq®, Qsymia®) are also regulated as Schedule IV drugs.

Annual registration is required for any facility that manufactures, distributes, dispenses, imports or exports any controlled substance. The registration is specific to the particular location, activity and controlled substance schedule. For example, separate registrations are needed for import and manufacturing, and each registration will specify which schedules of controlled substances are authorized.

The DEA typically inspects a facility to review its security measures prior to issuing a registration. Security requirements vary by controlled substance schedule, with the most stringent requirements applying to Schedule I and Schedule II substances. Required security measures include background checks on employees and physical control of inventory through measures such as cages, surveillance cameras and inventory reconciliations. Records must be maintained for the handling of all controlled substances, and periodic reports made to the DEA. Reports must also be made for thefts or losses of any controlled substance, and authorization must be obtained to destroy any controlled substance. In addition, special authorization and notification requirements apply to imports and exports.

To meet its responsibilities, the DEA conducts periodic inspections of registered establishments that handle controlled substances. Failure to maintain compliance with applicable requirements, particularly as manifested in loss or diversion, can result in enforcement action that could have a material adverse effect on our business, results of operations and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In certain circumstances, violations could eventuate in criminal proceedings.

Individual states also regulate controlled substances, and we and our contract manufacturers will be subject to state regulation on distribution of these products.

International Regulation

In addition to regulations in the United States, we are subject to a variety of foreign regulations regarding safety and efficacy and governing, among other things, clinical trials and commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain the necessary approvals by the comparable and respective regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and can involve additional product testing and additional review periods, and the time may be longer or shorter than that required to obtain FDA approval and, if applicable, DEA classification. The requirements governing, among other things, the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

Under EU regulatory systems, marketing authorizations may be submitted either under a centralized or decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all EU member states. The decentralized procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and assessment report, each member state must decide whether to recognize approval. In February 2019, we submitted a MAA for Fintepla for the treatment of seizures associated with Dravet syndrome under a centralized procedure to the EMA, which has accepted the MAA and initiated its review.

In addition to regulations in Europe and the United States, we are subject to a variety of other foreign regulations governing, among other things, the conduct of clinical trials, pricing and reimbursement and commercial distribution of our products. If we fail to comply with applicable foreign regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Healthcare Fraud and Abuse Laws

We are subject to various federal, state and local laws targeting fraud and abuse in the healthcare industry. These laws are applicable to manufacturers of products regulated by the FDA, such as us, and hospitals, physicians and other potential purchasers of such products.

In particular, the federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made under a federal healthcare program such as the TRICARE, Medicare and Medicaid programs. The term "remuneration" is not defined in the federal Anti-Kickback Statute and has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payments, ownership interests and providing anything at less than its fair market value. Moreover, the lack of uniform court interpretation of the Anti-Kickback Statute makes compliance with the law difficult. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, 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 civil False Claims Act (discussed below) or the civil monetary penalties statute, which imposes fines against any person who is determined to have presented or caused to be presented claims to a federal health care 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.

Additionally, many states have adopted laws similar to the federal Anti-Kickback Statute. Some of these state prohibitions apply to referral of patients for healthcare items or services reimbursed by any third-party payor, not only the Medicare and Medicaid programs in at least some cases, and do not contain safe harbors or statutory exceptions. Government officials have focused their enforcement efforts on marketing of healthcare services and products, among other activities, and have brought cases against numerous pharmaceutical and medical device companies, and certain sales and marketing personnel for allegedly offering unlawful inducements to potential or existing customers in an attempt to procure their business or reward past purchases or recommendations.

Another development affecting the healthcare industry is the increased use of the federal civil and criminal false claims laws, including the federal civil False Claims Act and, in particular, actions brought pursuant to the False Claims Act's "whistleblower" or "qui tam" provisions. The civil False Claims Act imposes liability on any person or entity who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. The qui tam provisions of the False Claims Act allow a private individual to bring civil actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government, and to share in any monetary recovery. In recent years, the number of suits brought by private individuals has increased dramatically. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties of $11,463 to $22,927 for each separate false claim. The False Claims Act has been used to assert liability on the basis of inadequate care, kickbacks and other improper referrals, improperly reported government pricing metrics such as Best Price or Average Manufacturer Price and improper promotion of off-label uses (i.e., uses not expressly approved by FDA in a drug's label). In addition, various states have enacted false claim laws analogous to the False Claims Act. Many of these state laws apply where a claim is submitted to any third-party payor and not merely a federal healthcare program.

The federal Civil Monetary Penalties Law prohibits, among other things, the offering or transferring of remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of Medicare or Medicaid payable items or services. Noncompliance with such beneficiary inducement provision of the federal Civil Monetary Penalties Law can result in civil money penalties for each wrongful act, assessment of three times the amount claimed for each item or service and exclusion from the federal healthcare programs.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) created several new federal crimes, including health care fraud, and false statements relating to health care matters. The health care fraud statute prohibits knowingly and willfully executing a scheme to defraud any health care benefit program, including private third-party payors. The false statements statute prohibits 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 health care benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the PPACA, also imposes new reporting and disclosure requirements on drug manufacturers for any "transfer of value" made or distributed to prescribers and other healthcare providers, and any ownership or investment interests held by physicians and their immediate family members during the preceding calendar year. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $165,786 per year (and up to an aggregate of $1.105 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests not reported in an annual submission. Manufacturers are required to report such data to the government by the 90th day of each calendar year.

Under California law, pharmaceutical companies must adopt a comprehensive compliance program that is in accordance with both the Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers (OIG Guidance) and the Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals (PhRMA Code). The PhRMA Code seeks to promote transparency in relationships between health care professionals and the pharmaceutical industry and to ensure that pharmaceutical marketing activities comport with the highest ethical standards. The PhRMA Code contains strict limitations on certain interactions between health care professionals and the pharmaceutical industry relating to gifts, meals, entertainment and speaker programs, among others. Also, certain states have imposed restrictions on the types of interactions that pharmaceutical companies or their agents (e.g., sales representatives) may have with health care professionals, including bans or strict limitations on the provision of meals, entertainment, hospitality, travel and lodging expenses, and other financial support, including funding for continuing medical education activities.

Federal and state government price reporting laws require manufacturers to calculate and report complex pricing metrics to government programs. Such reported prices may be used in the calculation of reimbursement and/or discounts on marketed products. Participation in these programs and compliance with the applicable requirements subject manufacturers to potentially significant discounts on products, increased infrastructure costs, and potentially limit the ability to offer certain marketplace discounts.

Healthcare Privacy and Security Laws

We may be subject to, or our marketing activities may be limited by, HIPAA, and its implementing regulations, including the final omnibus rule published on January 25, 2013, which established uniform standards for certain "covered entities" (healthcare providers, health plans and healthcare clearinghouses) governing the conduct of certain electronic healthcare transactions and protecting the security and privacy of protected health information. The American Recovery and Reinvestment Act of 2009, commonly referred to as the economic stimulus package, included sweeping expansion of HIPAA's privacy and security standards called the Health Information Technology for Economic and Clinical Health Act (HITECH) which became effective on February 17, 2010. Among other things, the new law makes HIPAA's privacy and security standards directly applicable to "business associates" — independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition to HIPAA and HITECH, there are state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act and CCPA), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators.

We are also subject to foreign privacy laws in the foreign jurisdictions in which we sell our testing products. The interpretation, application and interplay of consumer and health-related data protection laws in the U.S., Europe and elsewhere are often uncertain, contradictory and in flux. For example, the European Union enacted Regulation (EU) 2016/679 (General Data Protection Regulation, or GDPR), has been enacted in the European Union and went into full effect in May 2018. These texts introduce many changes to privacy and security in the European Union, including stricter rules on consent and security duties for critical industries, including for the health sector. The interpretation of some rules is still unclear, and some requirements will be completed by national legislation. More generally, foreign laws and interpretations governing data privacy and security are constantly evolving and it is possible that laws may be interpreted and applied in a manner that is inconsistent with current practices, subjecting entities to government-imposed fines or orders. These fines can be very high. For instance, the GDPR introduces fines of up to EUR 20 million or 4% of a group's worldwide annual turnover for certain infringements. In addition, privacy regulations differ widely from country to country.

Third-Party Payor Coverage and Reimbursement

The commercial success of our product candidates, if and when commercialized, will depend, in part, upon the availability of coverage and reimbursement from third-party payors at the federal, state and private levels. Third-party payors include governmental programs such as Medicare or Medicaid, private insurance plans and managed care plans. These third

-party payors may deny coverage or reimbursement for a product or therapy in whole or in part if they determine that the product or therapy was not medically appropriate or necessary. Also, third-party payors have attempted to control costs by limiting coverage through the use of formularies and other cost-containment mechanisms and the amount of reimbursement for particular procedures or drug treatments.

Changes in third-party payor coverage and reimbursement rules can impact our business. For example, the PPACA changes include increased rebates a manufacturer must pay to the Medicaid program, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, and established a new Medicare Part D coverage gap discount program, in which manufacturers must provide 50% point-of-sale discounts on products covered under Part D. Further, the law imposes a significant annual, nondeductible fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may require us to modify our business practices with health care practitioners. The Bipartisan Budget Act of 2018 increased the point-of-sale discount manufacturers must agree to offer under the Medicare part D coverage gap discount program from 50% to 70%, starting in 2019. Additionally, on December 14, 2018, a U.S. District Court Judge in the Northern District of Texas ("Texas District Court Judge"), ruled that the entire PPACA is invalid based primarily on the fact that the Tax Cuts and Jobs Act of 2017 repealed the tax-based shared responsibility payment imposed by the PPACA, on certain individuals who fail to maintain qualifying health coverage for all or part of a year, which is commonly referred to as the "individual mandate". While the Texas District Court Judge, as well as the current presidential administration and CMS, have stated that this ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the PPACA will impact the PPACA. PPACA and other healthcare reform measures continue to put pressure on pharmaceutical pricing, as well as increase our regulatory burdens and operating costs.

Other legislative changes have also been proposed and adopted in the United States since the PPACA was enacted. For example, in August 2011, the Budget Control Act of 2011, among other things included aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013, and, due to subsequent legislative amendments to the statute, will remain in effect through 2027 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Recently, there has been heightened governmental scrutiny over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted 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 drug products. Individual states have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and to encourage importation from other countries and bulk purchasing. These new laws may result in additional reductions in Medicare and other health care funding, which could have a material adverse effect on our customers and accordingly, our financial operations.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. There can be no assurance that our products will be considered medically reasonable and necessary for a specific indication, that our products will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be established even if coverage is available or that the third-party payors' reimbursement policies will not adversely affect our ability to sell our products profitably.

Manufacturing Requirements

We and our third-party manufacturers must comply with applicable FDA regulations relating to FDA's cGMP regulations and, if applicable, QSR requirements. The cGMP regulations include requirements relating to, among other things, organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports, and returned or salvaged products. The manufacturing facilities for our products must meet cGMP requirements to the satisfaction of the FDA pursuant to a pre-approval inspection before we can use them to manufacture our products. We and our third-party manufacturers are also subject to periodic unannounced inspections of facilities by the FDA and other authorities, including procedures and operations used in the testing and manufacture of our products to assess our compliance with applicable regulations. Failure to comply with statutory and regulatory requirements subjects a manufacturer to possible legal or regulatory action, including, among other things, warning letters, the seizure or recall of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations and civil and criminal penalties.

Other Regulatory Requirements

We are also subject to various laws and regulations regarding laboratory practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances in connection with our research. In each of these areas, as above, the FDA has broad regulatory and enforcement powers, including, among other things, the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals, any one or more of which could have a material adverse effect on us.

Employees

As of December 31, 2018, we employed 90 full-time employees. Of the full-time employees, 60 were engaged in product development, quality assurance and clinical development and regulatory activities, 7 were engaged in sales and marketing and 23 were engaged in general and administrative activities (including business and corporate development).

None of our employees are represented by a labor union, and we consider our employee relations to be good. We currently utilize two employer services companies to provide human resource services. These service companies are the employer of record for payroll, benefits, employee relations and other employment-related administration.

About Zogenix

We were formed as a Delaware corporation on May 11, 2006 as SJ2 Therapeutics, Inc. We changed our name to Zogenix, Inc. on August 28, 2006. Our principal executive offices are located at 5858 Horton Street, Suite 455, Emeryville, California 94608, and our telephone number is (510) 550-8300. We conduct our research and development activities and general and administrative functions primarily from our Emeryville, California location.

Available Information

Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports, are available for free at www.zogenix.com as soon as reasonably practicable after they are electronically filed with or furnished to the Securities and Exchange Commission (SEC). They are also available for free on the SEC's website at www.sec.gov. The information in or accessible through the SEC and our website are not incorporated into, and are not considered part of, this filing.

Item 1A. Risk Factors

We operate in a dynamic and rapidly changing environment that involves numerous risks and uncertainties. Certain factors may have a material adverse effect on our business prospects, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, in its entirety, in addition to other information contained in this Annual Report on Form 10-K and our other public filings with the Securities and Exchange Commission (SEC). Other events that we do not currently anticipate or that we currently deem immaterial may also affect our business, prospects, financial condition and results of operations.

Risks Related to Our Business and Industry

Our success depends substantially on our only product candidate in development, Fintepla. We cannot be certain that Fintepla or our product candidates will receive regulatory approval or be successfully commercialized.

We have only one product candidate in clinical development, Fintepla, and our business depends substantially on its successful development and commercialization. We currently have no drug products approved for sale, and we may not be able to develop marketable drug products in the future. Fintepla and our product candidates will require additional clinical and pre-clinical development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenues from product sales. The research, testing, manufacturing, labeling, approval, sale, marketing, distribution and promotion of drug products are subject to extensive regulation by the U.S. Food and Drug Administration (FDA) and other regulatory authorities in the United States and other countries, whose regulations differ from country to country.

We are not permitted to market our product candidates in the United States until we receive approval of a New Drug Application (NDA) from the FDA, or in any foreign countries until we receive the requisite approval from the regulatory authorities of such countries, and we may never receive such regulatory approvals. In February 2019, we completed our rolling submission of a NDA with the FDA and submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for Fintepla for the treatment of seizures associated with Dravet syndrome. The EMA has accepted the MAA and initiated its review. However, obtaining regulatory approval for a product candidate is a lengthy, expensive and uncertain process, and may not be successful. Any failure to obtain regulatory approval of Fintepla or our product candidates, or failure to obtain such approval for all of the indications and labeling claims we deem desirable, would limit our ability to generate future revenues, would potentially harm the development prospects of Fintepla and would have a material and adverse impact on our business.

Even if we successfully obtain regulatory approvals to market our product candidates, our revenues will be dependent, in part, on our ability to commercialize such products as well as the size of the markets in the territories for which we gain regulatory approval. If the markets for our product candidates are not as significant as we estimate, our business and prospects will be harmed.

Our clinical trials may fail to demonstrate acceptable levels of safety and efficacy for Fintepla or our product candidates, which could prevent or significantly delay their regulatory approval.

Fintepla and our product candidates are prone to the risks of failure inherent in drug development. Before obtaining U.S. regulatory approval for the commercial sale of Fintepla or our product candidates, we must gather substantial evidence from well-controlled clinical trials that demonstrate to the satisfaction of the FDA that the product candidate in question is safe and effective, and similar regulatory approvals would be necessary to commercialize our product candidates in other countries. Failure can occur at any stage of our clinical trials, and we could encounter problems that cause us to abandon or repeat clinical trials.

A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. If Fintepla is not shown to be safe and effective in clinical trials, the programs could be delayed or terminated, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

The results of previous clinical trials may not be predictive of future results, and the results of our current and planned clinical trials may not satisfy the requirements of the FDA or non-U.S. regulatory authorities.

The results from the prior clinical trials of Fintepla discussed elsewhere in this report may not necessarily be predictive of the results of future clinical trials or preclinical studies. Even if we are able to complete our planned clinical trials of Fintepla according to our current development timeline, the results from our prior clinical trials of Fintepla may not be replicated in these future trials. Clinical data are often susceptible to varying interpretations and analyses, and many companies that believed

their product candidates performed satisfactorily in prior clinical trials nonetheless have failed to obtain FDA approval. If we fail to produce positive results in our clinical trials of Fintepla, the development timeline and regulatory approval and commercialization prospects for Fintepla and our business and financial prospects, would be adversely affected.

Further, Fintepla may not be approved even though recent, positive top-line results showed that Fintepla met its primary and all key secondary endpoints in our ongoing Phase 3 clinical trials. The FDA or non-U.S. regulatory authorities may disagree with our trial design and our interpretation of data from preclinical studies and clinical trials. In addition, any of these regulatory authorities may change its requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a pivotal clinical trial that, if successful, would potentially form the basis for an application for approval by the FDA or another regulatory authority. Furthermore, any of these regulatory authorities may also approve our product candidates for fewer or more limited indications than we request or may grant approval contingent on the performance of costly post-marketing clinical trials.

Top-line data may not accurately reflect the complete results of a particular study or trial.

We may publicly disclose top-line or interim data from time to time, which is based on a preliminary analysis of then-available efficacy and safety data such as the top-line results we reported from Study 1504, 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 we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, top-line data should be viewed with caution until the final data are available. Further, 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 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. If the top-line data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Delays in the commencement or completion of clinical testing for Fintepla or pre-clinical or clinical testing for our product candidates could result in increased costs to us and delay or limit our ability to pursue regulatory approval for, or generate revenues from, such product candidates.

Clinical trials are very expensive, time consuming and difficult to design and implement. Delays in the commencement or completion of clinical testing for Fintepla or pre-clinical or clinical testing for our product candidates could significantly affect our product development costs and business plan.

Our Phase 3 program for Fintepla includes three randomized, double-blind placebo-controlled clinical trials of Fintepla as adjunctive therapy for patients with uncontrolled seizures who have Dravet syndrome and one randomized, double-blind placebo-controlled clinical trial of Fintepla for patients with Lennox-Gastaut Syndrome (LGS). In September 2017, we announced positive top line data from two identical clinical trials, Study 1501 in the U.S. and Canada and Study 1502 in Europe and Australia, which we collectively refer to as Study 1. Study 1 evaluated two dose levels of Fintepla (0.2 mg/kg/day and 0.8 mg/kg/day, up to a maximum daily dose of 30 mg) and met its primary efficacy endpoint of reducing convulsive seizures experienced by patients after treatment of Fintepla compared to treatment with a placebo. In December 2017, we reported additional data from Study 1. Study 1504 is evaluating a single dose a Fintepla (0.5 mg/kg/day, up to a maximum daily dose of 20 mg, which has been shown to be equivalent to 0.8mg/kg/day in patients not taking stiripentol), in patients taking stiripentol, valproate and/or clobazam. Study 1504 is a multi-national study commenced in the third quarter 2016 and is being conducted in western Europe and North America. We reported top-line results from the trial in July 2018. Notwithstanding the aforementioned plans, we may not be able to identify and enroll sufficient number of study participants and interpret results on these time frames, and consequently the completion of our ongoing Phase 3 clinical trials may be delayed.

In November 2017, we enrolled our first patient in our Phase 3 clinical trial of Fintepla as an adjunctive treatment of seizures associated with LGS, Study 1601. Study 1601 is divided in two parts. Part 1 is a double-blind, placebo-controlled investigation to assess the safety, tolerability and efficacy of Fintepla, low-dose fenfluramine, when added to a patient's current

anti-epileptic therapy. The trial will include two dose levels of Fintepla (0.2 mg/kg/day and 0.8 mg/kg/day, up to a maximum daily dose of 30 mg), as well as placebo. After establishing baseline seizure frequency for 4 weeks, randomized patients will be titrated to their dose over a 2-week titration period, followed by a 12-week fixed dose maintenance period. We are targeting a total of 225 patients (75 per treatment arm) in the trial. The primary endpoint of the clinical trial is change in the number of seizures that result in drops between baseline and the combined titration and maintenance periods at the 0.8 mg/kg/day dose. Part 2 of Study 1601 will be a 12-month open-label extension to evaluate the long-term safety, tolerability and effectiveness of Fintepla.

The completion of clinical trials can be delayed for a number of reasons, including delays related to:

- obtaining regulatory authorization to commence a clinical trial;
- reaching agreement on acceptable terms with clinical research organization (CROs), clinical investigators and trial sites;
- manufacturing or obtaining sufficient quantities of a product candidate and placebo for use in clinical trials;
- obtaining institutional review board (IRB) approval to initiate and conduct a clinical trial at a prospective site;
- identifying, recruiting and training suitable clinical investigators;
- identifying, recruiting and enrolling subjects to participate in clinical trials for a variety of reasons, including competition from other clinical trial programs for the treatment of similar indications;
- retaining patients who have initiated a clinical trial but may be prone to withdraw due to side effects from the therapy, lack of efficacy, personal issues, or for any other reason they choose, or who are lost to further follow-up;
- uncertainty regarding proper dosing; and
- scheduling conflicts with participating clinicians and clinical institutions.

In addition, if a significant number of patients fail to stay enrolled in any of our current or future clinical trials of Fintepla and such failure is not adequately accounted for in our trial design and enrollment assumptions, our clinical development program could be delayed. Clinical trials may also be delayed or repeated as a result of ambiguous or negative interim results or unforeseen complications in testing. In addition, a clinical trial may be suspended or terminated by us, the FDA, the IRB overseeing the clinical trial at issue, any of our clinical trial sites with respect to that site, or other regulatory authorities due to a number of factors, including:

- inability to design appropriate clinical trial protocols;
- inability by us, our employees, our CROs or their employees to conduct the clinical trial in accordance with all applicable FDA, drug enforcement administration (DEA) or other regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- discovery of serious or unexpected toxicities or side effects experienced by study participants or other unforeseen safety issues;
- lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and increased expenses associated with the services of our CROs and other third parties;
- lack of effectiveness of any product candidate during clinical trials;
- slower than expected rates of subject recruitment and enrollment rates in clinical trials;
- inability of our CROs or other third-party contractors to comply with all contractual requirements or to perform their services in a timely or acceptable manner;
- inability or unwillingness of medical investigators to follow our clinical protocols; and
- unfavorable results from on-going clinical trials and pre-clinical studies.

Additionally, changes in applicable regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to the FDA and IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial. If we experience delays in the completion of, or if we terminate, any of our clinical trials, the commercial prospects for Fintepla and our product candidates may be harmed, which may have a material adverse effect on our business, results of operations, financial condition and prospects.

Fast Track designation for Fintepla may not lead to a faster development or review process.

We have been granted a Fast Track designation for Fintepla in the United States for the treatment of Dravet syndrome. The Fast Track program is intended to expedite or facilitate the process for reviewing new drug candidates that meet certain criteria. Specifically, new drugs are eligible for Fast Track designation if they are intended, alone or in combination with one or more drugs, to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast Track designation applies to the combination of the drug candidate and the specific indication for which it is being studied. With a Fast Track drug candidate, the FDA may consider for review sections of the NDA 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.

Obtaining a Fast Track designation does not change the standards for product approval, but may expedite the development or approval process. Even though the FDA has granted such designation for Fintepla, it may not actually result in faster clinical development or regulatory review or approval. Furthermore, such a designation does not increase the likelihood that Fintepla will receive marketing approval in the United States.

Any breakthrough therapy designation that we may receive from the FDA for our product candidates may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval.

In February 2018, the FDA granted breakthrough therapy designation for Fintepla in the United States for the treatment of Dravet syndrome. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA are also eligible for accelerated approval. Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. We cannot be sure that any evaluation we may make of our product candidates as qualifying for breakthrough therapy designation will meet the FDA's expectations. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that such product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. For example, the FDA may rescind breakthrough therapy designation for Fintepla based on an assessment of whether Fintepla continues to meet the criteria for breakthrough therapy designation in light of the FDA's approval in June 2018 of Epidiolex for the treatment of seizures associated with Dravet syndrome and the FDA's approval in August 2018 of Diacomit for the treatment of seizures associated with Dravet syndrome in patients who are also taking clobazam and neither Epidiolex nor Diacomit was approved as an existing therapy at the time the FDA granted breakthrough therapy designation for Fintepla.

If the FDA does not conclude that certain of our product candidates satisfy the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements for such product candidates under Section 505(b)(2) are not as we expect, the approval pathway for those product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.

We are developing proprietary product candidates, including Fintepla, for which we may seek FDA approval through the Section 505(b)(2) regulatory pathway. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the Federal Food, Drug and Cosmetic Act (FDCA). Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from trials that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2), if applicable to us under the FDCA, would allow an NDA we submit to the FDA to rely in part on data in the public domain or the FDA's prior

conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development program for our product candidates by potentially decreasing the amount of clinical data that we would need to generate in order to obtain FDA approval. If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as we anticipated, we may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval.

Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot assure you that our product candidates will receive the requisite approvals for commercialization. In addition, the pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505(b)(2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our NDAs for up to 30 months or longer depending on the outcome of any litigation. It is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. However, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. In addition, even if we are able to utilize the Section 505(b)(2) regulatory pathway, there is no there is no guarantee this would ultimately lead to accelerated product development or earlier approval.

Moreover, even if our product candidates are approved under Section 505(b)(2), the approval may be subject to limitations on the indicated uses for which the products may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the products.

We have limited sales and marketing resources, and we may not be able to effectively market and sell our products.

We do not currently have all the necessary components of an organization for sales, marketing and distribution of pharmaceutical products, and therefore we must build this organization or make arrangements with third parties to perform these functions in order to commercialize any products that we successfully develop and for which we obtain regulatory approvals. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain sales and marketing personnel. We will also face competition in our search for collaborators and potential co-promoters, if we choose such an option. To the extent we may rely on third parties to co-promote or otherwise commercialize any product candidates in one or more regions that may receive regulatory approval, we are likely to receive less revenue than if we commercialized these products ourselves. Further, by entering into strategic partnerships or similar arrangements, we may rely in part on such third parties for financial and commercialization resources. Even if we are able to identify suitable partners to assist in the commercialization of our product candidates, they may be unable to devote the resources necessary to realize the full commercial potential of our products.

Further, we may lack the financial and managerial resources to establish a sales and marketing organization to adequately promote and commercialize any product candidates that may be approved. The establishment of a sales force will result in an increase in our expenses, which could be significant before we generate revenues from any newly approved product candidate. Even though we may be successful in establishing future partnership arrangements, such sales force and marketing teams may not be successful in commercializing our products, which would adversely affect our ability to generate revenue for such products, and could have a material adverse effect on our business, results of operations, financial condition and prospects.

We face intense competition, and if our competitors market and/or develop treatments for Dravet syndrome or other CNS disorders that are marketed more effectively, approved more quickly than our product candidates or demonstrated to be safer or more effective than our products, our commercial opportunities will be reduced or eliminated.

The pharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary therapeutics. We face competition from a number of sources, some of which may target the same indications as our product candidates, including large pharmaceutical companies, smaller pharmaceutical companies, biotechnology companies, academic institutions, government agencies and private and public research institutions, many of which have greater financial resources, sales and marketing capabilities, including larger, well-established sales forces, manufacturing capabilities, experience in obtaining regulatory approvals for product candidates and other resources than we do.

If approved for the chronic treatment of Dravet syndrome, Fintepla may compete against other products and product candidates. In June 2018, the FDA approved the first treatment of seizures associated with Dravet syndrome, as well as LGS, GW Pharmaceuticals' Epidiolex® (cannabidiol or CBD). Epidiolex is a liquid drug formulation of plant-derived purified cannabidiol, or CBD, which is a chemical component of the Cannabis sativa plant, more commonly known as marijuana. In August 2018, the FDA approved a second treatment, Biocodex's Diacomit® (stiripentol), for the treatment of seizures associated with Dravet syndrome in patients who are also taking clobazam. Stiripentol is approved in Europe, Canada, Australia and Japan for the treatment of Dravet syndrome when used in conjunction with valproate and/or clobazam. GW

Pharmaceuticals plc has filed a MAA in Europe for CBD in Dravet syndrome and LGS. Insys Therapeutics (Insys) is developing a synthetic cannabidiod (CBD) for the treatment of pediatric epilepsies, including Dravet syndrome. Insys previously advanced its synthetic CBD program, which has received orphan drug designation and Fast Track status by the FDA for use of CBD as a potential treatment for Dravet syndrome, into a Phase 1/2 clinical trial. Insys initiated Phase 2 development of its CBD product candidate for childhood absence epilepsy in December of 2017 and initiated a Phase 3 trial in infantile spasms, a pediatric epilepsy syndrome, in the first quarter of 2018. Ovid Therapeutics, Inc. is currently evaluating its product candidate OV935, a first-in-class inhibitor of the enzyme cholesterol 24-hydroxylase (CH24H), for the potential treatment of adult and pediatric patients with Dravet syndrome and LGS in Phase 2 clinical trials.

We expect Fintepla, if approved, to compete on the basis of, among other things, product efficacy and safety, time to market, price, coverage and reimbursement by third-party payors, extent of adverse side effects and convenience of treatment procedures. One or more of our competitors may develop other products that compete with ours, obtain necessary approvals for such products from the FDA, or other agencies, if required, more rapidly than we do or develop alternative products or therapies that are safer, more effective and/or more cost effective than any products developed by us. The competition that we will encounter with respect to any of our product candidates that receive the requisite regulatory approval and classification and are marketed will have an effect on our product prices, market share and results of operations. We may not be able to successfully differentiate any products that we are able to market from those of our competitors, successfully develop or introduce new products that are less costly or offer better results than those of our competitors or offer purchasers of our products payment and other commercial terms as favorable as those offered by our competitors. In addition, competitors may seek to develop alternative formulations of our product candidates and/or alternative drug delivery technologies that address our targeted indications.

The commercial opportunity for our product candidates could be significantly harmed if competitors are able to develop alternative formulations and/or drug delivery technologies outside the scope of our products. Compared to us, many of our potential competitors have substantially greater:

- capital resources;
- research and development resources, expertise and experience, including personnel and technology;
- drug development, clinical trial and regulatory resources and experience;
- sales and marketing resources and experience;
- manufacturing and distribution resources and experience;
- name recognition; and
- resources, experience and expertise in prosecution and enforcement of intellectual property rights.

As a result of these factors, our competitors may obtain regulatory approval of their products more rapidly than we are able to or may obtain patent protection or other intellectual property rights that limit or block us from developing or commercializing our product candidates. Our competitors may also develop drugs that are more effective, more useful, better tolerated, subject to fewer or less severe side effects, more widely prescribed or accepted or less costly than ours and may also be more successful than we are in manufacturing and marketing their products. If we are unable to compete effectively with the marketed therapeutics of our competitors or if such competitors are successful in developing products that effectively compete with any of our product candidates that are approved, our business, results of operations, financial condition and prospects may be materially adversely affected.

If Fintepla receives regulatory approval but does not achieve broad market acceptance or coverage by third-party payors, the revenues that we generate will be limited.

The commercial success of Fintepla, if approved by the FDA or other regulatory authorities will depend upon the acceptance of these products by physicians, patients, healthcare payors and the medical community. Adequate coverage and reimbursement of our approved product by third-party payors will also be critical for commercial success. The degree of market acceptance of any product candidates for which we may receive regulatory approval will depend on a number of factors, including:

- acceptance by physicians and patients of the product as a safe and effective treatment;
- any negative publicity or political action related to our or our competitors' products;

- the relative convenience and ease of administration;
- the prevalence and severity of adverse side effects;
- demonstration to authorities of the pharmacoeconomic benefits;
- demonstration to authorities of the improvement in burden of illness;
- limitations or warnings contained in a product's FDA-approved or EMA approved labeling;
- the clinical indications for which a product is approved;
- availability and perceived advantages of alternative treatments;
- the effectiveness of our or any current or future collaborators' sales, marketing and distribution strategies;
- pricing and cost effectiveness;
- our ability to obtain sufficient U.S. third-party payor coverage and reimbursement;
- our ability to obtain European countries' pricing authorities' coverage and reimbursement; and
- the willingness of patients to pay out of pocket in the absence of third-party payor coverage.

Our efforts to educate the medical community, U.S. third-party payors and European countries' health authorities on the benefits of Fintepla or any of our product candidates for which we obtain marketing approval from the FDA or other regulatory authorities and gain broad market acceptance may require significant resources and may never be successful. If our products do not achieve an adequate level of acceptance by physicians, third-party payors, pharmacists, patients, and the medical community, we may not generate sufficient revenue from these products to become or remain profitable.

We have a history of significant net losses and negative cash flow from operations. We cannot predict if or when we will become profitable and anticipate that our net losses and negative cash flow from operations will continue for at least the next year.

We were organized in 2006, began commercialization of Sumavel DosePro in January 2010 and launched the commercial sale of Zohydro ER in the United States in March 2014. We sold our Sumavel DosePro business in April 2014 and sold our Zohydro ER business in April 2015. Our business and prospects must be considered in light of the risks and uncertainties frequently encountered by pharmaceutical companies developing and commercializing new products.

Excluding gains from two discrete business divestitures, we have incurred significant net losses from our operations since the inception and have an accumulated deficit of $696.0 million as of December 31, 2018. In 2018, we used $111.7 million of cash in operations. We expect to continue to incur operating losses and negative cash flow from operating activities for at least the next year primarily as a result of costs incurred related to the development and commercialization of Fintepla. Additionally, in the event that Fintepla is approved in the United States or the EU, we will owe milestone payments related to our 2014 acquisition of worldwide development and commercialization rights to Fintepla. Our ability to generate revenues from Fintepla will depend on a number of factors including our ability to successfully complete clinical trials, obtain necessary regulatory approvals and negotiate arrangements with third parties to help finance the development of, and market and distribute, any product candidates that receive regulatory approval. In addition, we are subject to the risk that the marketplace will not accept our products.

Because of the numerous risks and uncertainties associated with our commercialization and product development efforts, we are unable to predict the extent of our future losses or when or if we will become profitable, if at all. If we do not generate significant sales from Fintepla our product candidate that may receive regulatory approval, there would likely be a material adverse effect on our business, results of operations, financial condition and prospects which could result in our inability to continue operations.

We rely on third parties to conduct our pre-clinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We have agreements with third-party CROs to conduct our ongoing Phase 3 program for Fintepla. We rely heavily on these parties for the execution of our clinical trials and pre-clinical studies, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol

and regulatory requirements. We and our CROs are required to comply with good clinical practice (GCP) requirements for clinical studies of our product candidates, and good laboratory practice (GLP) requirements for certain pre-clinical studies. The FDA enforces these regulations through periodic inspections of trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable regulations, the data generated in our pre-clinical studies and clinical trials may be deemed unreliable and the FDA may require us to perform additional pre-clinical studies or clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA and similar foreign regulators will determine that any of our clinical trials comply or complied with GCP regulations. In addition, our clinical trials must be conducted with product produced under current good manufacturing practice (cGMP), regulations, and require a large number of test subjects. Our inability to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If any of our relationships with these third-party CROs terminates, we may not be able to enter into arrangements with alternative CROs on commercially reasonable terms, or at all. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate additional revenues could be delayed.

Switching or adding additional CROs can involve substantial cost and require extensive management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, results of operations, financial condition and prospects.

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

From time to time we may consider strategic transactions, such as acquisitions of companies, asset purchases and out-licensing or in-licensing of products, product candidates or technologies. For example, in October 2014, we completed the acquisition of Brabant, which owns worldwide development and commercialization rights to Fintepla, and in October 2016, we completed an asset purchase agreement to acquire the global rights to a preclinical development program for orphan CNS disorders. Additional potential transactions that we may consider include a variety of different business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction may require us to incur non-recurring or other charges, may increase our near and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. For example, these transactions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention in order to develop acquired products, product candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions;
- significant or higher than expected acquisition and integration costs;
- write-downs of assets or goodwill or impairment charges;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management, personnel and ownership; and
- inability to retain key employees of any acquired businesses.

Accordingly, although there can be no assurance that we will undertake or successfully complete any additional transactions of the nature described above, any additional transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition and prospects.

We are dependent on numerous third parties in our manufacturing supply chain, all of which are currently single source suppliers, for the clinical supply of Fintepla, and if we experience problems with any of these suppliers, the development of Fintepla could be delayed.

We outsource all manufacturing and packaging of the clinical trial materials for Fintepla to third parties. For example, in February 2019, we entered into a master supply agreement with Aptuit (Oxford) Limited, an Evotec company ("Aptuit"), pursuant to which Aptuit will be our commercial manufacturer and supplier of the fenfluramine active pharmaceutical ingredient (API) used in our product candidate Fintepla, if approved, would require process validation, for which there can be no assurance of success. We may never be able to establish additional sources of supply for Fintepla.

Suppliers, including Aptuit, are subject to regulatory requirements covering, among other things, testing, quality control and record keeping relating to our product candidate, and are subject to ongoing inspections by regulatory agencies. Failure by any of our suppliers to comply with applicable regulations may result in long delays and interruptions, and increase our costs, while we seek to secure another supplier who meets all regulatory requirements, including obtaining regulatory approval to utilize the new supplier. Accordingly, the loss of any of our current suppliers could have a material adverse effect on our business, results of operations, financial condition and prospects.

Reliance on suppliers entails risks to which we would not be subject if we manufactured our product candidate ourselves, including:

- reliance on the third parties for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreements by the third parties because of factors beyond our control or the insolvency of any of these third parties or other financial difficulties, labor unrest, natural disasters or other factors adversely affecting their ability to conduct their business; and
- the possibility of termination or non-renewal of the agreements by the third parties, at a time that is costly or inconvenient for us, because of our breach of the manufacturing agreement or based on their own business priorities.

If our contract manufacturers or suppliers are unable to provide the quantities of our product candidate required for our clinical trials and, if approved, for commercial sale, on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement manufacturers or suppliers capable of production at a substantially equivalent cost, in substantially equivalent volumes and quality, and on a timely basis, we would likely be unable to meet demand for our products and would have to delay or terminate our pre-clinical or clinical trials, and we would lose potential revenue. It may also take a significant period of time to establish an alternative source of supply for our products, product candidates and components and to have any such new source approved by the FDA or any applicable foreign regulatory authorities. Furthermore, any of the above factors could cause the delay or suspension of initiation or completion of clinical trials, regulatory submissions or required approvals of our product candidates, cause us to incur higher costs and could prevent us from commercializing our product candidates successfully.

If we are unable to attract and retain key personnel, we may not be able to manage our business effectively or develop our product candidates or commercialize our products.

Our success depends on our continued ability to attract, retain and motivate highly qualified management and key clinical development, regulatory, sales and marketing and other personnel. As of December 31, 2018, we employed 90 full-time employees. Of the full-time employees, 60 were engaged in product development, quality assurance and clinical and regulatory activities, 7 were engaged in sales and marketing and 23 were engaged in general and administrative activities (including business and corporate development). If we are not able to retain our employee base, we may not be able to effectively manage our business or be successful in commercializing our products.

We are highly dependent on the development, regulatory, commercial and financial expertise of our senior management team. We may not be able to attract or retain qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses, especially in the San Francisco Bay Area where we operate. If we are not able to attract, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development and commercialization objectives, our ability to raise additional capital, our ability to implement our business strategy and our ability to maintain effective internal controls for financial reporting and disclosure controls and procedures as required by the

Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act. The loss of the services of any members of our senior management team, especially our Chief Executive Officer and President, Stephen J. Farr, Ph.D., could delay or prevent the development and commercialization of Fintepla and our product candidates. Further, if we lose any members of our senior management team, we may not be able to find suitable replacements, and our business may be harmed as a result.

Although we have employment agreements with each of our executive officers, these agreements are terminable by them at will at any time with or without notice and, therefore, do not provide any assurance that we will be able to retain their services. We do not maintain "key man" insurance policies on the lives of our senior management team or the lives of any of our other employees. In addition, we have clinical advisors who assist us in formulating our clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us, or may have arrangements with other companies to assist in the development of products that may compete with ours. If we are unable to attract and retain key personnel, our business, results of operations, financial condition and prospects will be adversely affected.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems and those of our current and our partners, contractors and consultants are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. For example, we have in the past experienced failures in our information systems and computer servers, which may have been the result of a cyber-attack. These failures resulted in an interruption of our normal business operations and required substantial expenditure of financial and administrative resources to remedy. We cannot be sure that similar failures will not occur in the future. System failures, accidents or security breaches can cause interruptions in our operations, and can result in a material disruption of our commercialization activities, drug development programs and our business operations. The loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval and post-market study compliance efforts and significantly increase our costs to recover or reproduce the data. Similarly, we rely on a large number of third parties to supply components for and manufacture our product candidates and conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the development of our product candidates could be delayed or otherwise adversely affected.

Cyber-attacks or other failures in telecommunications or information technology systems could result in information theft, data corruption and significant disruption of our business operations.

We use information technology, computer systems and networks to process, transmit and store electronic information in connection with our business activities. Cyber incidents, including deliberate attacks and attempts to gain unauthorized access to computer systems and networks, have increased in frequency, scope and sophistication in every industry. These threats pose a risk to the security of our systems and networks and the confidentiality, availability and integrity of our data, and may cause a disruption in our operations, harm our reputation and increase our stock trading risk. There can be no assurance that we will be successful in preventing cyber-attacks or successfully mitigating their effects. Similarly, there can be no assurance that our third-party collaborators, distributors and other contractors and consultants will be successful in protecting our data that is stored on their systems. A cyberattack or destruction or loss of data could have a material adverse effect on our business and prospects. In addition, we may suffer reputational harm or face litigation or adverse regulatory action as a result of cyber-attacks or other data security breaches and may incur significant additional expense to implement further data protection measures.

Fluctuations in the value of the Euro or UK pound sterling could negatively impact our results of operations and increase our costs.

We conduct research and development activities in the UK and other European countries and some of the payments for these activities are denominated in Euros and UK pounds sterling. As a result, we are exposed to foreign exchange risk, and our results of operations may be impacted by fluctuations in the exchange rate between the U.S. dollar and the Euro or UK pound sterling, such as the decline in value of the UK pound sterling following the results of the UK's referendum on withdrawal from the EU. A significant appreciation in the Euro or UK pound sterling relative to the U.S. dollar will result in higher expenses and cause increases in our net losses. Likewise, to the extent that we generate any revenues denominated in foreign currencies, or become required to make payments in other foreign currencies, fluctuations in the exchange rate between the U.S. dollar and those foreign currencies could also negatively impact our results of operations. We currently have not entered into any foreign currency hedging contracts to reduce the effect of changes in foreign currency exchange rates, and foreign currency hedging is inherently risky and may result in unanticipated losses.

If we are unable to achieve and maintain adequate levels of coverage and reimbursement for any of our other product candidates for which we may receive regulatory approval on reasonable pricing terms, their commercial success may be severely hindered.

Successful sales of any product candidates for which we may receive regulatory approval will depend on the availability of adequate coverage and reimbursement from third-party payors. Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors are critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Assuming coverage is approved, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

In addition, the market for our products will depend significantly on access to third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available.

In addition, regional healthcare authorities and individual hospitals are increasingly using competitive bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This can reduce demand for our products or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor.

Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions both in the United States and in international markets. Third-party coverage and reimbursement for any of our product candidates for which we may receive regulatory approval may not be available or adequate in either the United States or international markets, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability if our insurance coverage for those claims is inadequate.

The commercial use of our products and clinical use of our products and product candidates expose us to the risk of product liability claims. This risk exists even if a product or product candidate is approved for commercial sale by the FDA and manufactured in facilities regulated by the FDA such as the case with Zohydro ER, or an applicable foreign regulatory authority. Our products and product candidates are designed to affect important bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with Zohydro ER or our product candidates could result in injury to a patient or even death. For example, Zohydro ER is an opioid pain reliever that contains hydrocodone, which is a regulated "controlled substance" under the Controlled Substances Act of 1970, or CSA, and could result in harm to patients relating to its potential for abuse. Although we no longer sell Zohydro ER following the sale of the Zohydro ER business in April 2015, we retain all liabilities associated with the Zohydro ER business arising prior to such sale, including possible product liability exposure in connection with sales of Zohydro ER made prior to the sale of the Zohydro ER business. In addition, a liability claim may be brought against us even if our products or product candidates merely appear to have caused an injury.

Product liability claims may be brought against us by consumers, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with our products or product candidates, if approved, among others. If we cannot successfully defend ourselves against product liability claims, we will incur substantial liabilities. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- the inability to commercialize our product candidates;
- decreased demand for our product candidates, if approved;
- impairment of our business reputation;
- product recall or withdrawal from the market;

- withdrawal of clinical trial participants;
- costs of related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants; or
- loss of revenues.

We have obtained product liability insurance coverage for commercial product sales and clinical trials with a $20 million per occurrence and annual aggregate coverage limit. Our insurance coverage may not be sufficient to cover all of our product liability related expenses or losses and may not cover us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost, in sufficient amounts or upon adequate terms to protect us against losses due to product liability. If we determine that it is prudent to increase our product liability coverage based on approval of Fintepla, or otherwise, we may be unable to obtain this increased product liability insurance on commercially reasonable terms or at all. Large judgments have been awarded in class action or individual lawsuits based on drugs that had unanticipated side effects, including side effects that are less severe than those of Zohydro ER and our product candidates. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could decrease our cash and have a material adverse effect on our business, results of operations, financial condition and prospects.

We may never receive regulatory approval or commercialize our product candidate outside of the United States.

We intend to market Fintepla outside of the United States, if approved. For example, Fintepla has received orphan drug designation in the EU, and we completed a Phase 3 clinical trial, which included sites in Europe and Australia, in 2017, and submitted a MAA to the EMA for Fintepla for the treatment of seizures associated with Dravet syndrome in February 2019. The EMA has accepted the MAA and initiated its review. In order to market our products outside of the United States, we, or any potential partner, must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our products. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed in these "Risk Factors" regarding FDA approval in the United States, as well as other risks.

For example, in the European Economic Area (EEA), which comprised of 28 EU member states plus Iceland, Liechtenstein, and Norway, medicinal products can only be commercialized after obtaining a Marketing Authorization (MA). There are two types of MAs:

- The Community MA, which is issued by the European Commission through the Centralized · Procedure, based on the opinion of the Committee for Medicinal Products for Human Use (CHMP) of the EMA and which is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, and medicines that contain a new active substance indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU. Under the Centralized Procedure the maximum timeframe for the evaluation of a marketing authorization application is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP). Accelerated evaluation might be granted by the CHMP in exceptional cases, when the authorization of a medicinal product is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. Under the accelerated procedure the standard 210-day review period is reduced to 150 days.
- National MAs, which are issued by the competent authorities of the member states of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a member state of the EEA, this National MA can be recognized in other member states through the Mutual Recognition Procedure. If the product has not received a National MA in any member state at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure.

In the EEA, upon receiving marketing authorization, new chemical entities generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents regulatory authorities in the

EU from referencing the innovator's data to assess a generic application. During the additional two-year period of market exclusivity, a generic marketing authorization can be submitted, and the innovator's data may be referenced, but no generic product can be marketed until the expiration of the market exclusivity. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical entity and qualify for data exclusivity.

In the EEA, we have taken advantage of the hybrid application pathway of the EU Centralized Procedure, which is similar to the FDA's 505(b)(2) pathway. Hybrid applications may rely in part on the results of pre-clinical tests and clinical trials contained in the authorization dossier of the reference product, but must be supplemented with additional data. In territories where data is not freely available, we or our partners may not have the ability to commercialize our products without negotiating rights from third parties to refer to their clinical data in our regulatory applications, which could require the expenditure of significant additional funds. We, or any potential partner, may be unable to obtain rights to the necessary clinical data and may be required to develop our own proprietary safety effectiveness dossiers. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others.

Inability to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects detailed in these "Risk Factors" regarding FDA approval in the United States. As described above, such effects include the risks that our product candidates may not be approved at all or for all requested indications, which could limit the uses of our product candidates and have an adverse effect on their commercial potential or require costly, post-marketing studies. In addition, we, or any potential partner, may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution if we are unable to comply with applicable foreign regulatory requirements.

Our business involves the use of hazardous materials and we and our third-party manufacturers and suppliers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials owned by us, including the components of our product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending use and disposal. We cannot completely eliminate the risk of contamination, which could cause an interruption of our research and development efforts and business operations, injury to our employees and others, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources. We do not currently carry biological or hazardous waste insurance coverage.

In connection with the reporting of our financial condition and results of operations, we are required to make estimates and judgments which involve uncertainties, and any significant differences between our estimates and actual results could have an adverse impact on our financial position, results of operations and cash flows.

Our discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States (GAAP). The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities. Any significant differences between our actual results and our estimates and assumptions could negatively impact our financial position, results of operations and cash flows.

Changes in accounting standards and their interpretations could adversely affect our operating results.

Generally accepted accounting principles in the United States are subject to interpretation by the Financial Accounting Standards Board, the American Institute of Certified Public Accountants, the SEC, and various other bodies that promulgate and interpret appropriate accounting principles. These principles and related implementation guidelines and interpretations can be highly complex and involve subjective judgments. A change in these principles or interpretations could have a significant effect on our reported financial results, and could affect the reporting of transactions completed before the announcement of a change.

The results of the UK's referendum on withdrawal from the EU may have a negative effect on global economic conditions, financial markets and our business.

We are a company with worldwide operations, which includes significant business operations in Europe, and our wholly owned subsidiary Zogenix Europe Limited is incorporated under the laws of England and Wales. In June 2016, a majority of voters in the UK elected to withdraw from the EU in a national referendum. The referendum was advisory, and in March 2017, the government of the UK served notice under Article 50 of the Treaty of the European Union to formally initiate a withdrawal process. The UK and EU have had a two-year period under Article 50 to negotiate the terms of the UK's withdrawal from the EU. The withdrawal agreement and political declaration that were endorsed at a special meeting of the European Council in November 2018 did not receive the approval of the UK Parliament in January 2019. Further discussions are ongoing, although the European Commission has stated that the EU will not reopen the withdrawal agreement. Any extension of the negotiation period for withdrawal will require the consent of all remaining 27 member states of the EU. The referendum has created significant uncertainty about the future relationship between the UK and the EU, and has given rise to calls for certain regions within the UK to preserve their place in the EU by separating from the UK as well as for the governments of other EU member states to consider withdrawal.

These developments, or the perception that any of them could occur, have had and may continue to have a material adverse effect on global economic conditions and the stability of global financial markets, and could significantly reduce global market liquidity and restrict the ability of key market participants to operate in certain financial markets. Asset valuations, currency exchange rates and credit ratings may be especially subject to increased market volatility. Lack of clarity about future UK laws and regulations as the UK determines which EU laws to replace or replicate in the event of a withdrawal, including financial laws and regulations, tax and free trade agreements, intellectual property rights, supply chain logistics, environmental, health and safety laws and regulations, immigration laws and employment laws, could decrease foreign direct investment in the UK, increase costs, depress economic activity and restrict our access to capital. If the UK and the EU are unable to negotiate acceptable withdrawal terms or if other EU member states pursue withdrawal, barrier-free access between the UK and other EU member states or among the European economic area overall could be diminished or eliminated.

Since a significant proportion of the regulatory framework in the UK is derived from EU directives and regulations, the UK's withdrawal from the EU could materially impact the regulatory regime with respect to the approval of product candidates, disrupt the importation and export of active substances and other components of drug formulations, and disrupt the supply chain for clinical trial product and final authorized formulations. Any delay in obtaining, or an inability to obtain, any marketing approvals or otherwise, would prevent us from commercializing our product candidates in the UK and/or the EU. In view of the uncertainty surrounding the UK's future relationship with the EU, we are unable to predict the effects of such disruption to the regulatory framework and supply chain in Europe. Any of these factors, and/or those stated above, could have a material adverse effect on our business, financial condition and results of operations and affect our strategy in the European pharmaceutical market.

Risks Related to Our Financial Position and Capital Requirements

We have never generated net income from operations or positive cash flow from operations and are dependent upon external sources of financing to fund our business and development.

We launched our first approved product, Sumavel DosePro, in January 2010 and subsequently sold the business in April 2014. We launched our approved product, Zohydro ER, in March 2014 and subsequently sold the business in April 2015. In September 2017, our remaining revenue-generating agreement to manufacture and supply Sumavel DosePro to Endo International plc (Endo) was terminated. We have financed our operations primarily through the proceeds from the issuance of equity securities, the sale of the Sumavel DosePro and Zohydro ER businesses, and debt, and have incurred negative cash flow from operations in each year since our inception. For the years ended December 31, 2018, 2017 and 2016, we incurred net losses of $123.9 million, $126.8 million and $69.7 million, respectively, and our cash used in operating activities was $111.7 million, $75.9 million and $72.9 million, respectively. As of December 31, 2018, we had an accumulated deficit of $696.0 million. The losses and negative cash flow from operations have had a material adverse effect on our stockholders' equity and working capital.

We expect to continue to incur net losses and negative cash flow from operating activities for at least the next year to conduct clinical trials to support regulatory approval of our product candidates. As a result, we will remain dependent upon external sources of financing to fund our business and the development and commercialization of any approved products and product candidates. To the extent we need to raise additional capital in the future, we cannot ensure that debt or equity financing will be available to us in amounts, at times or on terms that will be acceptable to us, or at all. Any shortfall in our cash resources could require that we delay or abandon certain development and commercialization activities and could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

We will require additional funding in the future to carry out our plan of operations and if we are unable to raise capital when needed, we may be forced to delay, reduce or eliminate our product development programs or future commercialization efforts.

Our operations have consumed substantial amounts of cash since inception. We will require additional capital in the future to fund our operations, including:

- further development of our product candidates to support potential regulatory approval; and
- commercialize any of our product candidates, or any products or product candidates that we may develop, in-license or otherwise acquire, if any such product candidates receive regulatory approval.

In addition, our estimates of the amount of cash necessary to fund our business and development activities may prove to be wrong, and we could spend our available financial resources much faster than we currently expect. Our future funding requirements will depend on many factors, including, but not limited to:

- the rate of progress and cost of our clinical trials and other product development programs for our product candidates and any future product candidates that we may develop, in-license or acquire;
- the timing of regulatory approval for any of our product candidates and the commercial success of any approved products;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with our product candidates;
- the costs of establishing or outsourcing sales, marketing and distribution capabilities, should we elect to do so;
- the costs, terms and timing of completion of outsourced commercial manufacturing supply arrangements for any product candidate;
- the effect of competing technological and market developments; and
- the terms and timing of any additional collaborative, licensing, co-promotion or other arrangements that we may establish, including our ability to secure a global strategic development and commercialization partner for Fintepla.

Until we can generate a sufficient amount of product revenue and cash flow from operations and achieve profitability, we expect to finance future cash needs through public or private equity offerings, debt financings, receivables financings or corporate collaboration and licensing arrangements. We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unsuccessful in raising additional funds when needed, we may be required to significantly delay, reduce the scope of or eliminate one or more of our development programs or our commercialization efforts, or cease operating as a going concern. We also may be required to relinquish, license or otherwise dispose of rights to product candidates or products that we would otherwise seek to develop or commercialize ourselves on terms that are less favorable than might otherwise be available. If we raise additional funds by issuing equity securities, substantial dilution to existing stockholders would likely result. If we raise additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business. If we are unable to maintain sufficient financial resources, including by raising additional funds when needed, our business, financial condition and results of operations will be materially and adversely affected and we may be unable to continue as a going concern.

Our results of operations and liquidity needs could be materially negatively affected by market fluctuations and economic downturn.

Our results of operations and liquidity could be materially negatively affected by economic conditions generally, both in the United States and elsewhere around the world. Domestic and international equity and debt markets have experienced and may continue to experience heightened volatility and turmoil based on domestic and international economic conditions and concerns. In the event these economic conditions and concerns continue or worsen and the markets continue to remain volatile, our results of operations and liquidity could be adversely affected by those factors in many ways, including making it more difficult for us to raise funds if necessary, and our stock price may decline. In addition, we maintain significant amounts of cash and cash equivalents at one or more financial institutions that are not federally insured. If economic instability continues, we cannot provide assurance that we will not experience losses on these investments.

Raising additional funds by issuing securities may cause dilution to existing stockholders and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights.

We may need to raise additional funds through public or private equity offerings, debt financings, receivables or royalty financings or corporate collaboration and licensing arrangements. For example, we currently have an at-the-market sales agreement with Cantor Fitzgerald & Co (Cantor) for the offer and sale of up to $75.0 million of shares of our common stock from time to time. To the extent that we raise additional capital by issuing equity securities or convertible debt, your ownership interest in us will be diluted. Debt financing typically contains covenants that restrict operating activities.

If we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish potentially valuable rights to our current product or product candidates or proprietary technologies, or grant licenses on terms that are not favorable to us. If adequate funds are not available, our ability to achieve profitability or to respond to competitive pressures would be significantly limited and we may be required to delay, significantly curtail or eliminate the commercialization and development of our product or product candidates.

We may be unable to benefit from favorable UK tax legislation.

As a company that carries out extensive research and development activities, we benefit from the UK's small and medium-sized enterprises (SMEs) R&D tax relief scheme. For each discrete tax year, we have an option to receive an enhanced UK tax deduction on our eligible R&D activities or, when we are in a net operating loss position for that year, we can elect to surrender net operating losses that arose from our eligible R&D activities in exchange for a cash payment from the UK tax authorities for amounts up to 33.35% of qualifying expenditures. Qualifying expenditures largely comprise employment costs for research staff, consumables and certain internal overhead costs incurred as part of research projects. The majority of our R&D activities consist of qualifying expenditures under the UK's SME R&D tax relief scheme. To date, aggregate cash payments received under this tax relief scheme were approximately $10.1 million. We may not be able to continue to benefit from the UK's SME R&D tax relief scheme in the future as we increase our personnel and expand our business as this means we may no longer qualify as an SME. In addition, changes in UK tax legislation may reduce or limit any future claims. For example, on October 29, 2018, the UK Government proposed that from April 1, 2020, the amount of cash claims that a qualifying loss-making SME may receive through the SME R&D tax relief scheme in any one year will be capped at three times that SME's total Pay As You Earn and National Insurance Contributions liability for that year.

Our ability to utilize our net operating loss and research and development income tax credit carryforwards may be limited.

Under Section 382 of the Internal Revenue Code of 1986, as amended (IRC), substantial changes in our ownership may limit the amount of net operating loss and research and development income tax credit carryforwards, and certain other attributes (such as any future carryovers resulting from any business interest deductions that are disallowed under the recently-enacted U.S. tax legislation) (collectively, tax attributes) that could be utilized annually in the future to offset taxable income, if any. Specifically, this limitation may arise in the event of a cumulative change in ownership of our company of more than 50% within a three-year period as determined under the Code, which we refer to as an ownership change. Any such annual limitation may significantly reduce the utilization of these tax attributes before they expire. Prior to our initial public offering in November 2010, we performed an IRC Section 382 and 383 analysis and determined that we had one ownership change, which occurred in August 2006 upon the issuance of convertible preferred stock. We performed an additional IRC Section 382 and 383 analysis upon the issuance of common stock in our follow-on public offering in September 2011, and together with the issuance of common stock in our initial public offering and certain other transactions involving our common stock, resulted in an additional ownership change. We had a third ownership change as defined by IRC Sections 382 and 383, which occurred in January 2014. There was no forfeiture in federal and California net operating loss carryforwards or research and development income tax credits as a result of the third ownership change. Based on the Company's most recent assessment through December 31, 2018, no reduction was made to the federal and state net operating loss carryforwards or federal and state tax income tax credit carryforwards under these rules. Any future equity financing transactions, private placements and other transactions that occur within the specified three-year period may trigger additional ownership changes, which could further limit our use of such tax attributes. Any such limitations, whether as the result of prior or future offerings of our common stock or sales of common stock by our existing stockholders, could have an adverse effect on our consolidated results of operations in future years. Furthermore, under recently enacted U.S. tax legislation, although the treatment of tax losses generated before December 31, 2017 has generally not changed, tax losses generated in calendar year 2018 and beyond may only offset 80% of our taxable income. This change may require us to pay federal income taxes in future years despite generating a loss for federal income tax purposes in prior years.

Recent U.S. tax legislation may materially adversely affect our financial condition, results of operations and cash flows.

The Tax Cut and Jobs Act of 2017 (Tax Act) has significantly changed the U.S. federal income taxation of U.S. corporations, including by reducing the U.S. corporate income tax rate, limiting interest deductions, adopting elements of a

territorial tax system, imposing a one-time transition tax (repatriation tax) on all undistributed earnings and profits of certain U.S.-owned foreign corporations, revising the rules governing net operating losses and the rules governing foreign tax credits, and introducing new anti-base erosion provisions. Many of these changes are effective immediately, without any transition periods or grandfathering for existing transactions. While we have completed the accounting for the income tax effects of the Tax Act on our financial statements as of December 31, 2018, the Tax Act is unclear in many respects and could be subject to potential amendments and technical corrections, as well as interpretations and implementing regulations by the Treasury and Internal Revenue Service (IRS), any of which could lessen or increase certain adverse impacts of the legislation. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation, which often uses federal taxable income as a starting point for computing state and local tax liabilities. If clarifying guidance is provided in the future, it may have a material adverse effect on our financial results.

We are exposed to fluctuations in the market values of our investments.

As of December 31, 2018, our cash, cash equivalents and marketable securities totaled $514.2 million. Our cash equivalents and marketable securities include money market funds and certificate of deposits, securities issued by the U.S. government and its agencies, corporate debt securities and commercial paper meeting the criteria of our investment policy, which prioritizes the preservation of capital. These investments are subject to general credit, liquidity, market and interest rate risks, instability in the global financial markets, or other factors. As a result, the value or liquidity of our investments could decline and result in a material impairment, which could have a material adverse effect on our financial results and the availability of cash to fund our operations.

Risks Related to Government Regulation

Fintepla and any of our product candidates are subject to extensive regulation, and we cannot give any assurance that it will receive regulatory approval or be successfully commercialized.

We currently are developing Fintepla for the treatment of seizures associated with Dravet syndrome and LGS, and we completed our rolling submission of a NDA with the FDA for the treatment of seizures associated with Dravet syndrome in February 2019. The research, testing, manufacturing, labeling, approval, sale, marketing, distribution and promotion of drug products, among other things, are subject to extensive regulation by the FDA and other regulatory authorities in the United States. We are not permitted to market Fintepla or any of our product candidates in the United States unless and until we receive regulatory approval from the FDA. We cannot provide any assurance that we will obtain regulatory approval for any of our product candidates, or that any such product candidates will be successfully commercialized.

Under the policies agreed to by the FDA under the Prescription Drug User Fee Act (PDUFA), the FDA is subject to a two-tiered system of review times for new drugs: standard review and priority review. For drugs that do not contain a new molecular entity, such as Fintepla, a standard review means the FDA has a goal to complete its review of the NDA and respond to the applicant within ten months from the date of receipt of an NDA. The review process and the PDUFA target action date may be extended if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the submission. The FDA's review goals are subject to change, and the duration of the FDA's review may depend on the number and type of other NDAs that are submitted to the FDA around the same time period.

The FDA may also refer applications for novel products or products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. Although the FDA is not bound by the recommendation of an advisory committee, the matters discussed at the advisory committee meeting, and in particular any concerns regarding safety, could limit our ability to successfully commercialize our product candidates subject to advisory committee review.

As part of its review of an NDA, the FDA may inspect the facility or facilities where the drug is manufactured. If the FDA's evaluations of the NDA and the clinical and manufacturing procedures and facilities are favorable, the FDA will issue an action letter, which will be either an approval letter, authorizing commercial marketing of the drug for a specified indication, or a Complete Response letter containing the conditions that must be met in order to secure approval of the NDA. These conditions may include deficiencies identified in connection with the FDA's evaluation of the NDA submission or the clinical and manufacturing procedures and facilities. Until any such conditions or deficiencies have been resolved, the FDA may refuse to approve the NDA. If and when those conditions have been met to the FDA's satisfaction, the FDA will issue an approval letter. The FDA has substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. For example:

- the FDA may not deem a product candidate safe and effective;
- the FDA may not find the data from pre-clinical studies and clinical trials sufficient to support approval;

- the FDA may require additional pre-clinical studies or clinical trials;
- the FDA may not approve of our third-party manufacturers' processes and facilities; or
- the FDA may change its approval policies or adopt new regulations.

Our lead product candidate Fintepla and any of our other product candidates may not achieve their specified endpoints in clinical trials. Further, Fintepla and our other product candidates may not be approved even if they achieve their specified endpoints in clinical trials. The FDA may disagree with our trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials. The FDA may also approve a product candidate for fewer or more limited indications than we request or may grant approval contingent on the performance of costly post-approval clinical trials. In addition, the FDA may not approve the labeling claims that we believe are necessary or desirable for the successful commercialization of our product candidates. Approval may also be contingent on a risk evaluation and mitigation strategy (REMS) program, which can limit the labeling and distribution of a drug product.

The safety and effectiveness of Fintepla has been evaluated in a single, continuing, long-term, open-label, study in patients with Dravet syndrome in Belgium. We initiated a Phase 3 clinical trial for Fintepla as an adjunctive treatment of seizures in children with Dravet syndrome in North America in January 2016 (Study 1501) and in Europe and Australia in June 2016 (Study 1502). In September 2017, we announced positive top-line results from Study 1501 and Study 1502 via a prospective merged study analysis approach whereby top-line results from the first approximately 120 subjects randomized into either Study 1501 or 1502 would have their study results analyzed and be reported initially as "Study 1". In September 2016, we initiated Cohort 1 of Study 1504 that investigated the pharmacokinetic profile and safety of Fintepla when co-administered with the stiripentol regimen (stiripentol, valproate and/or clobazam). Based on the results of the Cohort 1 pharmacokinetic and safety portion of the trial, in February 2017 we initiated the Cohort 2 safety and efficacy portion of Study 1504 at multiple sites located in France, the Netherlands, United States, Canada, Germany, the United Kingdom and Spain. In July 2018, we reported positive top-line results from Study 1504, which are consistent with those reported in Study 1.

If we are unable to obtain regulatory approval for Fintepla or any of our product candidates on the timeline we anticipate, we may not be able to execute our business strategy effectively and our ability to generate revenues may be limited.

We may not be able to maintain orphan drug designation or obtain or maintain orphan drug exclusivity for Fintepla.

We have obtained orphan drug designation for Fintepla in the United States and Europe for both the treatment of Dravet syndrome and LGS. In the United States, under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is intended to treat a rare disease or condition affecting fewer than 200,000 individuals in the United States or, if it affects more than 200,000 people, there is no reasonable expectation that costs of research and development of the drug for the indication can be recovered by sales in the United States. In the EU, a drug may receive orphan designation if the prevalence of the condition in the EU is of no more than five in 10,000 or it if is unlikely that marketing of the medicine would generate sufficient returns to justify the investment needed for its development. Orphan drug designation in the United States confers certain benefits, including tax incentives and waiver of the applicable application fee upon submission of the product for approval in the rare disease or condition. In the EU, sponsors who obtain orphan designation benefit from a number of incentives, including protocol assistance and fee reductions.

If a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is eligible for a period of marketing exclusivity, which precludes the FDA or EMA from approving another marketing application for the same drug to treat the same rare disease or condition for that time period, except in limited circumstances. The applicable period is seven years in the United States and ten years in Europe. Also, we are only able to attain orphan drug status in Europe if we are able to demonstrate to EMA that Fintepla has incremental benefit over any other approved product for that orphan disorder. In July 2018, we reported positive top-line results from Study 1504 and in February 2019, we submitted a MAA to the EMA for Fintepla for the treatment of seizures associated with Dravet syndrome. The EMA has accepted the MAA and initiated its review. Currently in Europe, only stiripentol has orphan drug status, which has been approved for treatment of seizures in Dravet syndrome, but others could be approved.

The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

Orphan drug exclusivity may not effectively protect the product from competition in the United States because different drugs can be approved for the same condition. Even after an orphan drug is approved and granted exclusivity, the FDA and EMA can subsequently approve the same or a similar drug for the same condition during the exclusivity period if the FDA or

the EMA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

Any of our product candidates that receive regulatory approval will be subject to ongoing and continued regulatory review, which may result in significant expense and limit our ability to commercialize such products.

Even after we achieve U.S. regulatory approval for a product, the FDA may still impose significant restrictions on the approved indicated uses for which the product may be marketed or on the conditions of approval. For example, a product's approval may contain requirements for potentially costly post-approval studies and surveillance, including Phase 4 clinical trials, to monitor the safety and efficacy of the product, or the implementation of a REMS program. We may also be subject to ongoing FDA obligations and continued regulatory review with respect to the manufacturing, processing, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for any approved product. These requirements may include submissions of safety and other post-marketing information and reports, establishment registration and drug listing, as well as continued compliance with cGMP for our marketed and investigational products, and with GCP and GLP requirements, which are regulations and guidelines enforced by the FDA for all of our products in clinical and pre-clinical development, and for any clinical trials that we conduct post-approval. To the extent that a product is approved for sale in other countries, we may be subject to similar restrictions and requirements imposed by laws and government regulators in those countries.

In the case of any product candidates containing controlled substances, we and our contract manufacturers will also be subject to ongoing DEA regulatory obligations, including, among other things, annual registration renewal, security, recordkeeping, theft and loss reporting, periodic inspection and annual quota allotments for the raw material for commercial production of our products. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations, quality system regulation requirements for medical device components or similar requirements, if applicable. If we or a regulatory agency discovers previously unknown problems with an approved product, such as adverse events of unanticipated severity or frequency, or problems with the facility where, or processes by which, the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturer or us, including requiring product recall, notice to physicians, withdrawal of the product from the market or suspension of manufacturing.

If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- impose restrictions on the marketing or manufacturing of a product, suspend or withdraw product approvals or revoke necessary licenses;
- issue warning letters, show cause notices or untitled letters describing alleged violations, which may be publicly available;
- commence criminal investigations and prosecutions;
- impose injunctions, suspensions or revocations of necessary approvals or other licenses;
- impose fines or other civil or criminal penalties;
- suspend any ongoing clinical trials;
- deny or reduce quota allotments for the raw material for commercial production of our controlled substance products;
- delay or refuse to approve pending applications or supplements to approved applications filed by us;
- refuse to permit drugs or precursor chemicals to be imported or exported to or from the United States;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products or require us to initiate a product recall.

In addition, labeling, advertising and promotion of any approved products are subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about prescription drug products. In particular, a drug may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling, although the FDA does not regulate the prescribing practices of physicians. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have

improperly promoted off-label uses may be subject to significant liability, including substantial monetary penalties and criminal prosecution.

The FDA's regulations, policies or guidance may change and new or additional statutes or government regulations may be enacted that could prevent or delay regulatory approval of our product candidates or further restrict or regulate post-approval activities. For example, in December 2016, the 21st Century Cures Act was signed into law, which is intended, among other things, to modernize the regulation of drugs and biologics and to spur innovation. If we are not able to achieve and maintain regulatory compliance, we may not be permitted to market our drugs, which would adversely affect our ability to generate revenue and achieve or maintain profitability.

In addition, we cannot predict the likelihood, nature or extent of adverse government regulation that may arise from pending or future legislation or administrative action, either in the United States or abroad. For example, certain policies of the current presidential administration may impact our business and industry. Namely, the current presidential administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these requirements will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, 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 the 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 other government agencies 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, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA 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.

Fintepla may cause undesirable side effects or have other unexpected properties that could delay or prevent approval or result in post-approval regulatory action.

If we or others identify undesirable side effects, or other previously unknown problems, caused by Fintepla or any of our other product candidates with the same or related active ingredients, during development or after obtaining U.S. regulatory approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may not permit us to initiate our studies or could put them on hold;
- regulatory authorities may not approve, or may withdraw their approval of the product;
- regulatory authorities may require us to recall the product;
- regulatory authorities may add new limitations for distribution and marketing of the product;
- regulatory authorities may require the addition of warnings in the product label or narrowing of the indication in the product label;
- we may be required to create a Medication Guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way the product is administered or modify the product in some other way;
- we may be required to implement a REMS program;
- the FDA may require us to conduct additional clinical trials or costly post-marketing testing and surveillance to monitor the safety or efficacy of the product;

- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of the above events resulting from undesirable side effects or other previously unknown problems could prevent us from achieving or maintaining market acceptance of the affected product, if approved, and could substantially increase the costs of commercializing our product candidates.

Healthcare reform measures and changes in policies, funding, staffing and leadership at the FDA and other agencies could hinder or prevent the commercial success of any of our product candidates that may be approved by the FDA.

In the United States, there have been a number of legislative and regulatory changes to the healthcare system in ways that could affect our future results of operations and the future results of operations of our customers. There have been and continue to be a number of initiatives at the federal and state levels that seek to reduce healthcare costs. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the PPACA, was signed into law, which includes measures to significantly change the way health care is financed by both governmental and private insurers. Among the provisions of the PPACA of greatest importance to the pharmaceutical industry are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23% and 13% of the average manufacturer price for most branded and generic drugs, respectively;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts, which, through subsequent legislative amendments, was be increased to 70%, starting in 2019, off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing both the volume of sales and manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report certain financial arrangements with physicians and others, including reporting any "transfer of value" made or distributed to prescribers and other healthcare providers and reporting any investment interests held by physicians and their immediate family members during each calendar year. Manufacturers are required to report such data to the Centers for Medicare & Medicaid Services, or CMS, by the 90th day of each calendar year;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians;
- a licensure framework for follow-on biologic products;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

There have been judicial and Congressional challenges to certain aspects of the PPACA, and we expect there will be additional challenges and amendments to the PPACA in the future, particularly in light of the current presidential administration and U.S. Congress. In addition, Congress could consider subsequent legislation to replace repealed elements of the PPACA. Recently, the Tax Act was enacted, which, among other things, removes penalties for not complying with the PPACA's

individual mandate to carry health insurance. Further, on December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseverable feature of the PPACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the PPACA are invalid as well. While the Trump Administration and the Centers for Medicare & Medicaid Services have both stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, if any, will impact the law. At this time, the full effect that the PPACA and any subsequent legislation would have on our business remains unclear.

Other legislative changes have also been proposed and adopted in the United States since the PPACA was enacted. For example, in August 2011, the Budget Control Act of 2011, among other things included aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013, and, due to subsequent legislative amendments to the statute, will remain in effect through 2027 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Recently, there has been heightened governmental scrutiny over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted 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 drug products. For example, in an effort to lower prescription drug prices, on January 31, 2019, the Department of Health and Human Services issued a proposed rule that removes from existing anti-kickback statute safe harbor protection certain reductions in price paid by pharmaceutical manufacturers to Medicare Part D plan sponsors, Medicaid managed care organizations, and those entities' pharmacy benefit managers (PBMs) and instead, adds two new safe harbors that protect certain point-of-sale price reductions offered directly to patients by pharmaceutical manufacturers as well as certain fixed fee service payments from pharmaceutical manufacturer to PBMs. Individual states have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and to encourage importation from other countries and bulk purchasing. These new laws may result in additional reductions in Medicare and other health care funding, which could have a material adverse effect on our customers and accordingly, our financial operations.

Furthermore, regulatory authorities' assessment of the data and results required to demonstrate safety and efficacy can change over time and can be affected by many factors, such as the emergence of new information, including on other products, changing policies and agency funding, staffing and leadership. We cannot be sure whether future changes to the regulatory environment will be favorable or unfavorable to our business prospects. For example, average review times at the FDA for marketing approval applications have fluctuated over the last ten years, and we cannot predict the review time for any of our submissions with any regulatory authorities. In addition, review times can be affected by a variety of factors, including budget and funding levels and statutory, regulatory and policy changes.

In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the European Union or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than European Union, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most European Union member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing European Union and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize our product candidates, if approved. In markets outside of the United States and European Union, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

We may incur liability if our continuing medical or health education programs and/or product promotions are determined, or are perceived, to be inconsistent with regulatory guidelines.

The FDA provides guidelines with respect to appropriate promotion and continuing medical and health education activities. Although we endeavor to follow these guidelines, the FDA or the Office of the Inspector General U.S. Department of Health and Human Services may disagree, and we may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions. In addition, management's attention could be diverted and our reputation could be damaged.

If we do not comply with federal and state healthcare laws, including fraud and abuse and health information privacy and security laws, we could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected.

As a pharmaceutical company, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which constrains our marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities, by prohibiting, among other things, soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, and which may apply to entities like us which provide coding and billing advice to customers;
- federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and its implementing regulations, which impose certain requirements relating to the privacy, security and transmission of individually identifiable health information;
- federal "sunshine" requirements that require drug manufacturers to report and disclose any "transfer of value" made or distributed to physicians and teaching hospitals, and any investment or ownership interests held by such physicians and their immediate family members. Manufacturers are required to report data to the government by the 90th day of each calendar year;
- federal price reporting laws, which require us to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on our commercial products;
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and
- similar healthcare laws and regulations in the European Union and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and requirements regarding the collection, distribution, use, security, and storage of personally identifiable information and other data relating to individuals (including the European Union enacted Regulation (EU) 2016/679 (General Data Protection Regulation)).

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under the U.S. federal Anti-Kickback Statute, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

In addition, there has been a recent trend of increased state regulations that require drug manufacturers to file reports with states regarding pricing and marketing information, and require the tracking and reporting of gifts, compensation and other remuneration to physicians. Certain states mandate implementation of commercial compliance programs to ensure compliance with these laws and impose restrictions on drug manufacturer marketing practices and tracking and reporting of gifts, compensation and other remuneration to physicians. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may be found out of compliance of one or more of the requirements.

To the extent that any product we make is sold in a foreign country, we may be subject to similar foreign laws and regulations. If we or our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in governmental health care programs, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, imprisonment, and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could materially adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

Import/export regulations and tariffs may change and increase our costs.

We are subject to risks associated with the regulations relating to the import and export of products and materials. We cannot predict whether the import and/or export of our products will be adversely affected by changes in, or enactment of, new quotas, duties, taxes or other charges or restrictions imposed by any country in the future. Any of these factors could adversely affect our business, results of operations, financial condition and prospects.

Risks Related to Intellectual Property

Our success depends in part on our ability to protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.

Our commercial success depends in large part on obtaining and maintaining patent, trademark and trade secret protection of our product candidates, their respective components, formulations, methods used to manufacture them and methods of treatment, as well as successfully defending these patents against third-party challenges. Our ability to stop unauthorized third parties from making, using, selling, offering to sell or importing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

We in-licensed certain data from a continuing, long-term, open-label study in 15 Dravet syndrome patients, as well as certain intellectual property related to fenfluramine for the treatment of Dravet syndrome from the Universities of Antwerp and Leuven in Belgium, or the Universities.

Prior to receiving rights to 4 U.S. patents in 2017, we did not own or control any issued patents covering Fintepla or its use. There is no guarantee that any of our pending applications will issue as patents. The patents covering the API in Fintepla have expired and therefore it is not subject to patent protection. The initial applications covering methods of treatment using Fintepla were licensed by us and not written by our attorneys. Neither we nor our licensors had control over the drafting and initial prosecution of these applications. Further, the counsel previously handling the matter might not have given the same attention to the drafting and prosecution to these applications as we would have if we had been the owners and originators of the applications and had control over the drafting and prosecution. In addition, the former counsel handling the matter may not have been completely familiar with U.S. patent law or the patent law in various countries, possibly resulting in inadequate disclosure and/or filing of applications at times which do not meet appropriate priority requirements. The named inventors on the pending applications and others involved in the protection of the intellectual property related to Fintepla did not and may still not have sufficient knowledge relating to preferred procedures related to the protection of intellectual property. They published papers which adversely affected our rights. Although they have been advised with respect to procedures going forward, we cannot directly control their actions. All of these factors and others could result in the inability to obtain the issuance of additional applications in the United States or elsewhere in the world.

The patent positions of pharmaceutical, biopharmaceutical and medical device companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in patents in these fields has emerged to date in the United States. There have been recent changes regarding how patent laws are interpreted, and both the U.S. Patent and Trademark Office, or USPTO, and

Congress have recently made significant changes to the patent system. There have been three U.S. Supreme Court decisions that now show a trend of the Supreme Court which is distinctly negative on patents. The trend of these decisions along with resulting changes in patentability requirements being implemented by the USPTO could make it increasingly difficult for us to obtain and maintain patents on our products. We cannot accurately predict future changes in the interpretation of patent laws or changes to patent laws which might be enacted into law. Those changes may materially affect our patents, our ability to obtain patents and/or the patents and applications of our collaborators and licensors. The patent situation in these fields outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in the patents we own or to which we have a license or third-party patents.

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

- others may be able to make or use compounds that are the same or similar to the pharmaceutical compounds used in our product candidates but that are not covered by the claims of our patents or our in-licensed patents;
- the APIs in Fintepla are, or may soon become, commercially available in generic drug products, and no patent protection will be available without regard to formulation or method of use;
- we or our licensors, as the case may be, may not be able to detect infringement against our patents or in-licensed patents, which may be especially difficult for manufacturing processes or formulation patents;
- we or our licensors, as the case may be, might not have been the first to make the inventions covered by our owned or in-licensed issued patents or pending patent applications;
- we or our licensors, as the case may be, might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that our pending patent applications will not result in issued patents;
- it is possible that our owned or in-licensed U.S. patents are not Orange-Book eligible;
- it is possible that there are dominating patents to Fintepla of which we are not aware;
- it is possible that there are prior public disclosures that could invalidate our or our licensors' patents, as the case may be, or parts of our or their patents;
- it is possible that others may circumvent our owned or in-licensed patents;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to ours;
- the claims of our owned or in-licensed issued patents or patent applications, if and when issued, may not cover our system or products or our system of product candidates;
- our owned or in-licensed issued patents may not provide us with any competitive advantages, or may be narrowed in scope, be held invalid or unenforceable as a result of legal administrative challenges by third parties;
- we may not develop additional proprietary technologies for which we can obtain patent protection; or
- the patents of others may have an adverse effect on our business.

We also may rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect, and we have limited control over the protection of trade secrets used by our licensors, collaborators and suppliers. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, state laws in the Unites States vary, and their courts as well as courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. If our confidential or proprietary

information is divulged to or acquired by third parties, including our competitors, our competitive position in the marketplace will be harmed and our ability to successfully penetrate our target markets could be severely compromised.

If any of our owned or in-licensed patents are found to be invalid or unenforceable, or if we are otherwise unable to adequately protect our rights, it could have a material adverse impact on our business and our ability to commercialize or license our technology and products.

If we fail to comply with our obligations in our intellectual property licenses with third parties, we could lose license rights that are important to our business.

Our existing license with the Universities impose various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, our licensors may have the right to terminate the license, in which event we would not be able to develop or market the affected products. If we lose such license rights, our business, results of operations, financial condition and prospects may be materially adversely affected. We may enter into additional licenses in the future and if we fail to comply with obligations under those agreements, we could suffer similar consequences.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights, and we may be unable to protect our rights to our products and technology.

If we or our collaborators or licensors choose to go to court to stop a third party from using the inventions claimed in our owned or in-licensed patents, that third party may ask the court to rule that the patents are not infringed, invalid and/or should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we or they, as the case may be, were successful in stopping the infringement of these patents. In addition, there is a risk that the court will decide that these patents are not valid and that we or they, as the case may be, do not have the right to stop others from using the inventions.

There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the third party on the ground that such third-party's activities do not infringe our owned or in-licensed patents. In addition, the U.S. Supreme Court has recently changed some tests regarding granting patents and assessing the validity of patents. As a consequence, issued patents may be found to contain invalid claims according to the newly revised standards. Some of our own or in-licensed patents may be subject to challenge and subsequent invalidation or significant narrowing of claim scope in a reexamination or other post-grant proceeding before the USPTO, or during litigation, under the revised criteria which make it more difficult to obtain patents.

We may also not be able to detect infringement of our own or in-licensed patents, which may be especially difficult for methods of manufacturing or formulation products. While we intend to take actions reasonably necessary to enforce our patent rights, we depend, in part, on our licensors and collaborators to protect a substantial portion of our proprietary rights.

If we are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidate and use our proprietary technologies without infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields relating to Fintepla. As the medical device, biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that others may assert that our products or product candidates infringe the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of medical devices, drugs, products or their methods of use. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our products, product candidates, technology or methods.

In addition, there may be issued patents of third parties of which we are currently unaware, that are infringed or are alleged to be infringed by our product candidate or proprietary technologies. Because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our owned and in-licensed issued patents or our pending applications, or that we or, if applicable, a licensor were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering our product candidates or technology similar to ours. Any such patent application may have priority over our owned and in-licensed patent applications or patents, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to those owned or in-licensed to us, we or, in the case of in-licensed technology,

the licensor may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such proceedings may be decided against us if the other party had independently arrived at the same or similar invention prior to our own or, if applicable, our licensor's invention, resulting in a loss of our U.S. patent position with respect to such inventions. In addition, if another party has reason to assert a substantial new question of patentability against any of our claims in our owned and in-licensed U.S. patents, the third party can request that the USPTO reexamine the patent claims, which may result in a loss of scope of some claims or a loss of the entire patent. In addition to potential infringement claims, interference and reexamination proceedings, we may become a party to patent opposition proceedings in the European Patent Office, Australian Patent Office or other jurisdictions where either our patents are challenged, or we are challenging the patents of others. The costs of these proceedings could be substantial, and it is possible that our efforts would be unsuccessful. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates and/or proprietary technologies infringe their intellectual property rights. These lawsuits are costly and could adversely affect our results of operations and divert the attention of managerial and technical personnel. There is a risk that a court would decide that we or our commercialization partners are infringing the third party's patents and would order us or our partners to stop the activities covered by the patents. In addition, there is a risk that a court will order us or our partners to pay the other party damages for having violated the other party's patents.

If a third-party's patent was found to cover our product candidate, proprietary technologies or their uses, we or our collaborators could be enjoined by a court and required to pay damages and could be unable to commercialize our product candidates or use our proprietary technologies unless we or they obtained a license to the patent. A license may not be available to us or our collaborators on acceptable terms, if at all. In addition, during litigation, the patent holder could obtain a preliminary injunction or other equitable relief which could prohibit us from making, using or selling our products, technologies or methods pending a trial on the merits, which could be years away.

There is a substantial amount of litigation involving patent and other intellectual property rights in the device, biotechnology and pharmaceutical industries generally. If a third party claims that we or our collaborators infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;
- substantial damages for infringement, which we may have to pay if a court decides that the product at issue infringes on or violates the third party's rights, and if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;
- a court order prohibiting us from selling or licensing the product unless the third party licenses its patent rights to us, which it is not required to do;
- if a license is available from a third party, we may have to pay substantial royalties, upfront fees and/or grant cross-licenses to intellectual property rights for our products; and
- redesigning our products or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on our owned and in-licensed patents are due to be paid to the USPTO in several stages over the lifetime of the patents. Future maintenance fees will also need to be paid on other patents which may be issued to us or our licensors. We have systems in place to remind us to pay these fees, and we employ outside firms to remind us or our in-licensor to pay annuity fees due to foreign patent agencies on our pending foreign patent applications. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

We also may rely on trade secrets and confidentiality agreements to protect our technology and know-how, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect, and we have limited control over the protection of trade secrets used by our licensors, collaborators and suppliers. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. If our confidential or proprietary information is divulged to or acquired by third parties, including our competitors, our competitive position in the marketplace will be harmed and our ability to successfully generate revenues from our product candidates, if approved by the FDA or other regulatory authorities, could be adversely affected.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the device, biotechnology and pharmaceutical industries, we employ individuals who were previously employed at other device, biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management, which would adversely affect our financial condition.

Risks Relating to the Securities Markets and an Investment in Our Stock

The market price of our common stock has fluctuated and is likely to continue to fluctuate substantially.

The market prices for securities of biotechnology and pharmaceutical companies have historically been highly volatile, and the market has recently experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. Since the commencement of trading in connection with our initial public offering in November 2010, the publicly traded shares of our common stock have themselves experienced significant price and volume fluctuations. During the year ended December 31, 2018, the price per share for our common stock on the Nasdaq Global Market has ranged from a low sale price of $33.42 to a high sale price of $62.75. This market volatility is likely to continue. These and other factors could reduce the market price of our common stock, regardless of our operating performance. In addition, the trading price of our common stock could change significantly, both over short periods of time and the longer term, due to many factors, including those described elsewhere in this “Risk Factors” section and the following:

- FDA or international regulatory actions and whether and when we receive regulatory approval for Fintepla;
- the development status of Fintepla, including the results from our clinical trials;
- variations in the level of expenses related to Fintepla clinical development programs, including relating to the timing of invoices from, and other billing practices of, our CROs and clinical trial sites;
- changes in operating performance and stock market valuations of other pharmaceutical companies and price and volume fluctuations in the overall stock market;
- deviations from securities analysts’ estimates or the impact of other analyst comments;

- ratings downgrades by any securities analysts who follow our common stock;
- additions or departures of key personnel;
- third-party payor coverage and reimbursement policies;
- developments concerning current or future strategic collaborations, and the timing of payments we may make or receive under these arrangements;
- developments affecting our contract manufacturers, component fabricators and service providers;
- the development and sustainability of an active trading market for our common stock;
- future sales of our common stock by our officers, directors and significant stockholders;
- other events or factors, including those resulting from war, incidents of terrorism, natural disasters, security breaches, system failures or responses to these events;
- changes in accounting principles; and
- discussion of us or our stock price by the financial and scientific press and in online investor communities.

In addition, the stock markets, and in particular the Nasdaq Global Market, have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many pharmaceutical companies. Stock prices of many pharmaceutical companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies. The realization of any of the above risks or any of a broad range of other risks, including those described in these "Risk Factors" could have a dramatic and material adverse impact on the market price of our common stock.

Our quarterly operating results may fluctuate significantly.

Our quarterly operating results are difficult to predict and may fluctuate significantly from period to period, particularly because the success and costs of our Fintepla development programs are uncertain and therefore our future prospects are uncertain. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of development and/or regulatory expenses related to Fintepla development programs;
- results of clinical trials for Fintepla;
- any intellectual property infringement lawsuit in which we may become involved;
- the level of underlying demand for any of our product candidates that may receive regulatory approval;
- our ability to control production spending and underutilization of production capacity;
- those of our competitors; and
- our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially.

We may become involved in securities class action litigation that could divert management's attention and adversely affect our business and could subject us to significant liabilities.

The stock markets have experienced significant price and volume fluctuations that have affected the market prices for the common stock of pharmaceutical companies. These broad market fluctuations as well a broad range of other factors, including the realization of any of the risks described in these "Risk Factors," may cause the market price of our common stock to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies generally experience significant stock price volatility. We may become involved in this type of litigation in the future. Litigation often is expensive and diverts management's attention and resources, which could adversely affect our business. Any adverse

determination in any such litigation or any amounts paid to settle any such actual or threatened litigation could require that we make significant payments.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. As of December 31, 2018, we had research coverage by only 10 securities analysts. If these securities analysts cease coverage of our company, the trading price for our stock would be negatively impacted. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

Future sales of our common stock or securities convertible or exchangeable for our common stock may depress our stock price.

Persons who were our stockholders prior to the sale of shares in our initial public offering in November 2010 continue to hold a substantial number of shares of our common stock that they are able to sell in the public market, subject in some cases to certain legal restrictions. Significant portions of these shares are held by a small number of stockholders. If these stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. The perception in the market that these sales may occur could also cause the trading price of our common stock to decline. As of December 31, 2018, we had 42,078,164 shares of common stock outstanding. The majority of these shares are freely tradeable, without restriction, in the public market.

In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our employee benefit plans are eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and Rule 144 and Rule 701 under the Securities Act of 1933, as amended, or the Securities Act, and, in any event, we have filed a registration statement permitting shares of common stock issued on exercise of options to be freely sold in the public market. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Certain of our directors and executive officers have established, or may establish programmed selling plans under Rule 10b5-1 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, for the purpose of effecting sales of our common stock. Any sales of securities by these stockholders, warrantholders or executive officers and directors, or the perception that those sales may occur, could have a material adverse effect on the trading price of our common stock.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the chief executive officer, the president or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than 66 2/3% of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than 66 2/3% of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and

- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then- current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

We have never paid dividends on our capital stock, and we do not anticipate paying any cash dividends in the foreseeable future.

The continued operation and expansion of our business will require substantial funding. Investors seeking cash dividends in the foreseeable future should not purchase our common stock. We have paid no cash dividends on any of our classes of capital stock to date and we currently intend to retain our available cash to fund the development and growth of our business. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend upon results of operations, financial condition, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. Any return to stockholders will therefore be limited to the appreciation in the market price of their stock, which may never occur.

We have incurred and will continue to incur significant increased costs as a result of operating as a public company, and our management is required to devote substantial time to meet compliance obligations.

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses. We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC and the Nasdaq Stock Market LLC that impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and financial condition. In addition, on July 21, 2010, the Dodd-Frank Wall Street Reform and Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas. The requirements of these rules and regulations have increased and will continue to increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and may also place considerable strain on our personnel, systems and resources. Our management and other personnel have devoted and will continue to devote a substantial amount of time to these new compliance initiatives. In addition, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, our board committees or as executive officers.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. Ensuring that we have adequate internal financial and accounting controls and procedures in place is a costly and time-consuming effort that needs to be re-evaluated frequently. In particular, commencing in fiscal 2011, we performed system and process evaluation and testing of our internal controls over financial reporting which allowed management to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act, or Section 404. Our future testing may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement. We expect to incur significant expense and devote substantial management effort toward ensuring compliance with Section 404. Pursuant to Section 404(c) of the Sarbanes-Oxley Act, our independent registered public accounting firm is required to deliver an attestation report on the effectiveness of our internal control over financial reporting. We currently do not have an internal audit function, and we may need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. Implementing any appropriate changes to our internal controls may require specific compliance training for our directors, officers and employees, entail substantial costs to modify our existing accounting systems, and take a significant period of time to complete. Such changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate consolidated financial statements or other

reports on a timely basis, could increase our operating costs and could materially impair our ability to operate our business. Moreover, effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent fraud. If we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal controls that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities, which would entail expenditure of additional financial and management resources.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

As of December 31, 2018, our corporate headquarters, which includes executive offices and research and development and business operations, consist of approximately 22,000 square feet of leased office and laboratory space in Emeryville, California. In October 2018, we entered into a new lease agreement with our current landlord for our new headquarters, which is also located in Emeryville, California, that includes approximately 37,307 square feet of office and laboratory space under a noncancellable lease that expires on June 30, 2027 and has a renewal option for an additional five years. Upon completion of our relocation to our new headquarters, which is expected to be by the end of the second quarter of 2019, the lease agreement for our existing headquarters will be terminated. We also lease limited office space in Maidenhead, United Kingdom under a month-to-month arrangement.

We believe that our facilities are adequate to meet our needs for the immediate future, and that, should it be needed, suitable additional space will be available to accommodate expansion of our operations.

Item 3. Legal Proceedings

We are currently not a party to any material legal proceedings.

Item 4. Mine Safety Disclosures

Not Applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

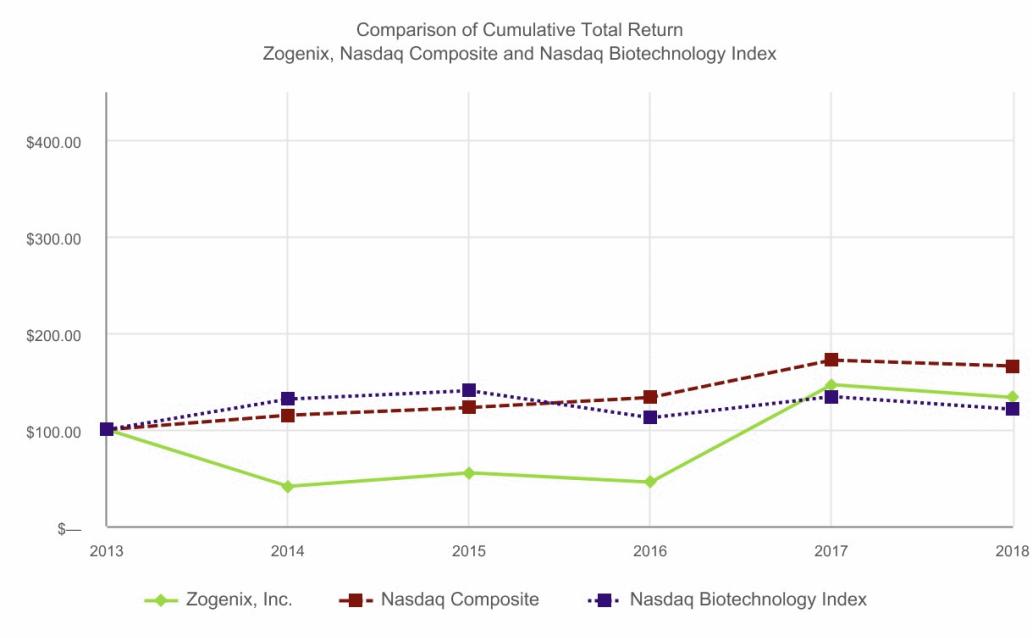
Zogenix common stock is listed on the Nasdaq Global Market under the symbol "ZGNX".

Holders of Common Stock

According to the records of our transfer agent, there were 10 holders of record of our common stock on February 15, 2019. Because many of such shares are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

Performance Graph

The following stock performance graph illustrates a comparison of the total cumulative stockholder return on our common stock over the five year period ended December 31, 2018 to the Nasdaq Composite Index and the Nasdaq Biotechnology Index. The graph assumes an initial investment of $100 on December 31, 2013, and that all dividends were reinvested. The comparisons in the graph are required by the SEC and are not intended to forecast or be indicative of possible future performance of our common stock.



Dividend Policy

We have never declared or paid any cash dividends on our capital stock and do not anticipate paying any cash dividends in the foreseeable future. We expect to retain available cash to finance ongoing operations and the potential growth of our business. Any future determination to pay dividends on our common stock will be at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant.

Equity Compensation Plan Information

See Part III, Item 12, "Security Ownership of Certain Beneficial Owners and Management and related Stockholder Matters" for information regarding securities authorized for issuance under equity compensation plans.

Recent Sales of Unregistered Securities

None.

Issuer Repurchases of Equity Securities

None.

Item 6. Selected Financial Data.

The following table summarizes certain of our selected financial data. The selected statement of operations data for the years ended December 31, 2018, 2017 and 2016 and the consolidated balance sheet data as of December 31, 2018 and 2017 should be read in conjunction with the audited financial statements and related notes, Management's Discussion and Analysis of Financial Condition and Results of Operations and other financial information presented elsewhere in this Form 10-K. The selected statements of operations data for the years ended December 31, 2015 and 2014 and the consolidated balance sheet data as of December 31, 2016, 2015 and 2014 have been derived from audited financial statements not included herein.

Our historical results for any prior period do not necessarily indicate our results to be expected for any future period.

	Year Ended December 31,				
	2018	2017	2016	2015	2014
	(In Thousands, Except Per Share Amounts)				
Statement of Operations Data					
Revenue:					
Contract manufacturing revenue [1]	$ —	$ 9,821	$ 28,525	$ 24,369	$ 15,392
Net product revenue	—	—	—	—	9,840
Service and other product revenue	—	—	325	2,813	3,715
Total revenue	—	9,821	28,850	27,182	28,947
Operating expenses:					
Cost of contract manufacturing [1]	—	10,729	22,173	22,356	14,342
Cost of goods sold	—	—	—	—	5,263
Royalty expense	—	—	295	345	591
Research and development	100,925	67,449	41,840	27,860	11,893
Selling, general and administrative	38,950	25,885	26,996	26,347	34,639
Loss on contract termination	—	478	—	—	—
Change in fair value of contingent consideration [2]	1,300	24,100	1,800	(2,000)	—
Restructuring costs	—	—	—	—	—
Asset impairment charges [3]	—	1,116	8,431	—	838
Net gain on sale of business	—	—	—	—	(79,980)
Total operating expenses (income)	141,175	129,757	101,535	74,908	(12,414)
(Loss) income from operations	(141,175)	(119,936)	(72,685)	(47,726)	41,361
Other income (expense):					
Interest income (expense), net	7,164	(1,554)	(2,382)	(2,959)	(3,070)
Loss on sale of marketable securities [4]	—	—	—	(5,746)	—
Loss on extinguishment of debt[5]	—	(4,876)	—	—	(1,254)
Change in fair value of common stock warrant liabilities	169	297	5,387	(1,103)	25,332
Change in fair value of embedded derivatives	—	—	—	—	(14)
Other income (expense)[6]	10,126	47	46	(71)	(784)
Total other (expense) income	17,459	(6,086)	3,051	(9,879)	20,210
(Loss) income from continuing operations before income taxes	(123,716)	(126,022)	(69,634)	(57,605)	61,571
Income tax benefit (expense) [7]	—	—	948	15,901	(84)
Net (loss) income from continuing operations	$ (123,716)	(126,022)	(68,686)	(41,704)	61,487
Net (loss) income from discontinued operations	(198)	(795)	(1,021)	67,848	(52,900)
Net (loss) income	$ (123,914)	(126,817)	(69,707)	26,144	8,587
Net (loss) income per share, continuing operations, basic	$ (3.27)	$ (4.62)	$ (2.77)	$ (1.94)	$ 3.45
Net (loss) income per share, continuing operations, diluted	$ (3.27)	$ (4.62)	$ (2.77)	$ (1.94)	$ 3.44

(1) Amounts relate to supplying Sumavel DosePro to Endo under a long-term supply agreement (Supply Agreement), which was terminated in 2017. See Note 3 to our consolidated financial statements included in this Form 10-K.

(2) Reflects changes in the estimated fair value of the contingent consideration liability related to potential regulatory and sales-based milestone payments. See Notes 2 and 5 to our consolidated financial statements included in this Form 10-K.

(3) Includes the impairment of long-lived assets used in the production of Sumavel DosePro in 2016 and 2017. See Note 3 to our consolidated financial statements included in this Form 10-K.

(4) Represents loss on sale of marketable securities, which was included as part of the sales consideration received from the divestiture of our Zohydro ER business.

(5) Reflects loss on extinguishment of our term loan and a working capital advance note payable in 2017 and the early termination of a financing agreement with Healthcare Royalty Partners in 2014.

(6) Includes income recognized for qualifying research and development expenditures under UK's SME R&D tax relief scheme. See Notes 2 and 13 to our consolidated financial statements included in this Form 10-K.

(7) Tax benefit in 2015 resulted from the sale of Zohydro ER.

	As of December 31,				
	2018	2017	2016	2015	2014
	(In Thousands)				
Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$ 514,187	$ 293,503	$ 155,349	$ 155,349	$ 42,205
Working capital	474,355	283,720	154,517	154,517	33,741
Total assets	648,331	417,613	305,822	305,822	202,835
Long-term debt, less current portion	—	18,824	15,899	15,899	21,703
Accumulated deficit	(695,954)	(572,040)	(375,516)	(375,516)	(401,660)
Total stockholders' equity	522,801	301,521	182,760	182,760	55,279

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

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with "Selected Financial Data" and our consolidated financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, including, but not limited, to those set forth under "Item 1A — Risk Factors" and elsewhere in this Annual Report on Form 10-K.

Overview

We are a pharmaceutical company developing and commercializing transformative central nervous system (CNS) therapies for people living with serious and life-threatening rare CNS disorders and medical conditions. Our current primary area of therapeutic focus is rare, or "orphan" childhood-onset epilepsy disorders.

We currently own and control worldwide development and commercialization rights to Fintepla/ZX008, our lead product candidate. Fintepla is low-dose fenfluramine under development for the treatment of seizures associated with two rare and catastrophic forms of childhood-onset epilepsy: Dravet syndrome and Lennox-Gastaut syndrome (LGS).

Fintepla for Patients with Dravet Syndrome

Dravet syndrome is a rare form of pediatric-onset epilepsy with life threatening consequences for patients and for which current treatment options are very limited. Fintepla has received orphan drug designation in the United States and the European Union (EU) for the treatment of Dravet syndrome. In addition, Fintepla for the treatment of Dravet syndrome received Fast Track designation from the U.S. Food and Drug Administration (FDA) in January 2016. We have completed multiple clinical trials of Fintepla for the treatment of Dravet syndrome, including Study 1, a double-blind placebo-controlled studies of Fintepla as adjunctive therapy for patients with uncontrolled seizures who have Dravet syndrome, Study 1504, which investigated the pharmacokinetic profile and safety of Fintepla when co-administered with the stiripentol regimen and Study 1503, our ongoing open-label extension (OLE) trial to study the long-term safety and effectiveness of Fintepla, which is available to eligible patients who have completed our Phase 3 trials. In February 2019, we completed our rolling submission of a New Drug Application (NDA) with the FDA and submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for Fintepla for the treatment of seizures associated with Dravet syndrome. The EMA has accepted the MAA and initiated its review. Both applications were based on data from Study 1 and Study 1504 in Dravet syndrome and the interim analysis from the ongoing OLE trial Study 1503.

Fintepla for Patients with LGS

LGS is another rare, refractory, debilitating pediatric-onset epilepsy with life threatening consequences for patients and for which current treatment options are limited and suboptimal. Beginning in first quarter of 2016, we funded an open-label, dose-finding, investigator-initiated study of the effectiveness and tolerability of Fintepla as an adjunctive therapy in patients with LGS. In December 2016, we presented initial data from an interim analysis of the first 13 patients to have completed at least 12 weeks of this Phase 2 clinical trial at the 70th Annual Meeting of the AES. In this interim analysis, Fintepla was observed to provide clinically meaningful improvement in major motor seizure frequency in patients with severe refractory LGS, with 7 out of 13 patients (54%) achieving at least a 50% reduction in the number of major motor seizures, at doses below the 0.8 mg/kg/day maximum allowed dose. In addition, Fintepla was generally well tolerated without any observed signs or symptoms of valvulopathy or pulmonary hypertension. We believe these data indicate that Fintepla has the potential to be a safe and effective adjunctive treatment of major motor seizures for patients with LGS. Based on the strength of the LGS data generated, in the first quarter of 2017, we submitted an Investigational New Drug Application (IND) to the FDA to initiate a Phase 3 program of Fintepla in LGS. Our IND for Fintepla as a potential treatment for LGS became effective in April 2017. In the first half of 2017, Fintepla received orphan drug designation for the treatment of LGS from the FDA in the United States and the EMA in the EU.

Study 1601

In November 2017, we announced the initiation of our multicenter global Phase 3 clinical trial of Fintepla as an adjunctive treatment for seizures in patients with LGS (Study 1601). Study 1601 is planned for up to 85 sites in North America, Europe, Asia-Pacific, South America, South Africa and Australia and is divided in two parts. Part 1 is a double-blind, placebo-controlled investigation to assess the safety, tolerability and efficacy of Fintepla, low-dose fenfluramine, when added to a

patient's current anti-epileptic therapy. The trial will include two dose levels of Fintepla (0.2 mg/kg/day and 0.8 mg/kg/day, up to a maximum daily dose of 30 mg), as well as placebo. After establishing baseline seizure frequency for 4 weeks, randomized patients will be titrated to their dose over a 2-week titration period, followed by a 12-week fixed dose maintenance period. We are targeting a total of 225 randomized patients (75 per treatment arm) in the trial. The primary endpoint of the clinical trial is change in the number of seizures that result in drops between baseline and the combined titration and maintenance periods at the 0.8 mg/kg/day dose. The key secondary endpoints include change in the number of seizures that result in drops between baseline and the combined titration and maintenance periods at the 0.2 mg/kg/day dose, and the proportion of patients achieving a 50 percent reduction in drop seizures. Part 2 of the clinical trial will be a 12-month open-label extension to evaluate the long-term safety, tolerability and effectiveness of Fintepla. In December 2018, we announced that we expect to complete enrollment for Study 1601 in the second half of 2019 and be able to announce top-line results from the study in the first quarter of 2020.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in conformity with generally accepted accounting principles in the United States (GAAP). The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, expenses and related disclosures. We evaluate our estimates and assumptions on an ongoing basis. Our estimates are based on historical experience and various other assumptions that we believe to be reasonable under the circumstances. Actual results could differ from those estimates.

We believe that the assumptions and estimates associated with revenue recognition, the impairment assessments related to goodwill, indefinite-lived intangible assets and other long-lived assets, business combinations, discontinued operations, fair value measurements, clinical trials expense accrual and stock-based compensation have the greatest potential impact on our consolidated financial statements. Therefore, we consider these to be our critical accounting policies and estimates. For further information on all of our significant accounting policies, see Note 2 to our consolidated financial statements included in this Form 10-K.

Contingent Consideration Liabilities Resulting from a Business Combination

In conjunction with our business combination we have recorded contingent consideration liabilities payable upon the achievement of specified development, regulatory approval or sales-based milestone events. The contingent consideration liabilities are measured at their respective fair values as of the acquisition date. The models used in valuing the contingent consideration liabilities are based on significant unobservable inputs, including but not limited to:

- estimates of revenues related to the products or product candidates;
- the probability of success for unapproved product candidates considering their stages of development;
- the time to complete the development and approval of product candidates;
- the life of the potential commercialized products and associated risks, including the inherent difficulties and uncertainties in developing a product candidate such as obtaining FDA and other regulatory approvals;
- risks related to the viability of and potential alternative treatments in any future target markets; and
- risk adjusted discount rates.

We revalue contingent consideration obligations each quarter following the acquisition and record increases or decreases in fair value within the change in fair value of contingent consideration line item in our consolidated statements of operations.

Increases or decreases in the fair value of our contingent consideration liabilities can result from updates to assumptions such as the expected timing or probability of achieving the specified milestones, changes in projected revenues, changes in time periods to attain events or revenue targets, or changes in discount rates. Significant judgment is employed in determining these assumptions as of the acquisition date and for each subsequent period. Updates to assumptions could have a significant impact on our results of operations in any given period. Actual results may differ from estimates.

We believe the fair values used to record contingent consideration liabilities incurred in connection with the business combination are based upon reasonable estimates and assumptions given the facts and circumstances as of the related valuation dates.

Goodwill and Indefinite-Lived Intangible Assets

Goodwill and indefinite-lived intangible assets are reviewed for impairment at least annually in the fourth quarter, and more frequently if events or other changes in circumstances indicate that the carrying amount of the assets may not be recoverable. Impairment of goodwill and indefinite-lived intangibles is determined to exist when the fair value is less than the carrying value of the net assets being tested.

Goodwill

We determined that we have only one operating segment and reporting unit. Accordingly, our review of goodwill impairment indicators is performed at the entity-wide level. In performing each annual impairment assessment and any interim impairment assessment, we determine if we should qualitatively assess whether it is more likely than not that the fair value goodwill is less than its carrying amount (the qualitative impairment test). Some of the factors considered in the assessment include general macro-economic conditions, conditions specific to the industry and market, cost factors, the overall financial performance and whether there have been sustained declines in the Company's share price. If we conclude it is more likely than not that the fair value of the reporting unit is less than its carrying amount, or elect not to use the qualitative impairment test, a quantitative impairment test is performed using a two-step process. The first step of the goodwill qualitative impairment assessment compares the fair value of the reporting unit to its carrying value. If the fair value of the reporting unit exceeds its carrying amount, goodwill of the reporting unit is considered not impaired, and the second step of the impairment test is not required. We use our market capitalization as an indicator of fair value. We believe that since our reporting unit is publicly traded, the ability of a controlling shareholder to benefit from synergies and other intangible assets that arise from control might cause the fair value of our reporting unit as a whole to exceed our market capitalization. However, we believe that the fair value measurement need not be based solely on the quoted market price of an individual share of our common stock, but also can consider the impact of a control premium in measuring the fair value of its reporting unit. Should our market capitalization be less than our total stockholder's equity as of our annual test date or as of any interim impairment testing date, we would also consider market comparables, recent trends in our stock price over a reasonable period and, if appropriate, use an income approach (discounted cash flow) to determine whether the fair value of our reporting unit is greater than our carrying amount. If we were to use an income approach, we would establish a fair value by estimating the present value of our projected future cash flows expected to be generated from our business. The discount rate applied to the projected future cash flows to arrive at the present value would be intended to reflect all risks of ownership and the associated risks of realizing the stream of projected future cash flows. Our discounted cash flow methodology would consider projections of financial performance for a period of several years combined with an estimated residual value. The most significant assumptions we would use in a discounted cash flow methodology are the discount rate, the residual value and expected future revenues, gross margins and operating costs, along with considering any implied control premium. The second step, if required, compares the implied fair value of the reporting unit goodwill with the carrying amount of that goodwill. If the carrying amount of the reporting unit's goodwill exceeds its implied fair value, an impairment charge is recognized in an amount equal to that excess. Implied fair value is the excess of the fair value of the reporting unit over the fair value of all identified assets and liabilities. In 2018, we elected to bypass the qualitative goodwill impairment assessment. As of October 1, 2018, we determined through step one of our quantitative impairment test that the fair value of our single reporting unit significantly exceeded its carrying value and concluded that goodwill was not impaired. We did not recognize any goodwill impairment in any of the years presented.

Indefinite-Lived Intangible Asset

Our indefinite-lived intangible asset consists of in-process research and development (IPR&D) acquired in a business combination that are used in research and development activities but have not yet reached technological feasibility, regardless of whether they have alternative future use. The primary basis for determining the technological feasibility or completion of these projects is obtaining regulatory approval to market the underlying products in an applicable geographic region. We classify in-process research and development acquired in a business combination as an indefinite-lived intangible asset until the completion or abandonment of the associated research and development efforts. Upon completion of the associated research and development efforts, we perform a final test for impairment and will determine the useful life of the technology and begin amortizing the assets to reflect their use over their remaining lives. Upon permanent abandonment, we would write-off the remaining carrying amount of the associated in-process research and development intangible asset.

In performing each annual impairment assessment and any interim impairment assessment, we determine if we should qualitatively assess whether it is more likely than not that the fair value of our IPR&D asset is less than its carrying amount (the qualitative impairment test). If we conclude that is the case, or elect not to use qualitative impairment test, we would proceed with quantitatively determining the fair value of the IPR&D asset and comparing its fair value to its carrying value to determine the amount of impairment, if any (the quantitative impairment test).

In performing the qualitative impairment test, we consider the results of the most recent quantitative impairment test and identify the most relevant divers of the fair value for the IPR&D asset. The most relevant drivers of fair value we have identified are consistent with the assumptions used in the quantitative estimate of the IPR&D asset discussed below. Using these

drivers, we identify events and circumstances that may have an effect on the fair value of the IPR&D asset since the last time the IPR&D's fair value was quantitatively determined. We then weigh these factors to determine and conclude if it is not more likely than not that the IPR&D asset is impaired. If it is more likely than not that the IPR&D asset is impaired we proceed with quantitatively determining the fair value of the IPR&D asset.

We use the income approach to determine the fair value of our IPR&D asset. This approach calculates fair value by estimating the after-tax cash flows attributable to an in-process project over its useful life and then discounting these after-tax cash flows back to a present value. This estimate includes significant assumptions regarding the estimates that market participants would make in evaluating the IPR&D asset, including the probability of successfully completing clinical trials and obtaining regulatory approval to market the IPR&D asset, the timing of and the expected costs to complete IPR&D projects, future net cash flows from potential drug sales, which are based on estimates of the sales price of the drug, the number of patients who will be diagnosed and treated and our competitive position in the marketplace, and appropriate discount and tax rates. Any impairment to be recorded is calculated as the difference between the fair value of the IPR&D asset as of the date of the assessment with the carrying value of the IPR&D asset on our consolidated balance sheet.

For 2018, we performed a qualitative test and concluded that it is more-likely-than-not that the fair value of our IPR&D asset exceeded the carrying value and no further testing was required. We did not recognize any IPR&D impairment in any of the years presented.

For asset purchases outside of business combinations, we expense any purchased research and development assets as of the acquisition date if they have no alternative future uses.

Impairment of Long-Lived Assets

We evaluate long-lived assets periodically for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset (group) may not be recoverable. An impairment loss would be recognized when the carrying amount of the assets (asset group) exceeds the estimated undiscounted net cash flows. The amount of the impairment loss to be recorded is calculated as the excess of the carrying value of the assets (asset group) over their fair value.

In the fourth quarter of 2016, Endo informed us of their decision to discontinue Sumavel DosePro and we commenced the wind down of our manufacturing operations related to the supply of Sumavel DosePro to Endo (see Note 6 to our consolidated financial statements included in this Form 10-K). As a result, we performed an analysis to estimate cash flows from property and equipment used in the production of Sumavel DosePro in the fourth quarter of 2016. Based on this analysis, we recognized an impairment charge for long-lived assets of $6.4 million. In the first quarter of 2017, we recorded an additional asset impairment charge of $0.8 million for long-lived manufacturing assets associated with the production of Sumavel DosePro. There was no impairment to our long-lived assets in 2018.

Research and Development Expense and Accruals

Research and development costs include personnel-related costs, outside contracted services including clinical trial costs, facilities costs, fees paid to consultants, milestone payments prior to FDA approval, license fees prior to FDA approval, professional services, travel costs, dues and subscriptions, depreciation and materials used in clinical trials and research and development. Research and development costs are expensed as incurred unless there is an alternative future use in other research and development projects. The Company expenses costs relating to the purchase and production of pre-approval inventories as research and development expense in the period incurred until FDA approval is received.

Our expense accruals for clinical trials are based on estimates of the services received from clinical trial investigational sites and contract research organizations (CROs). Payments under some of the contracts we have with such parties depend on factors such as the milestones accomplished, successful enrollment of certain numbers of patients, site initiation and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If possible, we obtain information regarding unbilled services directly from these service providers. However, we may be required to estimate these services based on information available to our product development or administrative staff. If we underestimate or overestimate the activity associated with a study or service at a given point in time, adjustments to research and development expenses may be necessary in future periods. Historically, our estimated accrued liabilities have approximated actual expense incurred. Subsequent changes in estimates may result in a material change in our accruals. Payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received. Such payments are evaluated for current or long term classification based on when they will be realized.

Stock-Based Compensation

For equity awards that vest subject to the satisfaction of service requirements, compensation expense is measured based on the fair value of the award on the date of grant and is recognized as expense on a straight-line basis over the requisite service period. For stock awards which have a performance component, compensation cost is measured based on the fair value on the grant date (the date performance targets are established) and is expensed over the requisite service period for each separately vesting tranche when achievement of the performance objective becomes probable. We assess the probability of the performance objectives being met on a continuous basis.

We use a Black-Scholes option-pricing model to determine the fair value of our stock options. This fair value determined using this model is affected by our stock price, as well as assumptions regarding a number of subjective variables. These variables include the expected stock price volatility over the expected term of the option, the expected term of the option and the risk-free interest rate associated with the expected term of the option. The expected term of employee options granted is determined using the simplified method (based on the midpoint between the vesting date and the end of the contractual term).We estimate expected volatility based on our historical stock prices over the expected term. If any of the assumptions used in the Black-Scholes option pricing model change significantly, stock-based compensation expense may differ materially in the future from that recorded in the current period. We recognize forfeitures as they occur.

We expect to continue to grant stock options and awards in the future, and to the extent that we do, our actual stock-based compensation expense recognized in future periods will likely increase.

Income Taxes

We account for income taxes under the asset and liability method of accounting. We recognize deferred tax assets and liabilities for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, as well as for operating loss and tax credit carryforwards. We measure deferred tax assets and liabilities using enacted tax rates expected to apply to taxable income in the years in which we expect to recover or settle those temporary differences. We recognize the effect of a change in tax rates on deferred tax assets and liabilities in the results of operations in the period that includes the enactment date. We reduce the measurement of a deferred tax asset, if necessary, by a valuation allowance if it is more likely than not that we will not realize some or all of the deferred tax asset.

We account for uncertain tax positions by recognizing the financial statement effects of a tax position only when, based upon technical merits, it is more likely than not that the position will be sustained upon examination.

Significant judgment is required in determining the accounting for income taxes. In the ordinary course of business, many transactions and calculations arise where the ultimate tax outcome is uncertain. Our judgments, assumptions and estimates relative to the accounting for income taxes take into account current tax laws, our interpretation of current tax laws, and possible outcomes of future audits conducted by foreign and domestic tax authorities. Although we believe that our estimates are reasonable, the final tax outcome of matters could be different from our assumptions and estimates used when determining the accounting for income taxes. Such differences, if identified in future periods, could have a material effect on the amounts recorded in our consolidated financial statements.

Results of Operations

Comparison of Years Ended December 31, 2018, 2017 and 2016

Revenue

	Year Ended December 31,			2017 to 2018		2016 to 2017	
(Dollars in thousands)	2018	2017	2016	$ change	% change	$ change	% change
Contract manufacturing revenue	$ —	$ 9,821	$ 28,525	$ (9,821)	(100)%	$ (18,704)	(66)%
Other	—	—	325	—	— %	(325)	(100)%
Total revenue	$ —	$ 9,821	$ 28,850	$ (9,821)	(100)%	$ (19,029)	(66)%

We did not generate any revenue in 2018 as we currently do not have any products approved for sale. Revenue generated in 2017 and 2016 resulted from supplying Sumavel DosePro to Endo under the Supply Agreement, which terminated in September 2017.

Cost of Contract Manufacturing

(Dollars in thousands)	Year Ended December 31, 2018	2017	2016	2017 to 2018 $ change	2017 to 2018 % change	2016 to 2017 $ change	2016 to 2017 % change
Cost of contract manufacturing	$ —	$ 10,729	$ 22,173	$ (10,729)	(100)%	$ (11,444)	(52)%

The decrease in cost of manufacturing in 2017 as compared to 2016 corresponded to the decrease in revenue in 2017 as compared to 2016. Cost of contract manufacturing in 2017 included a $2.2 million write-down of inventory to its net realizable value.

Research and Development Expenses

(Dollars in thousands)	Year Ended December 31, 2018	2017	2016	2017 to 2018 $ change	2017 to 2018 % change	2016 to 2017 $ change	2016 to 2017 % change
Research and development	$ 100,925	$ 67,449	$ 41,840	$ 33,476	50 %	$ 25,609	61 %

Research and development expenses consist of expenses incurred in developing, testing and seeking marketing approval of our product candidates, including: license and milestone payments; payments made to third-party clinical research organizations, or CROs, and investigational sites, which conduct our clinical trials on our behalf, and consultants; expenses associated with regulatory submissions, pre-clinical development and clinical trials; payments to third-party manufacturers, which produce our active pharmaceutical ingredient and finished product; personnel related expenses, such as salaries, benefits, travel and other related expenses, including stock-based compensation; and facility, maintenance, depreciation and other related expenses.

We utilize contract manufacturing organizations, CROs, contract laboratories and independent contractors to produce product candidate material and for the conduct of our pre-clinical studies and clinical trials. We track third-party costs by program. We recognize the expenses associated with the services provided by CROs based on estimated progress toward completion at the end of each reporting period. We coordinate clinical trials through a number of contracted investigational sites and recognize the associated expense based on a number of factors, including actual and estimated subject enrollment and visits, direct pass-through costs and other clinical site fees. The table below sets forth information regarding our research and development costs for our major development programs.

The table below sets forth information regarding our research and development costs for our major development programs.

	Year Ended December 31, 2018	2017	2016
		(In Thousands)	
Research and development expenses:			
Fintepla for Dravet syndrome	$ 52,765	$ 44,181	$ 29,133
Fintepla for LGS	15,295	3,638	—
Relday [1]	—	40	439
Other [2]	32,865	19,590	12,268
Total	$ 100,925	$ 67,449	$ 41,840

(1) In August 2017, the development and license agreement with respect to Relday was terminated and all product rights reverted back to its owner.

(2) Other research and development expenses include employee and infrastructure resources that are not tracked on a program-by-program basis.

The increases in Fintepla for Dravet syndrome expense in 2018 as compared to 2017, and in 2017 as compared to 2016 were attributable to the progression and expansion of our clinical trial activities related to our Phase 3 development program of Fintepla in Dravet syndrome including Study 1, Study 1504 and Study 1503.

The increase in Fintepla for LGS expense in 2018 as compared to 2017 was primarily attributable to the initiation of (Study 1601) in November 2017.

We use our employee and infrastructure resources across our product and product candidate development programs. Therefore, we have not tracked salaries, other personnel related expenses, facilities or other related costs to our product

development activities on a program-by-program basis. The increases in research and development expense, other in 2018 as compared to 2017, and in 2017 as compared to 2016 were primarily attributable to increased headcount to support our increased clinical trial activities.

Selling, General and Administrative Expenses

	Year Ended December 31,			2017 to 2018		2016 to 2017	
(Dollars in thousands)	2018	2017	2016	$ change	% change	$ change	% change
Selling	$ 15,734	$ 4,762	$ 6,002	$ 10,972	230 %	$ (1,240)	(21)%
General and administrative	23,216	21,123	20,994	2,093	10 %	129	1 %
Total	$ 38,950	$ 25,885	$ 26,996	$ 13,065	50 %	$ (1,111)	(4)%

Selling expense consists primarily of salaries and benefits of marketing and commercial personnel, marketing and advertising costs, service fees under our co-promotion agreement and product sample costs.

Selling expense increased significantly in 2018 as compared to 2017 due primarily to an increase in marketing and commercial headcount and commercial expenses including marketing and pricing studies to prepare for a potential commercial launch of Fintepla. The decrease in selling expense in 2017 as compared to 2016 reflected lower spend on market research activities related to Fintepla.

General and administrative expenses consist primarily of salaries and related costs for personnel in executive, finance, accounting, business development and internal support functions. In addition, general and administrative expenses include professional fees for legal, public relations, patent protection, tax and accounting services.

General and administrative expense increased by $2.1 million in 2018 as compared to 2017 due primarily to increased general and administrative headcount as we build our infrastructure to support the expansion of our operations. General and administrative expenses remained flat in 2017 as compared to 2016.

Change in Fair Value of Contingent Consideration and Asset Impairment Charges

	Year Ended December 31,			2017 to 2018		2016 to 2017	
(Dollars in thousands)	2018	2017	2016	$ change	% change	$ change	% change
Change in fair value of contingent consideration	$ 1,300	$ 24,100	$ 1,800	$ (22,800)	(95)%	$ 22,300	1,239 %
Asset impairment charges	$ —	$ 1,116	$ 8,431	$ (1,116)	(100)%	$ (7,315)	(87)%

The contingent consideration liability resulted from our October 2014 acquisition of worldwide development and commercialization rights to Fintepla, where we agreed to pay additional consideration upon the achievement of certain regulatory-related and commercial-related milestones.

In 2018, we recorded a charge of $1.3 million to reflect an increase in the estimated fair value of contingent consideration liability primarily to reflect a reduction in the discount periods due to the passage of time, partially offset by a change in discount rate.

In 2017, we revised the fair value estimates for contingent consideration liability to incorporate increased probabilities of success as a result of positive top-line data from Study 1 in September 2017, and the initiation of Study 1601 in November 2017. Accordingly, we recorded a charge associated with the resulting change in the estimated fair value of $24.1 million.

In 2016, we recorded a charge of $1.8 million to reflect an increase in the estimated fair value of contingent consideration liability resulting from adjustments to the estimated time frame necessary to achieve the developmental milestones, changes in market interest rates as well as the passage of time.

Asset impairment charges incurred in 2017 and 2016 were primarily associated with long-lived assets used in the contract manufacturing of Sumavel DosePro to our single customer Endo under the Supply Agreement, which terminated in 2017.

Other income (expense)

(Dollars in thousands)	Year Ended December 31, 2018	2017	2016	2017 to 2018 $ change	2017 to 2018 % change	2016 to 2017 $ change	2016 to 2017 % change
Interest income	$ 7,170	$ 1,090	$ 443	$ 6,080	558 %	$ 647	146 %
Interest expense	(6)	(2,644)	(2,825)	2,638	(100)%	181	(6)%
Loss on extinguishment of debt	—	(4,876)	—	4,876	(100)%	(4,876)	— %
Change in fair value of common stock warrant liabilities	169	297	5,387	(128)	(43)%	(5,090)	94 %
Other income (expense), net	10,126	47	46	10,079	21,445 %	1	(2)%
Total other income (expense)	$ 17,459	$ (6,086)	$ 3,051	$ 23,545	(135)%	$ (9,137)	299 %

Interest Income

In 2018, we invested our excess cash from net proceeds received from our August 2018 follow-on offering in marketable securities. Interest income increased in 2018 as compared to 2017 and was attributable to interest earned from purchases of and investments in marketable securities. Interest income increased in 2017 as compared to 2016 and was attributable to interest earned from higher average cash and cash equivalents balances.

Interest Expense

In 2018, we had no debt. Interest expense incurred in 2017 and 2016 were primarily attributable to our term loan which was repaid in 2017 and amortization of imputed interest on an interest-free working capital advance related to the Supply Agreement, which was settled in 2017. See Note 8 to our consolidated financial statements for additional information.

Loss on Extinguishment of Debt

Loss on extinguishment of debt in 2017 consisted of a $1.5 million loss resulting from the early prepayment of our term loan and a $3.4 million noncash charge for the extinguishment of the working capital advance note payable related to the Supply Agreement resulting in the write-off of unamortized debt discount. See Note 8 to our consolidated financial statements for additional information.

Change in Fair Value of Common Stock Warrant Liabilities

The change in fair value of common stock warrant liabilities resulted from the periodic remeasurement of the estimated fair value (see Note 5 to our consolidated financial statements for additional discussion). The decrease in fair value of common stock warrant liabilities in 2017 as compared to 2016 was due to the expiration of outstanding warrants in July 2017, which were exercisable for 1.9 million shares of common stock with an exercise price of $20.00 per share. The warrants were issued in connection with a 2012 common stock public offering. As of December 31, 2018, we had outstanding warrants to purchase up to 28,125 shares of common stock at an exercise price of $72.00 per share that are measured at fair value at each reporting date. These warrants will expire in July 2021 if not exercised.

Other Income (Expense), Net

Other income (expense), net increased by $10.1 million in 2018 as compared to 2017 and was attributable to income related to claims submitted under UK's small and medium sized enterprises (SME) research and development (R&D) tax relief scheme for qualifying expenditures incurred in the 2015 and 2016 tax years. See Notes 2 and 13 in Part IV, Item 15, Notes to Consolidated Financial Statements for additional details. Other income (expense), net in 2017 and 2016 consisted of foreign currency transaction gains and losses.

Income Taxes

(Dollars in thousands)	Year Ended December 31, 2018	2017	2016	2017 to 2018 $ change	2017 to 2018 % change	2016 to 2017 $ change	2016 to 2017 % change
Income tax benefit	$ —	$ —	$ 948	$ —	(100)%	$ (948)	(100)%

In 2017 and 2018, no tax provision has been recognized because of our operating losses and the full valuation allowance provided on all deferred tax assets, including net operating losses. In 2016, we recognized a tax benefit of $0.9 million primarily due to the impact of changes in tax laws (tax rate reductions) enacted in the UK, which decreased our deferred tax liability.

LIQUIDITY AND CAPITAL RESOURCES

Since we commenced operations in 2006, our operations have been financed primarily through equity and debt financings and proceeds from two business divestitures—Sumavel DosePro and Zohydro ER. Excluding gains from business divestitures, we have incurred significant net losses from operations and negative cash flows from operating activities since inception. As of December 31, 2018, we have an accumulated deficit of $696.0 million. We currently do not have an approved product for sale and we have no source of revenue. We expect to continue to incur significant operating losses and negative cash flows from operations to advance our product candidates through development and commercialization. Additionally, upon acceptance of our regulatory submissions or approval by the FDA or the EMA for Fintepla, if at all, we will owe milestone payments related to our acquisition of worldwide development and commercialization rights to Fintepla. For example, the EMA's acceptance of our MAA in February 2019 triggered a $10.0 million development milestone payment due to the former owners of Brabant and an additional $10.0 million milestone payment shall become due and payable if our NDA, filed in February 2019, is accepted by the FDA. We do not know when, or if, we will generate any revenue from product sales and do not expect to generate significant revenue from product sales unless and until we obtain regulatory approval of, and commercialize Fintepla. To date, we have relied primarily on the proceeds from equity offerings to finance our operations. Our recent equity offerings include the following transactions.

In the third quarter of 2017, we sold a total of 1,550,880 shares of our common stock pursuant to an at-the-market sale agreement with Cantor Fitzgerald & Co. (ATM Agreement) resulting in net proceeds of approximately $19.4 million.

In October 2017, we completed an underwritten public offering for the sale of 7,700,000 shares of our common stock. Net proceeds raised from the offering amounted to approximately $271.3 million.

In the second quarter of 2018, we sold a total of 740,417 shares of our common stock pursuant to the ATM Agreement and received net proceeds of approximately $30.3 million.

In August 2018, we completed an underwritten public offering for the sale of 6,000,000 shares of our common stock. Net proceeds raised from the offering were approximately $292.9 million.

The following table summarizes our cash and cash equivalents and marketable securities as of December 31, 2018 and 2017:

	2018	2017	$ Change
	(In Thousands)		
Cash and cash equivalents	$ 68,454	$ 293,503	$ (225,049)
Marketable securities	445,733	—	445,733
Total	$ 514,187	$ 293,503	$ 220,684

A summary of our cash flows for the periods presented was as follows:

	Year Ended December 31,		
	2018	2017	2016
	(In Thousands)		
Operating activities	$ (111,658)	$ (75,874)	$ (72,880)
Investing activities	(444,750)	(76)	(103)
Financing activities	331,359	277,902	(817)

Operating Activities

Net cash used in operating activities of $111.7 million in 2018 was primarily attributable to a net loss of $123.9 million, offset by noncash charges of $14.8 million including $15.5 million of stock-based compensation, and a net cash inflow from changes in operating assets and liabilities of $2.5 million. The change in our net operating assets and liabilities was primarily due to increases in accrued expenses related to an increase in our research and development activities and timing of prepayments for CRO clinical costs.

Net cash used in operating activities of $75.9 million in 2017 was primarily attributable to a net loss of $126.8 million, offset by aggregate noncash charges of $39.5 million including $24.1 million from the fair value remeasurement of our contingent consideration liability, and a net cash inflow from changes in operating assets and liabilities of $11.4 million. The increase in cash provided by the net change in operating assets and liabilities was primarily attributable to cash received under the Supply Agreement for previously delivered product. Certain working capital balances which were net settled by the

extinguishment of the working capital advance note payable pursuant to the termination of the Supply Agreement were accounted for as a noncash activity.

Net cash used in operating activities of $72.9 million in 2016 was primarily attributable to a net loss of $69.7 million and a net cash outflow from changes in operating assets and liabilities of $17.8 million, offset by aggregate noncash charges of $14.6 million. The primary use of cash from changes in working capital was attributable to an $11.2 million increase in trade accounts receivable due to the timing of shipments and collections. Other uses of cash in operating activities include personnel-related costs, research and development costs for Fintepla, other professional services, including legal and accounting, and increases in our accounts payable and accrued expenses due to the timing of payments. Cash provided by changes in working capital items was primarily attributable to lower inventory purchases of Sumavel DosePro raw materials due to the anticipated wind down of our contract manufacturing operations related to the supply of Sumavel DosePro to our single customer.

Investing Activities

Net cash used in investing activities in 2018 included cash outflows of $569.5 million from the purchase of available-for-sale securities and $1.0 million for construction of tenant improvements at our new corporate headquarters. Cash outflows were partially offset by cash inflows of $125.8 million from maturities of available-for-sale securities.

Net cash used in investing activities in 2017 and 2016 was primarily related to purchases of computers and other office equipment.

Financing Activities

Net cash provided by financing activities of $331.4 million in 2018 consisted of net proceeds of $292.9 million from a follow-on offering of common stock, $30.2 million from the sale of common stock pursuant to the ATM Agreement and $9.7 million from issuance of common stock under equity incentive plans, offset by $1.4 million for payment of employee withholding taxes related to net share settlement of equity awards.

Net cash provided by financing activities of $277.9 million in 2017 consisted of net proceeds of $271.3 million from a follow-on offering of common stock, $19.4 million from sale of common stock pursuant to the ATM Agreement and $9.2 million from issuance of common stock under equity incentive plans, offset by $21.9 million to repay all outstanding indebtedness.

Net cash used in financing activities of $0.8 million in 2016 consisted of $1.2 million for net debt repayment, offset by cash receipts of $0.4 million from issuance of common stock under equity incentive plans.

Future Funding Requirements

Our principal uses of cash are research and development expenses, selling, general and administrative expenses and other working capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the rate of progress and cost of our clinical trials and other product development programs for our product candidates and any future product candidates that we may develop, in-license or acquire;
- the timing of regulatory approval for any of our product candidates and the commercial success of any approved products;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with our product candidates;
- the costs of establishing or outsourcing sales, marketing and distribution capabilities, should we elect to do so;
- the costs, terms and timing of completion of outsourced commercial manufacturing supply arrangements for any product candidate;
- the effect of competing technological and market developments; and
- the terms and timing of any additional collaborative, licensing, co-promotion or other arrangements that we may establish, including our ability to secure a global strategic development and commercialization partner for Fintepla.

Until we can generate a sufficient amount of product revenue and cash flow from operations and achieve profitability, we expect to finance future cash needs through public or private equity offerings, debt financings, receivables financings or corporate collaboration and licensing arrangements. We cannot be certain that additional funding will be available on acceptable

terms, or at all. If we are unsuccessful in raising additional funds when needed, we may be required to significantly delay, reduce the scope of or eliminate one or more of our development programs or our commercialization efforts, or cease operating as a going concern. We also may be required to relinquish, license or otherwise dispose of rights to product candidates or products that we would otherwise seek to develop or commercialize ourselves on terms that are less favorable than might otherwise be available. If we raise additional funds by issuing equity securities, substantial dilution to existing stockholders would likely result. If we raise additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business. If we are unable to maintain sufficient financial resources, including by raising additional funds when needed, our business, financial condition and results of operations will be materially and adversely affected and we may be unable to continue as a going concern.

Contractual Obligations and Commitments

The following table describes our contractual cash obligations and commitments as of December 31, 2018:

	Payments due by period				
	Total	Less than 1 year	1-3 years	4-5 years	More than 5 years
	(In Thousands)				
Operating lease obligations (1)	$ 15,821	$ 1,201	$ 3,479	$ 3,845	$ 7,296

(1) Represents the minimum rental payments, net of sublease income.

In connection with our acquisition of Fintepla, we may be required to make certain regulatory and sales-based milestone payments. We cannot, at this time, determine when or if the related milestones will be achieved or whether the events triggering the commencement of payment obligations will occur. Therefore, such payments were not included in the table above. See Notes 2 and 5 to our consolidated financial statements in this Form 10-K for additional details of our potential milestone payment obligations.

Recent Accounting Pronouncements

For the summary of recent accounting pronouncements applicable to our consolidated financial statements, see Note 2, Summary of Significant Accounting Policies, in Part IV, Item 15, Notes to Consolidated Financial Statements, which is incorporated herein by reference.

Off-Balance Sheet Arrangements

We have not engaged in any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

As part of our investment portfolio, we own financial instruments that are sensitive to market risks. The primary objective of our investment activities is to preserve our capital until it is required to fund operations, including our research and development activities.

Interest Rate Risk

As of December 31, 2018, we had cash, cash equivalents and marketable securities of $514.2 million. We invest our excess cash primarily in money market funds and certificates of deposit, securities issued by the U.S. government and its agencies, corporate debt securities and commercial paper. These investments are denominated in U.S. Dollars. We place our investments with high quality credit issuers and, by policy, limit the amount of credit exposure to any one issuer. A portion of our investments consisting of interest-bearing securities are subject to interest rate risk and could decline in value if interest rates fluctuate. The portfolio includes cash equivalents and investments in marketable securities with active secondary or resale markets to ensure portfolio liquidity. Due to the conservative nature of these instruments, we do not believe that we have a material exposure to interest rate risk. A 100 basis points change in interest rates would not have a significant impact on the total value of our portfolio. We had no debt outstanding as of December 31, 2018.

Foreign Exchange Risk

As a result of our UK operations, we face exposure to movements in foreign currency exchange rates, primarily the British Pound Sterling and the Euro against the U.S. Dollar. The current exposures arise primarily from cash and payables and accruals denominated in the British Pound Sterling and the Euro. We have not hedged our foreign currency since the exposure has not been material to our historical operating results. Based on our foreign currency exchange rate exposures at September 30, 2018, a hypothetical 10% adverse fluctuation in the average exchange rate of the Euro or the British Pound Sterling would not have had a material impact on our consolidated financial statements. We will continue to monitor and evaluate our exposure to foreign exchange risk as a result of entering into transactions denominated in currencies other than the U.S. Dollar.

Item 8. Financial Statements and Supplementary Data

The financial statements and supplementary data required by Item 8 are included herein, commencing on page F-1 of this report.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Conclusions 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 Exchange Act reports is recorded, processed, summarized and reported within the timelines specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by SEC Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as of the end of the period covered by this report. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2018 at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

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

Management's Annual Report on Internal Control Over Financial Reporting

Internal control over financial reporting refers to the process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer, and effected by our board of directors, management and other personnel, 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, and 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 our assets; (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 our receipts and expenditures are being made only in accordance with authorizations of our management and directors; 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.

Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Because of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

Management is responsible for establishing and maintaining adequate internal control over our financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. 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. Management has used the framework set forth in the report entitled "*Internal Control — Integrated Framework (2013)"* published by the Committee of Sponsoring Organizations of the Treadway Commission to evaluate the effectiveness of our internal control over financial reporting. Based on this evaluation, management has concluded that our internal control over financial reporting was effective as of December 31, 2018, the end of our most recent fiscal year. Pursuant to Section 404(c) of the Sarbanes-Oxley Act, our independent registered public accounting firm has issued an attestation report on the effectiveness of our internal control over financial reporting for the year ended December 31, 2018, which is included below.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Zogenix, Inc.

Opinion on Internal Control over Financial Reporting

We have audited Zogenix, Inc.'s internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) ("the COSO criteria"). In our opinion, Zogenix, Inc. ("the Company") maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on the COSO criteria.

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, 2018 and 2017, the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2018, and the related notes and our report dated February 28, 2019 expressed an unqualified opinion thereon.

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 Annual 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 included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and 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/ Ernst & Young LLP

Redwood City, California
February 28, 2019

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Information required by this item will be contained in our Definitive Proxy Statement to be filed with the Securities and Exchange Commission in connection with our 2019 Annual Meeting of Stockholders, which is expected to be filed not later than 120 days after the end of our fiscal year ended December 31, 2018, under the headings "Election of Directors," "Corporate Governance and Other Matters," "Executive Officers," and "Section 16(a) Beneficial Ownership Reporting Compliance," and is incorporated herein by reference .

We have adopted a Code of Business Conduct and Ethics that applies to our officers, directors and employees which is available on our internet website at www.zogenix.com. The Code of Business Conduct and Ethics contains general guidelines for conducting the business of our company consistent with the highest standards of business ethics, and is intended to qualify as a "code of ethics" within the meaning of Section 406 of the Sarbanes-Oxley Act of 2002 and Item 406 of Regulation S-K. In addition, we intend to promptly disclose (1) the nature of any amendment to our Code of Business Conduct and Ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions and (2) the nature of any waiver, including an implicit waiver, from a provision of our code of ethics that is granted to one of these specified officers, the name of such person who is granted the waiver and the date of the waiver on our website in the future.

Item 11. Executive Compensation

Information required by this item will be contained in our Definitive Proxy Statement under the heading "Executive Compensation and Other Information" and is incorporated herein by reference.

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

Information required by this item will be contained in our Definitive Proxy Statement under the headings "Security Ownership of Certain Beneficial Owners and Management" and is incorporated herein by reference.

Item 13. Certain Relationships, Related Transactions and Director Independence

Information required by this item will be contained in our Definitive Proxy Statement under the headings "Certain Relationships and Related Party Transactions" and "Independence of the Board of Directors" and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services

Information required by this item will be contained in our Definitive Proxy Statement under the heading "Independent Registered Public Accounting Firm's Fees" and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) *Documents filed as part of this report.*

1. *Financial Statements.* The following consolidated financial statements of Zogenix, Inc., together with the report thereon of Ernst & Young LLP, an independent registered public accounting firm, are included in this Annual Report on Form 10-K:

2. *Financial Statement Schedules.*

All schedules are omitted as the required information is inapplicable, or the information is presented in the consolidated financial statements or related notes.

3. *Exhibits.*

A list of exhibits to this Annual Report on Form 10-K is set forth on the Exhibit Index immediately preceding the signature page to this Annual Report on Form 10-K and is incorporated herein by reference.

(b) See Exhibit Index.

(c) See Item 15(a)(2) above.

Zogenix, Inc.

Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Zogenix, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Zogenix, Inc. (the "Company") as of December 31, 2018 and 2017, the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2018, and the related notes (collectively referred to as 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, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, 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, 2018, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework) and our report dated February 28, 2019 expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's 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 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 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 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 financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2007.

Redwood City, California
February 28, 2019

Zogenix, Inc.

Consolidated Balance Sheets
(In thousands, except per share amounts)

	December 31,	
	2018	2017
Assets		
Current assets:		
Cash and cash equivalents	$ 68,454	$ 293,503
Marketable securities	445,733	—
Prepaid expenses	6,718	5,994
Other current assets	11,825	5,206
Total current assets	532,730	304,703
Property and equipment, net	2,870	245
Indefinite-lived intangible asset	102,500	102,500
Goodwill	6,234	6,234
Other assets	3,997	3,931
Total assets	$ 648,331	$ 417,613
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 7,989	$ 3,356
Accrued clinical trial expenses	10,621	8,657
Accrued compensation	5,277	6,616
Other accrued liabilities	1,845	1,842
Current portion of contingent consideration	32,300	—
Common stock warrant liabilities	343	512
Total current liabilities	58,375	20,983
Contingent consideration, net of current portion	45,900	76,900
Deferred tax liability	17,425	17,425
Other long-term liabilities	3,830	784
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000 shares authorized, none issued and outstanding	—	—
Common stock, $0.001 par value; 50,000 shares authorized; 42,078 and 34,808 shares issued and outstanding at December 31, 2018 and 2017, respectively.	42	35
Additional paid-in capital	1,218,710	873,526
Accumulated deficit	(695,954)	(572,040)
Accumulated other comprehensive income	3	—
Total stockholders' equity	522,801	301,521
Total liabilities and stockholders' equity	$ 648,331	$ 417,613

See accompanying notes to the consolidated financial statements.

Zogenix, Inc.

Consolidated Statements of Operations
(In thousands, except per share amounts)

	Year Ended December 31,		
	2018	**2017**	**2016**
Revenue:			
Contract manufacturing revenue	$ —	$ 9,821	$ 28,525
Other	—	—	325
Total revenue	—	9,821	28,850
Operating expenses (income):			
Cost of contract manufacturing	—	10,729	22,173
Royalty expense	—	—	295
Research and development	100,925	67,449	41,840
Selling, general and administrative	38,950	25,885	26,996
Loss on contract termination	—	478	—
Change in fair value of contingent consideration	1,300	24,100	1,800
Asset impairment charges	—	1,116	8,431
Total operating expenses	141,175	129,757	101,535
Loss from operations	(141,175)	(119,936)	(72,685)
Other income (expense):			
Interest income	7,170	1,090	443
Interest expense	(6)	(2,644)	(2,825)
Loss on extinguishment of debt	—	(4,876)	—
Change in fair value of common stock warrant liabilities	169	297	5,387
Other income (expense), net	10,126	47	46
Total other income (expense)	17,459	(6,086)	3,051
Loss from continuing operations before income taxes	(123,716)	(126,022)	(69,634)
Income tax benefit	—	—	948
Loss from continuing operations	(123,716)	(126,022)	(68,686)
Loss from discontinued operations, net of tax	(198)	(795)	(1,021)
Net loss	$ (123,914)	$ (126,817)	$ (69,707)
Net loss per share, basic and diluted:			
Continuing operations	$ (3.27)	$ (4.62)	$ (2.77)
Discontinued operations	$ —	$ (0.03)	$ (0.04)
Total	$ (3.27)	$ (4.65)	$ (2.81)
Weighted average common shares outstanding, basic and diluted	37,884	27,301	24,785

See accompanying notes to the consolidated financial statements.

Zogenix, Inc.

Consolidated Statements of Comprehensive Loss
(in thousands)

	Year Ended December 31,		
	2018	2017	2016
Net loss	$ (123,914)	$ (126,817)	$ (69,707)
Other comprehensive income:			
Net unrealized gains on marketable securities, net of tax	3	—	—
Comprehensive loss	$ (123,911)	$ (126,817)	$ (69,707)

See accompanying notes to the consolidated financial statements.

Zogenix, Inc.

Consolidated Statements of Stockholders' Equity
(in thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2015	24,772	$ 25	$ 558,251	$ —	$ (375,516)	$ 182,760
Net loss	—	—	—	—	(69,707)	(69,707)
Issuance of common stock under employee equity plans	41	—	350	—	—	350
Stock-based compensation	—	—	7,353	—	—	7,353
Balance at December 31, 2016	24,813	25	565,954	—	(445,223)	120,756
Net loss	—	—	—	—	(126,817)	(126,817)
Issuance of common stock, net of issuance costs of $18.1 million	9,256	9	290,582	—	—	290,591
Issuance of common stock upon net exercise of common stock warrants	26	—	—	—	—	—
Issuance of common stock under employee equity plans	713	1	10,835	—	—	10,836
Stock-based compensation	—	—	6,155	—	—	6,155
Balance at December 31, 2017	34,808	35	873,526	—	(572,040)	301,521
Net loss	—	—	—	—	(123,914)	(123,914)
Net unrealized gain on marketable securities, net of tax	—	—	—	3	—	3
Issuance of common stock, net of issuance costs of $20.2 million	6,740	7	323,128	—	—	323,135
Issuance of common stock under employee equity plans	563	—	7,994	—	—	7,994
Shares repurchased for tax withholdings related to net share settlement of employee equity awards	(33)	—	(1,430)	—	—	(1,430)
Stock-based compensation	—	—	15,492	—	—	15,492
Balance at December 31, 2018	42,078	$ 42	$ 1,218,710	$ 3	$ (695,954)	$ 522,801

See accompanying notes to the consolidated financial statements.

Zogenix, Inc.

Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,		
	2018	**2017**	**2016**
Cash flows from operating activities:			
Net loss	$ (123,914)	$ (126,817)	$ (69,707)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	15,492	6,155	7,353
Depreciation	155	425	1,402
Amortization of debt issuance costs and debt discount	—	887	991
Net accretion and amortization of investments in marketable securities	(1,998)	—	—
Change in fair value of common stock warrant liabilities	(169)	(297)	(5,387)
Change in fair value of contingent consideration	1,300	24,100	1,800
Inventory write-down	—	2,232	—
Asset impairment charges	—	1,116	8,431
Loss on extinguishment of debt	—	4,876	—
Changes in operating assets and liabilities:			
Trade accounts receivable	—	9,356	(11,181)
Inventory	—	2,583	4,983
Prepaid expenses and other current assets	(9,335)	(801)	(3,394)
Other assets	266	(2,784)	471
Accounts payable, accrued and other liabilities	6,545	4,340	(1,778)
Deferred revenue	—	(1,245)	(5,839)
Deferred tax liability	—	—	(1,025)
Net cash used in operating activities	(111,658)	(75,874)	(72,880)
Cash flows from investing activities:			
Purchases of marketable securities	(569,515)	—	—
Proceeds from maturities of marketable securities	125,783	—	—
Purchases of property and equipment	(1,018)	(76)	(103)
Net cash used in investing activities	(444,750)	(76)	(103)
Cash flows from financing activities:			
Proceeds from borrowings	—	—	2,167
Principal repayments of long-term debt	—	(20,000)	(3,334)
Payment of fees to extinguish long-term debt	—	(1,865)	—
Proceeds from issuance of common stock under equity incentive plans	9,654	9,176	350
Taxes paid related to net share settlement of equity awards	(1,430)	—	—
Proceeds from issuance of common stock, net of issuance costs	323,135	290,591	—
Net cash provided by (used in) financing activities	$ 331,359	$ 277,902	$ (817)
Net (decrease) increase in cash, cash equivalents and restricted cash (1)	$ (225,049)	$ 201,952	$ (73,800)
Cash, cash equivalents and restricted cash at beginning of period (1)	$ 293,503	$ 91,551	$ 165,351
Cash, cash equivalents and restricted cash at end of period	$ 68,454	$ 293,503	$ 91,551
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ —	$ 1,475	$ 1,470
Noncash investing and financing activities:			
Purchases of property and equipment in accounts payable and accrued liabilities	$ 1,762	$ —	$ —
Extinguishment of working capital advance note payable under the Supply Agreement through net settlement of balances owed to the Company (2)	$ —	$ 7,000	$ —

(1) Amounts in 2016 have been retrospectively adjusted to reflect the adoption of new accounting guidance that was effective January 1, 2018. See Note 2 for further information.

(2) See Notes 3 and 8 for further information.

See accompanying notes to the consolidated financial statements.

Zogenix, Inc.

Notes to Consolidated Financial Statements

1. Organization and Description of Business

Zogenix, Inc. and subsidiaries (the Company) is a pharmaceutical company developing and commercializing transformative central nervous system (CNS) therapies for people living with serious and life-threatening rare CNS disorders and medical conditions. The Company is currently focused on developing and commercializing CNS therapies to address rare, or "orphan" childhood-onset epilepsy disorders.

The Company was incorporated as SJ2 Therapeutics, Inc. in May 2006 in the State of Delaware and changed its name to Zogenix, Inc. in August 2006. The Company is in the development stage and generates no revenue. Previously, the Company performed contract manufacturing services in supplying Sumavel DosePro to Endo International plc (Endo) under a long-term supply agreement (Supply Agreement), which was terminated in 2017.

Future Funding Requirements

Excluding gains from two discrete business divestitures, the Company has incurred significant net losses and negative cash flows from operating activities resulting in an accumulated deficit of $696.0 million as of December 31, 2018. Management expects to continue to incur significant operating losses and negative cash flows from operations as the Company continues to incur costs related to its ongoing Phase 3 clinical trials of Fintepla in North America and the European Union (EU) in Dravet syndrome and a Phase 3 clinical trial in Lennox-Gastaut syndrome (LGS), which commenced in November 2017. Additionally, upon acceptance of the Company's regulatory submissions or approval for Fintepla/ZX008 by the U.S. Food and Drug Administration (FDA) or the European Medicines Agency (EMA), if at all, the Company will owe milestone payments under an existing agreement in connection with the Company's prior acquisition of Fintepla. Through December 31, 2018, the Company has relied primarily on the proceeds from equity offerings to finance its operations. Until such time, if ever, the Company can generate a sufficient amount of revenue to finance its cash requirements, the Company may need to continue to rely on additional financing to achieve its business objectives. However, if such financing is not available at adequate levels when needed, the Company may be required to significantly delay, scale back or discontinue one or more of the product development programs or commercialization efforts or other aspects of its business plans, and its operating results and financial condition would be adversely affected.

2. Summary of Significant Accounting Policies

Basis of Presentation

These consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (GAAP) and include the accounts of Zogenix and its wholly-owned subsidiaries. The functional currency of the Company's foreign subsidiaries is the U.S. dollar. All intercompany transactions have been eliminated in consolidation.

Certain reclassifications have been made to the prior period amounts to conform to the current year presentation. Specifically, "Accrued clinical trial expenses" and "Other accrued liabilities", which previously were reported as "Accrued expenses" on the consolidated balance sheet, are now reported as separate line items.

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results may differ materially from those estimates. The Company believes significant judgment is involved in determining and in estimating the valuation of stock-based compensation, accrued clinical expenses, and contingent consideration liabilities. These estimates form the basis for making judgments about the carrying values of assets and liabilities when these values are not readily apparent from other sources.

Business Combinations

The Company measures all assets acquired and liabilities assumed, including contingent consideration, at fair value as of the acquisition date. Contingent consideration obligations incurred in connection with a business combination are remeasured to their estimated fair values at each reporting period with the change in fair value recorded in operating expenses until the related contingencies are resolved. In addition, the Company capitalizes in-process research and development (IPR&D) and either amortizes it over the life of the product upon commercialization, or impairs it if the carrying value exceeds the fair value or if the project is abandoned. Post-acquisition adjustments in deferred tax liabilities are recorded in current period income tax expense in the period of the adjustment.

Fair Value of Financial Instruments

The Company's financial instruments, including cash and cash equivalents, other current assets, accounts payable and accrued liabilities, are carried at cost which approximates their fair value because of the short-term nature of these financial instruments. See Notes 4 and 5 for information on fair value for marketable securities, contingent consideration liabilities and the Company's outstanding common stock warrant liabilities.

Cash Equivalents and Marketable Securities

The Company considers cash equivalents to be only those investments which are highly liquid, readily convertible to cash and have an original maturity of three months or less at the date of purchase.

The Company invests its excess cash in marketable securities with high credit ratings including money market funds and certificates of deposit, securities issued by the U.S. government and its agencies, corporate debt securities and commercial paper, which are all classified as "available-for-sale". The Company considers all available-for-sale securities, including those with maturity dates beyond 12 months, as available to support current operational liquidity needs and, therefore, classifies all securities with maturity dates beyond three months at the date of purchase as current assets on the consolidated balance sheets. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity, which is included in interest income on the consolidated statements of operations and comprehensive loss. Realized gains and losses and declines in value determined to be other-than-temporary, if any, on marketable securities are included in other income (expense), net. The cost of securities sold is determined using the specific identification method.

The Company periodically evaluates whether declines in fair values of its marketable securities below their book value are other-than-temporary. This evaluation consists of several qualitative and quantitative factors regarding the severity and duration of the unrealized loss as well as the Company's ability and intent to hold the marketable security until a forecasted recovery occurs. Additionally, the Company assesses whether it has plans to sell the security or it is more likely than not it will be required to sell any marketable securities before recovery of its amortized cost basis. Factors considered include quoted market prices, recent financial results and operating trends, implied values from any recent transactions or offers of investee securities, credit quality of debt instrument issuers, other publicly available information that may affect the value of the marketable security, duration and severity of the decline in value, and management's strategy and intentions for holding the marketable security. To date, the Company has not recorded any impairment charges on its marketable securities related to other-than-temporary declines in market value.

Concentration of Risk

Cash equivalents and marketable securities are financial instruments that potentially subject the Company to concentration of credit risk. The Company maintains amounts on deposit with various financial institutions, which may exceed federally insured limits. However, management periodically evaluates the credit-worthiness of those institutions, and the Company has not experienced any losses on such deposits. The Company invests its excess cash primarily in money market funds and certificates of deposit, securities issued by the U.S. government and its agencies, corporate debt securities and commercial paper. The Company has established guidelines relative to diversification and maturities to maintain safety and liquidity. The Company has not experienced any credit losses related to these financial instruments and does not believe it is exposed to any significant credit risk related to these instruments.

Certain materials and key components that the Company utilizes in its operations are obtained through single suppliers. Since the suppliers of key components and materials must be named in a New Drug Application (NDA) filed with the FDA for a product, significant delays can occur if the qualification of a new supplier is required. If delivery of material from the

Company's suppliers were interrupted for any reason, the Company may be unable to supply any of its product candidates for clinical trials.

Property and Equipment, Net

Property and equipment is recorded at cost, net of accumulated depreciation. Depreciation is calculated on a straight-line basis over the estimated useful lives of the respective assets and primarily consists of the following:

Computer equipment and software	3 years
Furniture and fixtures	3-7 years
Leasehold improvements	Shorter of estimated useful life or lease term

Depreciation expense for 2018, 2017 and 2016 was $0.2 million, $0.4 million and $1.4 million, respectively.

Goodwill and Indefinite-Lived Intangible Assets

Goodwill and indefinite-lived intangible assets are reviewed for impairment at least annually in the fourth quarter, and more frequently if events or other changes in circumstances indicate that the carrying amount of the assets may not be recoverable. Impairment of goodwill and indefinite-lived intangibles is determined to exist when the fair value is less than the carrying value of the net assets being tested.

Goodwill

The difference between the purchase price and the fair value of assets acquired and liabilities assumed in a business combination is allocated to goodwill. Goodwill is evaluated for impairment on an annual basis as of October 1, and more frequently if indicators are present or changes in circumstances suggest that impairment may exist.

As of October 1, 2018, the Company performed a quantitative test and determined the fair value of its single reporting unit significantly exceeded its carrying value. As such, the Company concluded that goodwill was not impaired. The Company has not recognized any goodwill impairment in any of the years presented.

Indefinite-Lived Intangible Asset

The Company's indefinite-lived intangible asset consists of IPR&D acquired in a business combination that are used in research and development activities but have not yet reached technological feasibility, regardless of whether they have alternative future use. The primary basis for determining the technological feasibility or completion of these projects is obtaining regulatory approval to market the underlying products in an applicable geographic region. The Company classifies IPR&D acquired in a business combination as an indefinite-lived intangible asset until the completion or abandonment of the associated research and development efforts. Upon completion of the associated research and development efforts, the Company performed a final test for impairment and will determine the useful life of the technology and begin amortizing the assets to reflect their use over their remaining lives. Upon permanent abandonment, the Company would write-off the remaining carrying amount of the associated IPR&D intangible asset.

In performing each annual impairment assessment and any interim impairment assessment, the Company determines if it should qualitatively assess whether it is more likely than not that the fair value of its IPR&D asset is less than its carrying amount (the qualitative impairment test). If the Company concludes that is the case, or elect not to use qualitative impairment test, the Company would proceed with quantitatively determining the fair value of the IPR&D asset and comparing its fair value to its carrying value to determine the amount of impairment, if any (the quantitative impairment test).

In performing the qualitative impairment test, the Company considers the results of the most recent quantitative impairment test and identifies the most relevant drivers of the fair value for the IPR&D asset. The most relevant drivers of fair value identified are consistent with the assumptions used in the quantitative estimate of the IPR&D asset discussed below. Using these drivers of fair value, the Company identifies events and circumstances that may have an effect on the fair value of the IPR&D asset since the last time the IPR&D's fair value was quantitatively determined. The Company then weighs these factors to determine and conclude if it is not more likely than not that the IPR&D asset is impaired. If it is more likely than not that the IPR&D asset is impaired, the Company proceeds with quantitatively determining the fair value of the IPR&D asset.

The Company uses the income approach to determine the fair value of its IPR&D asset. This approach calculates fair value by estimating the after-tax cash flows attributable to an in-process project over its useful life and then discounting these after-tax cash flows back to a present value. This estimate includes significant assumptions regarding the estimates that market participants would make in evaluating the IPR&D asset, including the probability of successfully completing clinical trials and obtaining regulatory approval to market the IPR&D asset, the timing of and the expected costs to complete IPR&D projects, future net cash flows from potential drug sales, which are based on estimates of the sales price of the drug, the number of patients who will be diagnosed and treated and our competitive position in the marketplace, and appropriate discount and tax rates. Any impairment to be recorded is calculated as the difference between the fair value of the IPR&D asset as of the date of the assessment with the carrying value of the IPR&D asset on its consolidated balance sheet.

For 2018, the Company performed a qualitative test and concluded that it is more-likely-than-not that the fair value of the Company's IPR&D asset exceeded the carrying value and no further testing was required. The Company did not recognize any IPR&D impairment in any of the years presented.

Impairment of Long-Lived Assets

The Company evaluates long-lived assets periodically for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset (group) may not be recoverable. An impairment loss would be recognized when the carrying amount of the assets (asset group) exceeds the estimated undiscounted net cash flows. The amount of the impairment loss to be recorded is calculated as the excess of the carrying value of the assets (asset group) over their fair value.

The Company recognized an impairment charge for long-lived assets of $6.4 million in 2016 as a result of the decision by Endo International plc (Endo) to discontinue the sale of Sumavel DosePro and terminate the long-term manufacturing and supply agreement (the Supply Agreement) with the Company. In 2017, the Company recorded an impairment charge of $0.8 million for long-lived manufacturing assets associated with the production of Sumavel DosePro. There was no impairment to long-lived assets in 2018.

Common Stock Warrant Liabilities

In accordance with accounting guidance for common stock warrants that may potentially require cash settlement under certain circumstances, the Company classifies such common stock warrants as current liabilities on the consolidated balance sheet. The Company adjusts the carrying value of these common stock warrants to their estimated fair value at each reporting date with the increases or decreases in the fair value of such warrants recorded as change in fair value of warrant liabilities in the consolidated statement of operations.

Revenue Recognition

In 2018, the Company had no revenue as it had no contracts with customers. In 2017 and 2016, the Company recognized revenue from contract manufacturing services provided under the Supply Agreement with Endo, which terminated in September 2017. Contract manufacturing revenue was recognized under the legacy revenue recognition standard when all of the following criteria for revenue recognition have been met: (1) persuasive evidence of an arrangement existed (2) delivery has occurred or services have been rendered; (3) the fee was fixed or determinable; and (4) collectability was reasonably assured.

Research and Development Expense and Accruals

Research and development costs are expensed as incurred unless there is an alternative future use in other research and development projects. Research and development costs include personnel-related costs, outside contracted services including clinical trial costs, facilities costs, fees paid to consultants, milestone payments prior to FDA approval, license fees prior to FDA approval, professional services, travel costs, dues and subscriptions, depreciation and materials used in clinical trials and research and development. The Company expenses costs relating to the purchase and production of pre-approval inventories as research and development expense in the period incurred until FDA approval is received. Payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received. Such payments are evaluated for current or long-term classification based on when they will be realized.

The Company's expense accruals for clinical trials are based on estimates of the services received from clinical trial investigational sites and contract research organizations (CROs). Payments under some of the Company's contracts with such parties depend on factors such as the milestones accomplished, successful enrollment of certain numbers of patients, site initiation and the completion of clinical trial milestones. In accruing service fees, the Company estimates the time period over which services will be performed and the level of effort to be expended in each period. If possible, the Company obtains

information regarding unbilled services directly from these service providers. However, the Company may be required to estimate these services based on information available to its product development or administrative staff. If the Company underestimates or overestimates the activity associated with a study or service at a given point in time, adjustments to research and development expenses may be necessary in future periods.

For asset purchases outside of business combinations, the Company expenses any purchased research and development assets as of the acquisition date if they have no alternative future uses.

Income Taxes

Income taxes are accounted for under the asset and liability method of accounting. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, as well as for operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the results of operations in the period that includes the enactment date. The Company provides a valuation allowance against net deferred tax assets unless, based upon the available evidence, it is more likely than not that the deferred tax asset will be realized. The Company recognizes the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities based on the technical merits of the position.

UK's Research and Development (R&D) Tax Relief Scheme

The Company carries out extensive research and development activities that benefit from UK's small and medium-sized enterprises (SME) R&D tax relief scheme, whereby an entity has an option to receive an enhanced UK tax deduction on its eligible R&D activities or, when an SME entity is in a net operating loss position, elect to surrender net operating losses that arise from its eligible R&D activities in exchange for a cash payment from the UK tax authorities. As the tax incentives may be received without regard to an entity's actual tax liability, they are not subject to accounting for income taxes. Amounts realized under the SME R&D tax relief scheme are recorded as a component of other income after an election for tax relief in the form of cash payments has been made for a discrete tax year by submitting a claim and collectability is deemed probable and reasonably assured.

Leases

The Company leases office space facilities under non-cancelable operating lease agreements and recognizes related rent expense on a straight-line basis over the term of the lease. Landlord allowances and incentives received, including allowances for leasehold improvements and rent holidays, are recognized as reductions to rent expense on a straight-line basis over the term of the lease. Cash reimbursements for tenant improvement allowances not yet received are recorded in other current assets on the consolidated balance sheet. The Company does not assume renewals in its determination of the lease term unless they are deemed to be reasonably assured at the inception of the lease. The Company begins recognizing rent expense on the date it obtains the legal right to use and control the leased space. Deferred rent consists of the difference between cash payments and the rent expense recognized.

Foreign Currency Transactions

Gains or losses resulting from transactions denominated in foreign currencies are included in other expense, net in the consolidated statements of operations and were not material for all periods presented.

Stock-Based Compensation

The Company recognizes stock-based compensation for all equity awards made to employees based upon the awards' estimated grant date fair value. For equity awards that vest subject to the satisfaction of service requirements, compensation expense is measured based on the fair value of the award on the date of grant and is recognized as expense on a straight-line basis over the requisite service period. For stock awards which have a performance component, compensation cost is measured based on the fair value on the grant date (the date performance targets are established) and is expensed over the service period for each separately vesting tranche when the achievement of the performance condition becomes probable. The Company recognizes forfeitures as they occur.

Valuation of Stock Options

The fair value of each option granted was estimated on the date of grant using the Black-Scholes option-pricing model with the following assumptions:

- Expected term—The expected term of the option awards represents the period of time between the grant date of the option awards and the date the option awards are either exercised, converted or canceled, including an estimate for those option awards still outstanding. The Company used the simplified method, as permitted by the SEC for companies with a limited history of relevant stock option exercise activity, to determine the expected term for its option grants.
- Expected volatility—The expected volatility was calculated based on the Company's historical stock prices over the expected term, supplemented as necessary with historical volatility of the common stock of several peer companies with characteristics similar to those of the Company.
- Risk-free interest rate—The risk-free interest rate was based on the U.S. Treasury yield curve in effect at the time of grant and with a maturity that approximated the Company's expected term.
- Dividend yield—The dividend yield was based on the Company's dividend history and the anticipated dividend payout over its expected term.

Valuation of Restricted Stock Units

The fair value of each restricted stock unit was based on the Company's closing stock price on the date of grant. The Company is also required to make estimates as to the probability of achieving the specific performance criteria. If actual results are not consistent with the Company's assumptions and judgments used in making these estimates, the Company may be required to increase or decrease compensation expense, which could be material to the Company's results of operations.

Loss from Continuing Operations per Share

Basic net loss from continuing operations per share is calculated by dividing the net loss from continuing operations by the weighted average number of common shares outstanding for the period reduced by weighted average shares subject to repurchase, without consideration for common stock equivalents. Diluted net loss from continuing operations per share is computed by dividing the net loss from continuing operations by the weighted average number of common share equivalents outstanding for the period determined using the treasury-stock method and as-if converted method, as applicable. For purposes of this calculation, stock options, restricted stock units and warrants to purchase common stock are considered to be common stock equivalents and are only included in the calculation of diluted net loss from continuing operations per share when their effect is dilutive.

The calculation of diluted loss per share also requires that, to the extent the average market price of the underlying shares for the reporting period exceeds the exercise price of the warrants to purchase common stock and the presumed exercise of such securities are dilutive to loss per share for the period, adjustments to net income or net loss used in the calculation are required to remove the change in fair value of the common stock warrant liability for the period. Likewise, adjustments to the denominator are required to reflect the related dilutive shares.

The following table presents the computation of basic and diluted loss from continuing operations per share (in thousands, except per share amounts):

	2018	2017	2016
Numerator			
Net loss from continuing operations	$ (123,716)	$ (126,022)	$ (68,686)
Denominator			
Weighted average common shares outstanding, basic and diluted	37,884	27,301	24,785
Loss from continuing operations per share, basic and diluted	$ (3.27)	$ (4.62)	$ (2.77)

The following table presents the potential common shares outstanding that were excluded from the computation of diluted loss from continuing operations per share of common stock for the periods presented because including them would have been antidilutive (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Shares subject to outstanding common stock options	3,770	3,865	3,171
Shares subject to outstanding restricted stock units	289	237	85
Shares subject to outstanding warrants to purchase common stock	33	282	1,975
	4,092	4,384	5,231

Segment Information

The Company operates as a single segment, which is the business of developing and commercializing transformative therapies to improve the lives of patients living with rare diseases and their families. The Company's chief decision maker, the President and Chief Executive Officer, reviews the Company's operating results on an aggregate basis and manages the Company's operations as a single operating unit. Substantially all of the Company's long-lived assets are located in the U.S.

Accounting Pronouncements Recently Adopted

Accounting Standards Update (ASU) 2014-09, *Revenue from Contracts with Customers (Topic 606)* and subsequent amendments to the initial guidance, or collectively, Topic 606, amended the existing accounting standards for revenue recognition. The core principle of Topic 606 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration that is expected to be received for those goods or services. The Company adopted Topic 606 effective January 1, 2018 using the modified retrospective approach. The adoption of Topic 606 did not have a material impact on the Company's consolidated financial statements as the Company does not have any contracts with customers.

ASU 2016-15, *Statement of Cash Flows (Topic 230)* provides guidance on eight specific cash flow issues, thereby reducing the diversity in practice in how certain transactions are classified in the statement of cash flows. The amendments in this ASU should be applied retrospectively to all periods presented. The Company adopted ASU 2016-15 effective January 1, 2018. The adoption of this ASU did not have a material impact on the Company's consolidated financial statements.

ASU 2016-18, *Statement of Cash Flows (Topic 230), Restricted Cash,* amends Topic 230 to add or clarify guidance on the classification and presentation of restricted cash in the statement of cash flows. The guidance requires that the statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents rather than only cash and cash equivalents, as previously required. The Company adopted ASU 2016-18 effective January 1, 2018 on a retrospective basis to all periods presented. For the year ended December 31, 2016, the change in restricted cash due to the release from escrow of holdback funds related to the Company's divestiture of Zohydro ER of $10.0 million has been excluded from investing activity in the statement of cash flows as the amount has now been included in the beginning total cash, cash equivalents, and restricted cash balance. The adoption of the guidance did not have any impact on the Company's financial position or result of operations. As of December 31, 2018 and 2017, the Company did not have any restricted cash.

ASU 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business* narrows the definition of a business and provides additional guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. This accounting standards update is required to be applied prospectively to transactions occurring after the date of adoption. The Company adopted ASU 2017-09 effective January 1, 2018. The adoption of this ASU did not have a material impact on the Company's consolidated financial statements.

ASU 2017-09, *Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting* provides guidance on determining changes to the terms and conditions of share-based payment awards and require an entity to apply modification accounting under Topic 718 unless all of the following conditions are met: (1) the fair value of the modified award is the same as the fair value of the original award immediately before the original award is modified. If the modification does not affect any of the inputs to the valuation technique that the entity uses to value the award, the entity is not required to estimate the value immediately before and after the modification; (2) the vesting conditions of the modified award are the same as the vesting conditions of the original award immediately before the original award is modified; and (3) the classification of the modified award as an equity instrument or a liability instrument is the same as the classification of the original award immediately before the original award is modified. The amendments should be applied prospectively to an award modified on or after the adoption date. The Company adopted ASU 2017-09 effective January 1, 2018. The adoption of this ASU did not have a material impact on the Company's consolidated financial statements.

ASU 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* simplifies the accounting for share-based payment awards issued to nonemployees for goods and services, including fixing the estimated fair value of the stock award at the date of grant. ASU 2018-07 expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees. Consequently, the accounting for share-based payments to nonemployees and employees will be substantially aligned. The adoption of ASU 2018-07 requires a modified retrospective transition approach, with a cumulative-effect adjustment to retained earnings as of the beginning of the fiscal year. ASU 2018-07 is effective for public companies for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted, but no earlier than an entity's adoption date of Topic 606. The Company early adopted ASU 2018-07 effective July 1, 2018. The adoption of this ASU did not have a material impact on the Company's consolidated financial statements.

In December 2017, the SEC issued Staff Accounting Bulletin No. 118 (SAB 118), *Income Tax Accounting Implications of the Tax Cuts and Jobs Act* to address the application of GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Tax Cuts and Jobs Act of 2017 (Tax Act). In accordance with SAB 118, the Company recorded provisional tax impacts related to the revaluation of deferred tax assets and liabilities and the effects of the transition tax on undistributed foreign earnings and profits in its consolidated financial statements for the year ended December 31, 2017. As of December 31, 2018, the Company completed its accounting for the impact of the Tax Act and determined there were no material changes to its analysis originally performed. See Note 12 to the consolidated financial statements for additional details.

In August 2018, the SEC adopted amendments to certain disclosure requirements in Securities Act Release No. 33-10532, Disclosure Update and Simplification. These amendments eliminate, modify, or integrate into other SEC requirements certain disclosure rules. Among the amendments is the requirement to present an analysis of changes in stockholders' equity in the interim financial statements included in quarterly reports on Form 10-Q. The analysis, which can be presented as a footnote or separate statement, is required for the current and comparative quarter and year-to-date interim periods. The amendments became effective for all filings made on or after November 5, 2018. In light of the anticipated timing of effectiveness of the amendments and expected proximity of effectiveness to the filing date for most filers' quarterly reports, the SEC's Division of Corporate Finance issued a Compliance and Disclosure Interpretation related to Exchange Act Forms (CDI) – Question 105.09, that provides transition guidance related to this disclosure requirement. CDI – Question 105.09 states that the SEC would not object if the filer's first presentation of the changes in shareholders' equity is included in its Form 10-Q for the quarter that begins after the effective date of the amendments. Except for the requirement to provide the annual disclosure changes in stockholders' equity for interim periods, which will be included beginning with the Company's quarterly report on Form 10-Q ending March 31, 2019, the Company has adopted all relevant disclosure requirements.

Accounting Pronouncements Issued But Not Yet Effective

ASU 2016-02, *Leases (Topic 842)* establishes a right-of-use (ROU) model that requires all lessees to recognize ROU assets and liabilities for leases with a duration greater than one year on the balance sheet as well as provide disclosures with respect to certain qualitative and quantitative information regarding the amount, timing and uncertainty of cash flows arising from leases. Both a ROU asset and liability will initially be measured at the present value of the future minimum lease payments over the lease term. Subsequent measurement, including the presentation of expenses and cash flows, will depend on the classification of the lease as either a finance or an operating lease. Initial costs directly attributable to negotiating and arranging the lease will be included in the ROU asset. The new standard is effective for fiscal years beginning after December 15, 2018, and interim periods therein. Early adoption is permitted. Originally, entities were required to adopt ASU 2016-02 using a modified retrospective approach, which required prior periods to be presented under this new standard with various practical expedients allowed. In July 2018, the Financial Accounting Standards Board (FASB) issued ASU 2018-11, Leases (Topic 842): Targeted Improvements, which allows for a new transition method that offers the option to use the effective date as the date of initial application. The Company intends to elect this alternative transition method and therefore will not adjust comparative-period financial information and will continue to present all prior periods under previous lease accounting guidance. In addition, the Company intends to utilize the practical expedient that allows the Company to not reassess whether an expired or existing contract contains a lease, the classification of leases or initial direct costs. The Company has identified the population of its contracts subject to this guidance. While the Company is finalizing its evaluation of the impact of adopting this accounting standard update on its consolidated financial statements and related disclosures, the Company expects to recognize on its balance sheet for associated leases a new ROU asset ranging from $7.5 million to $9.5 million and lease liability ranging from $12.0 million to $14.0 million, with the difference between ROU assets and lease liability attributed to the elimination of remaining unamortized lease incentive obligations, deferred rent and a cease-use liability. The adoption of this standard are also expected to impact the Company's consolidated financial statement disclosures.

ASU 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. This standard update requires that certain financial assets be measured at amortized cost net of an allowance for estimated credit losses such that the net receivable represents the present value of expected cash collection. In addition, this standard update requires that certain financial assets be measured at amortized cost reflecting an allowance for estimated credit losses expected to occur over the life of the assets. The estimate of credit losses must be based on all relevant information including historical information, current conditions and reasonable and supportable forecasts that affect the collectability of the amounts. This standard update is effective as of the first quarter of 2020; however, early adoption is permitted. The Company intends to adopt this standard update in the first quarter of 2020. The Company is currently evaluating the impact that this standard update will have on its consolidated financial statements upon adoption.

ASU 2017-04, *Intangibles-Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment* simplifies how an entity is required to test goodwill for impairment by eliminating Step 2 from the goodwill impairment test. Step 2 measures a goodwill impairment loss by comparing the implied fair value of a reporting unit's goodwill with the carrying amount of that goodwill. Under the amendments in ASU 2017-04, an entity should recognize an impairment charge for the amount by which the carrying amount of a reporting unit exceeds its fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. The updated guidance requires a prospective adoption. ASU 2017-04 is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption is permitted for goodwill impairment tests performed on testing dates after January 1, 2017. The Company is currently evaluating the timing and impact of adopting this ASU on its consolidated financial statements and related disclosures.

ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement* modifies the disclosure requirements in Topic 820 by removing certain disclosure requirements related to the fair value hierarchy, modifying existing disclosure requirements related to measurement uncertainty and adding new disclosure requirements, such as disclosing the changes in unrealized gains and losses for the period included in other comprehensive income for recurring Level 3 fair value measurements held at the end of the reporting period and disclosing the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. This ASU is effective for public companies for fiscal years beginning after December 15, 2019, including interim periods within that fiscal year. Early adoption is permitted for any removed or modified disclosures. The Company is currently evaluating the timing and impact of adopting this ASU on its consolidated financial statements and related disclosures.

3. Strategic and License Agreements

Fintepla (ZX008)

In October 2014, the Company acquired Brabant Pharma Limited (Brabant) in a business combination and obtained worldwide development and commercialization rights to Fintepla (ZX008; low-dose fenfluramine), its lead product candidate. Under the terms of the sale and purchase agreement, the Company agreed to make future milestone payments to the former owners of Brabant for up to $95.0 million in the event the Company achieves certain milestones with respect to Fintepla, consisting of $50.0 million in regulatory milestones and $45.0 million in sales milestones. In February 2019, the Company completed a rolling submission of a NDA with the FDA and submitted a MAA to the EMA for Fintepla for the treatment of seizures associated with Dravet syndrome. The EMA has accepted the MAA, which triggered a $10.0 million development milestone payment. An additional $10.0 million milestone payment shall become due and payable if the NDA is accepted by the FDA.

In addition, the Company has a collaboration and license agreement with the Universities of Antwerp and Leuven in Belgium (the Universities) that runs through September 2045. Under the terms of the agreement, the Universities granted the Company an exclusive worldwide license to use the data obtained from a study related to low-dose fenfluramine for the treatment of Dravet syndrome, as well as certain other intellectual property. The Company is required to pay a mid-single-digit percentage royalty on net sales of products containing low-dose fenfluramine for the treatment of Dravet syndrome or, in the case of a sublicense of products containing low-dose fenfluramine for the treatment of Dravet syndrome, a percentage in the mid-twenties of the sub-licensing revenues. The agreement may be terminated by the Universities if the Company: (a) does not use commercially reasonable efforts to (i) develop and commercialize products containing low-dose fenfluramine for the treatment of Dravet syndrome or related conditions stemming from infantile epilepsy, or (ii) seek approval of products containing low-dose fenfluramine for the treatment of Dravet syndrome in the United States; or (b) if the Company becomes insolvent or makes an assignment for the benefit of creditors or should any petition in bankruptcy, or similar relief, be filed by or against the Company. The Company can terminate the agreement upon specified prior written notice to the Universities.

Contract Manufacturing Supply Agreement with Endo and Associated Exit Activities

In May 2014, the Company completed the sale of its Sumavel DosePro business. Concurrently with the sale, the Company entered into the Supply Agreement to be the exclusive supplier of Sumavel DosePro to Endo. The Supply Agreement was terminated in September 2017. The Company recorded a charge of $2.2 million in inventory write-down to reflect its current net realizable value as a result the termination agreement in 2017 and also recorded an impairment charge of $2.0 million in 2016 to write off the remaining carrying amount of a prepaid royalty associated with the Supply Agreement. These additional charges reflected ongoing negotiations over the course of finalizing the termination of the Supply Agreement and were included as a cost of contract manufacturing and a component of operating expenses, respectively, in the consolidated statements of operations.

Pursuant to the termination agreement, the Company also received cash consideration of $1.5 million from Endo for reimbursement of a portion of the Company's termination costs for its third-party suppliers and manufacturers related to Sumavel DosePro product. As part of the termination agreement, both parties also agreed to net settle outstanding accounts receivable of $4.7 million due from Endo and the Company's remaining purchased raw materials and other costs of $2.3 million against the $7.0 million working capital advance note payable due to Endo. In connection with the Endo termination agreement, the Company also executed termination agreements with its third-party suppliers and manufacturers related to the Sumavel DosePro product and incurred contract termination costs of $2.5 million. Excluding the non-cash loss on extinguishment of debt due to the write-off of unamortized discount related to imputed interest (see Note 8), these termination agreements resulted in a net loss on contract termination of $0.5 million, which was included in loss on contract termination within continuing operations in the consolidated statements of operations.

Other Asset Acquisitions

In October 2016, the Company paid $1.5 million to acquire the global rights to a preclinical development program for orphan CNS disorders in an asset acquisition. At the date of acquisition, the project had not yet reached technological feasibility, was deemed to have no alternative use, and was immediately charged to research and development expense. The asset purchase agreement provides for potential additional payments if certain development and sales milestones are achieved. Due to the preclinical stage of development and the nature of this arrangement, any future potential payments related to the attainment of the specified milestones over a period of several years are inherently uncertain.

4. Cash, Cash Equivalents and Marketable Securities

The following table summarizes the amortized cost and fair value of the Company's cash, cash equivalents and marketable securities as of December 31, 2018 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Current assets:				
Cash and cash equivalents:				
Cash	$ 5,222	$ —	$ —	$ 5,222
Money market funds	63,232	—	—	63,232
Total cash and cash equivalents	$ 68,454	$ —	$ —	$ 68,454
Marketable securities:				
Commercial paper	$ 152,940	$ —	$ —	$ 152,940
Corporate debt securities	60,622	58	(75)	60,605
Certificates of deposit	128,647	—	—	128,647
U.S. Treasuries	103,521	31	(11)	103,541
Total marketable securities	$ 445,730	$ 89	$ (86)	$ 445,733
Total cash, cash equivalents and marketable securities	$ 514,184	$ 89	$ (86)	$ 514,187

The following table summarizes the amortized cost and fair value of marketable securities based on stated effective maturities as of December 31, 2018 (in thousands):

	Amortized Cost	Fair Value
Due within one year	$ 408,479	$ 408,471
Due between one and two years	37,251	37,262
Total	$ 445,730	$ 445,733

As of December 31, 2017, cash and cash equivalents included $289.8 million of money market fund investments having a carrying value equaled to their fair value. The Company did not hold any marketable securities at December 31, 2017.

There have been no significant realized gains or losses on available-for-sale securities for the periods presented. Available-for-sale debt securities that were in a continuous loss position but were not deemed to be other than temporarily impaired were immaterial at December 31, 2018.

See Note 5 for further information regarding the fair value of the Company's financial instruments.

5. Fair Value Measurements

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. A three-level valuation hierarchy has been established under GAAP for disclosure of fair value measurements. The valuation hierarchy is based on the transparency of inputs to the valuation of an asset or liability as of the measurement date. The three levels are defined as follows:

- Level 1 - Observable inputs such as quoted prices in active markets;
- Level 2 - Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and
- Level 3 - Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

The following tables summarize assets and liabilities recognized or disclosed at fair value on a recurring basis at December 31, 2018 and 2017 (in thousands):

	Level 1	Level 2	Level 3	Total
December 31, 2018				
Assets:				
Cash equivalents:				
Money market funds	$ 63,232	$ —	$ —	$ 63,232
Marketable securities:				
Commercial paper	—	152,940	—	152,940
Corporate debt securities	—	60,605	—	60,605
Certificates of deposit	—	128,647	—	128,647
U.S. Treasury securities	—	103,541	—	103,541
Total assets(1)	$ 63,232	$ 445,733	$ —	$ 508,965
Liabilities:				
Common stock warrant liabilities (2)	$ —	$ —	$ 343	$ 343
Contingent consideration liabilities (3)	—	—	78,200	78,200
Total liabilities	$ —	$ —	$ 78,543	$ 78,543
December 31, 2017				
Assets:				
Cash equivalents:				
Money market funds (1)	$ 289,782	$ —	$ —	$ 289,782
Total assets	$ 289,782	$ —	$ —	$ 289,782
Liabilities:				
Common stock warrant liabilities (2)	$ —	$ —	$ 512	$ 512
Contingent consideration liabilities (3)	—	—	76,900	76,900
Total liabilities	$ —	$ —	$ 77,412	$ 77,412

(1) Fair value is determined by taking into consideration valuations obtained from third-party pricing services. The third-party pricing services utilize industry standard valuation models, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities; issuer credit spreads; benchmark securities; and other observable inputs.

(2) Represents the fair value of common stock warrants outstanding that may require cash settlement under certain circumstances. The Company estimated the fair value of the warrant liabilities using the Black-Scholes valuation model. As of December 31, 2018, common stock warrant liabilities consisted of warrants issued in July 2011 in connection with a debt financing arrangement. The warrants entitle the holder to purchase up to 28,125 shares of common stock at an exercise price of $72.00 per share and expires in July 2021.

(3) In connection with the acquisition of Brabant in 2014 (See Note 3), the Company may be required to pay future consideration that is contingent upon the achievement of specified development, regulatory approval or sales-based milestone events. The Company estimates the fair value of contingent purchase consideration liabilities using a probability-weighted income approach, which reflects the probability and timing of future payments. This fair value measurement is based on significant Level 3 inputs such as the anticipated timelines and probability of achieving development, regulatory approval or sales-based milestone events and projected revenues. The resulting probability-weighted cash flows are discounted at risk-adjusted rates. Subsequent to the acquisition date, at each reporting period prior to settlement, the Company revalues these liabilities by performing a review of the assumptions listed above and records an adjustment to reflect any changes in the estimated fair values of these contingent consideration liabilities. In the absence of any significant changes in key assumptions during a reporting period, the change in fair values of these contingent consideration liabilities would primarily reflect an increase in fair value from the passage of time. Significant judgment is used in determining Level 3 inputs and fair value measurements as of a reporting period. Updates to assumptions could have a significant impact on the Company's results of operations in a reporting period and actual results may differ from estimates. For example, significant increases in the estimated probability of achieving a milestone or projected revenues

would result in a significantly higher fair value measurement while significant decreases in the estimated probability of achieving a milestone or projected revenues would result in a significantly lower fair value measurement. Significant increases in the discount rate or in the anticipated timelines would result in a significantly lower fair value measurement while significant decreases in the discount rate or anticipated timelines would result in a significantly higher fair value measurement. The potential contingent consideration payments required upon achievement of development, regulatory approval and sales-based milestones related to the Company's acquisition of Brabant range from zero if none of the milestones are achieved to a maximum of $95.0 million (undiscounted). As of December 31, 2018, the Company classified $32.3 million of the total contingent consideration liabilities of $78.2 million as current liabilities. The classification was based upon the Company's reasonable expectation as to the timing of settlement of certain specified milestones.

There were no transfers between levels for all periods presented. See Note 4 for further information regarding the carrying value of the Company's financial instruments.

The following table provides a reconciliation of assets and liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) for the years ended December 31, 2018 and 2017 (in thousands):

	Contingent Purchase Consideration	Common Stock Warrant Liabilities
Balance at December 31, 2016	$ 52,800	$ 809
Additions	—	—
Settlements	—	—
Changes in fair value	24,100	(297)
Balance at December 31, 2017	76,900	512
Additions	—	—
Settlements	—	—
Changes in fair value	1,300	(169)
Balance at December 31, 2018	$ 78,200	$ 343

Changes in the estimated fair value of contingent purchase consideration are reflected as operating expenses in the consolidated statements of operations. Changes in the estimated fair value of common stock warrant liabilities are included within other income (expense) in the consolidated statements of operations.

6. Balance Sheet Components

The following tables provide details of selected balance sheet components (in thousands):

Property and Equipment, Net

Property and equipment, net consisted of the following:

	December 31,	
	2018	2017
Computer equipment and software	$ 216	$ 141
Leasehold improvements	3,210	976
Furniture and fixtures	880	407
Total	4,306	1,524
Less accumulated depreciation	(1,436)	(1,279)
Property and equipment, net	$ 2,870	$ 245

Other Long-Term Liabilities

Other long-term liabilities consisted of the following:

	December 31,	
	2018	2017
Deferred rent and lease incentive obligation	$ 3,685	$ 244
Other	145	540
	$ 3,830	$ 784

7. Commitments and Contingencies

The Company is not currently involved in any material legal proceedings. The Company may become involved in various legal proceedings and claims that arise in the ordinary course of business. Such matters are subject to uncertainty and there can be no assurance that such legal proceedings will not have a material adverse effect on its business, results of operations, financial position or cash flows.

See Note 3 for the Company's commitments under collaboration, license and purchase agreements.

Operating Leases

In October 2018, the Company entered into a new lease agreement for new headquarters and amended its existing headquarter lease, both with the same landlord. The new lease agreement provides for 37,307 square feet of office and laboratory space also located in Emeryville, California under a noncancellable lease that expires on June 30, 2027 and has a renewal option for an additional five years. The cash expected to be paid for base rent over the term of the new lease is approximately $15.3 million beginning in June 2019. The lease provides for lease incentives for tenant improvements of $3.1 million, a rent free period, and scheduled rent increases over the term of the lease. The Company is also required to pay its proportionate share of costs related to common area maintenance, property taxes, and other operating costs. Upon completion of its relocation to its new headquarters, which is expected to be by the end of the second quarter of 2019, the lease agreement for its existing headquarters will be terminated.

The Company was provided access to the leased space upon lease execution and recorded a $3.1 million lease incentive receivable within other current assets, with a corresponding lease incentive obligation as a component of deferred rent, in accrued liabilities or long-term liabilities, as appropriate.

The Company also has a noncancellable operating lease expiring in March 2020 for office space in San Diego, California, which previously served as the Company's headquarters prior to its relocation to Emeryville, California. In 2017, the Company vacated the leased premises upon entering into a noncancellable sublease agreement with a sublessee for the remainder of the Company's lease term. Because amounts to be received under the sublease were less than the amounts the Company is required to pay its lessor, the Company recorded a loss on lease of $0.6 million, net of adjustments to derecognize the related deferred rent liability, as a component of general and administrative expenses in the consolidated statements of operations. As of December 31, 2018, accrued liabilities related to this lease arrangement was $0.5 million, of which $0.1 million was long-term.

Rent expense for 2018, 2017 and 2016 was $1.6 million, $1.8 million and $1.9 million, respectively.

Future minimum rental payments under the Company's noncancellable operating leases, net of sublease rental income, were as follows (in thousands):

	Gross Rental Payments	Sublease Rental Income	Net Rental Payments
2019	$ 1,777	$ (576)	$ 1,201
2020	1,788	(148)	1,640
2021	1,839	—	1,839
2022	1,894	—	1,894
2023	1,951	—	1,951
Thereafter	7,296	—	7,296
Total	$ 16,545	$ (724)	$ 15,821

8. Debt

In December 2017, the Company used a portion of the proceeds from the Company's October 2017 common stock offering (see Note 9) and paid off its term loan with an outstanding principal balance of $20.0 million, plus accrued interest. The Company recognized a $1.5 million loss on early extinguishment of debt consisting of a noncash charge to write off the remaining unamortized debt issuance costs and debt discount. The Company also incurred $1.9 million in additional fees related to early extinguishment of the term loan, which had a scheduled maturity date of July 1, 2020.

In May 2014, the Company was provided with an interest-free working capital note payable of $7.0 million from Endo in connection with the Supply Agreement (See Note 3). The working capital advance note payable matured upon the termination of the Supply Agreement. The working capital advance note payable was initially recorded on the consolidated balance sheet net of a $4.7 million debt discount related to imputed interest. In September 2017, the Company and Endo terminated the Supply Agreement and the working capital advance note payable became due and payable in accordance with its terms. Pursuant to the termination agreement, the $7.0 million promissory note was extinguished to settle amounts owed to the Company for accounts receivable and purchased raw materials (See Note 5). In connection with the extinguishment, the Company recognized a non-cash charge upon debt extinguishment of $3.4 million to write off the remaining unamortized debt discount related to imputed interest. As of December 31, 2018 and 2017, the Company had no debt outstanding.

9. Stockholders' Equity

Preferred Stock

The Company has 10,000,000 shares of preferred stock authorized for issuance, par value of $0.001 per share. As of December 31, 2018 and 2017, no shares of preferred stock were issued and outstanding.

Common Stock

The Company has 50,000,000 shares of common stock authorized for issuance, par value of $0.001 per share. Holders of the Company's common stock are entitled to one vote per share. As of December 31, 2018 and 2017, there were 42,078,164 and 34,807,509 shares of common stock issued and outstanding.

The following table presents common stock reserved for future issuance for the following equity instruments as of December 31, 2018 and 2017 (in thousands):

	December 31,	
	2018	2017
Stock options and RSUs outstanding	4,033	3,651
Warrants to purchase common stock	28	38
Available for future issuance under employee equity plans	1,684	872
Total common stock reserved for future issuance	5,745	4,561

Sale of Common Stock

In the third quarter of 2017, the Company sold a total of 1,550,880 shares of its common stock pursuant to an at-the-market sales agreement with Cantor Fitzgerald & Co. (ATM Agreement) and received net proceeds of approximately $19.4 million, after deducting commissions and other offering expenses.

In October 2017, the Company completed an underwritten public offering for the sale of 7,700,000 shares of its common stock. The shares were sold to the public at an offering price of $37.50 per share. Net proceeds raised from the offering amounted to approximately $271.3 million, after deducting underwriting discounts and commissions and other offering expenses.

In the second quarter of 2018, the Company sold a total of 740,417 shares of its common stock pursuant to the ATM Agreement and received net proceeds of approximately $30.3 million, after deducting commissions and other offering expenses.

In August 2018, the Company completed an underwritten public offering for the sale of 6,000,000 shares of its common stock. The shares were sold to the public at an offering price of $52.00 per share. Net proceeds raised from the offering amounted to approximately $292.9 million, after deducting underwriting discounts and commissions and other offering expenses.

10. Stock-Based Compensation

Summary of Equity Incentive Plans

2006 Plan

The Company granted options under its 2006 Equity Incentive Award Plan, as amended (2006 Plan) until November 2010 upon adoption of the 2010 Plan (discussed below), which serves as the successor plan to the 2006 Plan. While no further grants may be made from the 2006 Plan, it continues to govern the terms of options that remain outstanding under the 2006 Plan. The 2006 Plan provided for the granting of incentive stock options, non-qualified stock options and rights to purchase restricted stock to eligible recipients. Stock options granted pursuant to the 2006 Plan had a contractual term of ten years and generally vest over four years.

2010 Plan

The Company's 2010 Equity Incentive Award Plan, which was amended in June 2012 (2010 Plan), became effective immediately prior to the completion of the Company's initial public offering in November 2010. The 2010 Plan provides for the granting of incentive stock options, non-qualified stock options, stock appreciation rights, restricted stock units and rights to purchase restricted stock to eligible recipients. Service-based options granted pursuant to the 2010 Plan has a contractual term of ten years and generally vest over four years. Performance-based awards are subject to the employee's continued service and become vested based on the completion of the applicable performance conditions. As amended in June 2012, the initial 280,459 shares reserved for issuance under the 2010 Plan was increased to 1,162,500 shares, plus any shares related to outstanding options granted under the 2006 Plan that are subsequently repurchased, forfeited, expire or are canceled. In addition, the 2010 Plan's evergreen provision was also amended such that, commencing on January 1, 2013, and on each January 1 through and including January 1, 2020, the aggregate number of shares available for issuance under the 2010 Plan shall be increased by that number of shares of the Company's common stock equal to the lower of:

- 4% of the Company's outstanding common stock on the applicable January 1; or
- an amount determined by the board of directors.

In March 2018, the Board approved an amendment and restatement of its non-employee director compensation policy. Under the amended and restated compensation policy, any non-employee director who is first elected to the board of directors is granted an option to purchase 20,000 shares of our common stock on the date of his or her initial election to the board of directors. In addition, on the date of each of the Company's Annual Meeting of Stockholders, each non-employee director is eligible to receive an option to purchase 15,000 shares of common stock.

As of December 31, 2018 and 2017, 1,550,351 and 756,524 shares of common stock were available for future issuance under the 2010 Plan, respectively.

Inducement Plan

In December 2013, the Company's board of directors (Board) adopted the Employment Inducement Equity Incentive Award Plan (Inducement Plan). The terms of the Inducement Plan are substantially similar to the terms of the 2010 Plan with two principal exceptions: (1) incentive stock options may not be granted under the Inducement Plan; and (2) the annual compensation paid by the Company to specified executives will be deductible only to the extent that it does not exceed $1.0 million, as the conditions of Section 162(m) of the Code applicable at the time will not be met. The Inducement Plan was adopted by the board of directors without stockholder approval pursuant to Rule 5635(c)(4) of the Nasdaq Listing Rules.

The Company has initially reserved 337,500 shares of the Company's common stock for issuance pursuant to awards granted under the Inducement Plan, which was subsequently increased to 637,500 shares in May 2018. In accordance with Rule 5635(c)(4) of the Nasdaq Listing Rules, awards under the Inducement Plan may only be made to an employee who has not previously been an employee or member of the board of directors of the Company or any parent or subsidiary, or following a bona fide period of non-employment by the Company or a parent or subsidiary, if he or she is granted such award in connection with his or her commencement of employment with the Company or a subsidiary and such grant is an inducement material to his or her entering into employment with the Company or such subsidiary. As of December 31, 2018 and 2017, there were 118,325 and 102,276 shares of common stock available for future issuance under the Inducement Plan, respectively.

2010 ESPP

In November 2010, the Board adopted the 2010 Employee Stock Purchase Plan (2010 ESPP), which allows employees to purchase shares of the Company's common stock during specified offering periods at a discount to the fair market value at the time of purchase. The ESPP is implemented by overlapping, twelve-month offering periods and each offering period may contain up to two purchase periods of six months each. At any one time, there may be up to two offering periods under the ESPP. In general, a new twelve-month offering period commences on each June 1 and December 1 of a calendar year.

Stock may be purchased under the ESPP at a price equal to 85% of the fair market value of the Company's stock on either the date of purchase or the first day of an offering period, whichever is lower. Eligible employees may elect to withhold up to 20% of their compensation through payroll deductions during an offering period for the purchase of stock. The ESPP contains a reset provision whereby if the price of the Company's common stock on the first day of a new offering period is less than the price on the first day of any preceding offering period, all participants in the preceding offering period with higher first day price will be automatically withdrawn from such offering periods and re-enrolled in the new offering period. The reset feature, when triggered, will be accounted for as a modification to the original offering period, resulting in incremental expense to be recognized over the twelve-month period of the new offering.

The ESPP limits the maximum number of shares that may be purchased by any one participant in an offering period to 2,500 shares. In addition, the Code limits purchases under an ESPP to $25,000 worth of stock in any one calendar year, valued as of the first day of the offering period. As of December 31, 2018 and 2017, there were 15,243 and 16,672 shares of common stock available for issuance under the 2010 ESPP, respectively.

Equity Incentive Plan Activity

The following sections summarize activity under the Company's equity incentive plans.

Stock Options

The following table summarizes the Company's stock option activity for 2018:

	Shares (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2017	3,392	$ 14.41		
Granted	889	$ 43.19		
Exercised	(434)	$ 16.84		
Canceled	(103)	$ 24.16		
Outstanding at December 31, 2018	3,744	$ 20.69	6.9	$ 64,906
Exercisable at December 31, 2018	2,415	$ 16.66	6.0	$ 48,735

The total intrinsic value of options exercised in 2018, 2017 and 2016 was $11.8 million, $14.3 million and $24,000, respectively.

Restricted Stock Units (RSUs)

The following table summarizes the Company's restricted stock unit activity for 2018:

	Shares (in thousands)	Weighted Average Fair Value per Share at Grant Date
Nonvested at December 31, 2017	259	$ 10.43
Granted	146	$ 42.76
Vested	(98)	$ 10.74
Canceled	(18)	$ 27.89
Nonvested at December 31, 2018	289	$ 25.56

The total intrinsic value of RSUs vested in 2018 was $4.2 million. No RSUs vested in 2017 and 2016. As of December 31, 2018, outstanding RSUs included approximately 154,000 shares granted in March 2017 to employees and executives that are performance-based. These performance-based awards vest upon FDA approval of the Company's NDA for Fintepla, provided such approval occurs within five years following the grant date. Due to the uncertainties associated with the FDA approval process, approval is not yet probable, as such term is used for accounting purposes, prior to the occurrence of the event. Accordingly, no compensation expense has been recognized to date. As of December 31, 2018, total unrecognized compensation costs related to such awards were $1.6 million.

As of December 31, 2018, nonvested restricted stock units outstanding not subject to a performance condition had a weighted average remaining contractual term of 1.7 years with an intrinsic value of $4.9 million.

Employee Stock Purchase Plan

Shares purchased by employees under the 2010 ESPP were 32,679 shares, 35,934 shares and 35,164 shares in 2018, 2017 and 2016, respectively. As of December 31, 2018 and 2017, 15,243 shares and 16,672 shares of common stock were reserved for issuance under the 2010 ESPP, respectively.

Valuation of Equity Awards

The Company used the Black-Scholes option-pricing model for determining the estimated fair value and stock-based compensation related to stock options and ESPP purchase rights granted. A summary of the assumptions used to estimate the fair values for the periods presented is as follows:

	Year Ended December 31,		
	2018	2017	2016
Stock Options			
Risk free interest rate	2.3% to 3.0%	1.8% to 2.3%	1.1% to 2.1%
Expected term	5.3 to 6.1 years	5.1 to 6.1 years	5.1 to 6.1 years
Expected volatility	80.1% to 85.2%	75.1% to 85.8%	76.5% to 78.1%
Expected dividend yield	—%	—%	—%
Weighted-average fair value of option on grant date	$30.87	$7.43	$6.69
Employee Stock Purchase Plan			
Risk free interest rate	2.1% to 2.7%	1.1% to 1.6%	0.5% to 0.8%
Expected term	0.5 to 1.0 years	0.5 to 1.0 years	0.5 to 1.0 years
Expected volatility	44.7% to 113.1%	54.8% to 152.8%	59.5% to 71.3%
Expected dividend yield	—%	—%	—%

Performance Stock Options

In October 2015, the Company granted employees certain performance-based stock options for retention purposes. The stock options would vest upon satisfaction of a specified regulatory milestone within three years of the date of grant. In 2017, management determined the achievement of the performance condition was no longer probable and the cumulative compensation expense previously recognized of $0.7 million was reversed. In September 2018, these awards were modified to allow for 90% of such options outstanding at the modification date to vest immediately. The remaining 10% of the awards were canceled in October 2018 since the performance condition was not met. This improbable to probable modification resulted in the calculation and recognition of incremental stock-based compensation expense of $3.5 million in 2018. The Company estimated the fair value of the modified stock options using the Black-Scholes model based on the following key assumptions:

Modification of Stock Options		
Exercise price	$	13.32
Common stock price on date of modification	$	49.60
Expected term		3.5 years
Expected volatility		79.9%
Expected dividend yield		—%

Stock-Based Compensation Expense

The following table summarizes the components of total stock-based compensation expense included in the consolidated statements of operations for the periods presented (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Cost of contract manufacturing	$ —	$ 71	$ 386
Research and development	6,317	1,933	1,924
Selling, general and administrative	9,175	4,151	5,043
Total	$ 15,492	$ 6,155	$ 7,353

As of December 31, 2018, there was approximately $29.6 million of total unrecognized compensation costs related to outstanding equity awards scheduled to be recognized over a weighted average period of 2.6 years.

11. Employee Benefit Plan

Effective February 1, 2007, the Company established a defined contribution 401(k) plan (the Plan) for all employees who are at least 21 years of age. Employees are eligible to participate in the Plan beginning on the first day of the month following one month of employment. Under the terms of the Plan, employees may make voluntary contributions as a percentage of compensation. The Plan also provides the Company to make discretionary matching contributions. In 2018, 2017 and 2016, the Company made discretionary matching contributions of $0.2 million, $0.2 million, $0.1 million, respectively.

12. Income Taxes

For financial reporting purposes, the components of loss from continuing operations before income taxes were as follows (in thousands):

	December 31,		
	2018	2017	2016
United States	$ (35,838)	$ (32,112)	$ (24,285)
Foreign	(87,878)	(93,910)	(45,349)
Total	$ (123,716)	$ (126,022)	$ (69,634)

At December 31, 2018, the Company's federal, state, and foreign net operating loss carryforwards were approximately $286.3 million, $190.3 million and $191.8 million, respectively, which may be subject to limitations as described below. If not utilized, the federal tax loss carryforwards incurred prior to 2018 will begin to expire in 2029 and the state tax loss carryforwards incurred prior to 2018 will begin to expire in 2021. Under the Tax Cut and Jobs Act of 2017 (Tax Act), 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 Tax Act. In

addition, the Company has federal and California research and development income tax credit carryforwards of approximately $3.4 million and $4.1 million, respectively. If not utilized, the federal research and development income tax credit carryforwards will begin to expire in 2027. The California research and development income tax credit carryforwards do not expire and can be carried forward indefinitely. Due to the net operating loss carryforwards, all years remain open for income tax examination by tax authorities in the United States, various states and foreign tax jurisdictions in which the Company files tax returns.

As of December 31, 2018, the Company has experienced at least three ownership changes. The first ownership change occurred in August 2006 upon the issuance of the Series A-1 convertible preferred. As a result of this ownership change, the Company has reduced its net operating loss carryforwards by $1.9 million and research and development income tax credits by $8,000. The Company had a second ownership change in September 2011 upon the issuance of common stock in a follow-on offering. As a result of the second ownership change, the Company has reduced its federal net operating loss carryforwards as of December 31, 2011 by $121.1 million and research and development income tax credits as of December 31, 2011 by $3.0 million. In addition, the Company also reduced its California net operating loss carryforwards as of December 31, 2011 by $53.3 million as a result of the second ownership change. The Company had a third ownership change in January 2014, which did not result in any reductions of federal and California net operating loss carryforwards or research and development income tax credits. Based on the Company's most recent assessment through December 31, 2018, no reduction was made to the federal and state net operating loss carryforwards or federal and state tax income tax credit carryforwards under these rules. Pursuant to the IRC, the use of the Company's net operating loss and research and development income tax credit carryforwards may be limited in the event of a future cumulative change in ownership of more than 50% within a three-year period.

A reconciliation of the Company's income tax benefit from continuing operations compared to the income tax benefit computed at the federal statutory tax is was as follows (in thousands):

	December 31,		
	2018	2017	2016
Income tax at federal statutory rate	$ (26,022)	$ (42,846)	$ (23,675)
State taxes, net of federal benefit	(8)	(19)	(65)
Change in valuation allowance	16,949	(11,208)	16,024
Impact of U.S. statutory rate change on revaluing deferred tax assets	—	36,085	—
Permanent interest disallowed	(35)	(150)	(1,832)
Impact of foreign rate change on deferred taxes	1,961	1,619	521
Other permanent differences[1]	(666)	8,236	630
Research and development tax credits	(51)	(274)	(145)
State tax rate benefit	169	56	578
Foreign rate differential	1,731	10,636	6,122
Stock-based compensation[1]	(1,344)	(2,462)	1,132
Net operating losses surrendered under UK's R&D tax relief scheme	6,322	—	—
Credits and other[1]	994	327	(238)
Income tax benefit	$ —	$ —	$ (948)

[1] Certain prior years' amounts in the table above have been reclassified to conform with current year's presentation.

The Tax Act has resulted in significant changes to the U.S. corporate income tax system. These changes include a federal statutory rate reduction from 35% to a flat rate of 21% for tax years beginning after December 31, 2017, limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, implementing a territorial tax system, and requiring a mandatory one-time tax on U.S. owned undistributed foreign earnings and profits known as the transition tax.

Pursuant to SAB 118, an entity may select between one of three scenarios to determine a reasonable estimate arising from the Tax Act. The scenarios are (i) a final estimate which effectively closes the measurement window; (ii) a reasonable estimate leaving the measurement window open for future revisions; and (iii) no estimate as the law is still being analyzed. The Company was able to provide a reasonable estimate for the revaluation of deferred taxes and the effects of the transition tax on undistributed foreign earnings and profits. As such, the Company has recorded a $36.1 million reduction in deferred tax assets for the revaluation of deferred taxes which was offset by a corresponding decrease to the Company's full valuation allowance. As of December 31, 2018, the Company completed its accounting for the impact of the Tax Act and determined there were no material changes to its analysis originally performed.

Significant components of the Company's deferred tax assets are presented below. A valuation allowance of $118.1 million and $101.1 million as of December 31, 2018 and 2017, respectively, has been established against the deferred tax assets for which it is more likely than not that the tax benefit will not be realized.

	December 31,	
	2018	2017
Deferred tax assets:		
Net operating losses	$ 103,187	$ 87,142
Capitalized research and development	1,537	2,155
Accrued expenses	1,300	1,310
Research and development credits	5,343	5,282
Amortization	528	630
Depreciation	—	163
Stock-based compensation[1]	5,868	4,334
Other, net[1]	775	98
Total gross deferred tax assets	118,538	101,114
Less valuation allowance	(118,064)	(101,114)
Net deferred tax assets	$ 474	$ —
Deferred tax liabilities:		
IPR&D	$ (17,425)	$ (17,425)
Depreciation	(474)	—
Total deferred tax liabilities	(17,899)	(17,425)
Net deferred tax liability	$ (17,425)	$ (17,425)

[1] Prior year's amounts have been reclassified to conform with current year's presentation.

In 2017 and 2018, no tax provision has been recognized because of the operating losses and the full valuation allowance provided on all deferred tax assets, including the net operating losses. In 2016, the Company recognized a tax benefit of $0.9 million primarily due to the impact of changes in tax laws (tax rate reductions) enacted in the UK, which decreased the Company's deferred tax liability.

The Company recognizes liabilities for uncertain tax positions based on a two-step process. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount which is more than 50% likely of being realized upon ultimate settlement.

The following table summarizes the activity related to the Company's unrecognized tax benefits (in thousands):

	December 31,		
	2018	2017	2016
Beginning balance of unrecognized tax benefits	$ 2,030	$ 1,248	$ 1,132
Gross increases based on tax positions related to current year	—	633	116
Gross decreases based on tax positions related to prior years	(634)	—	—
Gross increases based on tax positions related to prior years	91	149	—
Settlements with taxing authorities	—	—	—
Expiration of statute of limitations	—	—	—
Ending balance of unrecognized tax benefits	$ 1,487	$ 2,030	$ 1,248

As at December 31, 2018 and 2017, there were no unrecognized tax benefits that, if recognized, would affect the Company's effective tax rate as any tax benefit would increase a deferred tax asset, which is currently offset by a full valuation allowance.

The Company recognizes interest and, if applicable, penalties related to income tax matters as income tax expense. No interest or penalties have been recorded for all periods presented. The Company does not expect any significant increases or decreases to its unrecognized tax benefits in the next twelve months.

13. UK's R&D Tax Relief Scheme

The Company carries out extensive research and development activities that benefit from UK's small and medium-sized enterprises (SME) R&D tax relief scheme. Under this tax relief scheme, a SME has an option to receive an enhanced UK tax deduction on its eligible R&D activities or, when an SME entity is in a net operating loss position, can elect to surrender net operating losses that arise from its eligible R&D activities in exchange for a cash payment from the UK tax authorities. As the tax incentives may be received without regard to an entity's actual tax liability, they are not subject to accounting for income taxes. Amounts recognized by the Company for cash payment claims under the SME R&D tax relief scheme are recorded as a component of other income after an election for tax relief has been made for a discrete tax year by submitting a claim and collectability is deemed probable and reasonably assured.

In 2018, other income included $10.1 million related to elections the Company made to surrender net operating losses that arose from eligible R&D activities in exchange for cash under the SME R&D tax relief scheme. The balance consisted of a $3.0 million claim submitted in December 2017 for the Company's 2015 tax year, which was received in July 2018, and a $7.1 million claim submitted in December 2018 for the Company's 2016 tax year, which was received in February 2019. As of December 31, 2018, other current assets included a $7.1 million receivable related to the submitted claim for the Company's 2016 tax year. As of December 31, 2017, the Company did not record a receivable related to the submitted claim for its 2015 tax year as collectability was not probable or reasonably assured. The Company has not submitted claims or made elections to receive enhanced UK tax deductions on its eligible R&D activities for its 2017 or 2018 tax years.

14. Selected Quarterly Financial Information (Unaudited)

The following tables show a summary of the Company's quarterly financial information for each of the four quarters of 2018 and 2017 and have been prepared in accordance with GAAP for interim financial information. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included.

	2018 Quarter Ended			
	March 31	June 30	September 30	December 31
	(in thousands, except per share amounts)			
Revenue	$ —	$ —	$ —	$ —
Loss from continuing operations	$ (30,180)	$ (28,839)	$ (42,264)	$ (22,433)
Loss from discontinued operations	$ —	$ (198)	$ —	$ —
Net loss	$ (30,180)	$ (29,037)	$ (42,264)	$ (22,433)
Net loss per share, basic and diluted	$ (0.87)	$ (0.83)	$ (1.08)	$ (0.53)

	2017 Quarter Ended			
	March 31	June 30	September 30	December 31
	(in thousands, except per share amounts)			
Revenue	$ 2,696	$ 7,125	$ —	$ —
Loss from continuing operations	$ (21,126)	$ (22,453)	$ (42,660)	$ (39,783)
(Loss) income from discontinued operations	$ (181)	$ (555)	$ (134)	$ 75
Net loss	$ (21,307)	$ (23,008)	$ (42,794)	$ (39,708)
Net loss per share, basic and diluted	$ (0.86)	$ (0.93)	$ (1.68)	$ (1.17)

EXHIBIT INDEX

Exhibit No.	Description	Incorporated by Reference				Filed Herewith
		Form	File Number	Date of Filing	Exhibit No.	
2.1†	Sale and Purchase Agreement dated October 24, 2014 by and among the Registrant, Zogenix Europe Limited, Brabant Pharma Limited and Anthony Clarke, Richard Stewart, Ann Soenen-Darcis, Jennifer Watson, Rekyer Securities plc and Aquarius Life Science Limited, as sellers	8-K/A	001-34962	December 23, 2014	10.1	
3.1	Fifth Amended and Restated Certificate of Incorporation	S-1/A	333-169210	October 27, 2010	3.5	
3.2	Certificate of Amendment of Fifth Amended and Restated Certificate of Incorporation	10-Q	001-34962	November 8, 2012	3.2	
3.3	Certificate of Amendment of Fifth Amended and Restated Certificate of Incorporation	10-Q	001-34962	August 10, 2015	3.3	
3.4	Amended and Restated Bylaws	S-1/A	333-169210	October 27, 2010	3.7	
4.1	Form of the Registrant's Common Stock Certificate	S-1/A	333-169210	November 4, 2010	4.1	
4.2	Warrant dated July 18, 2011 issued by the Registrant to Cowen Healthcare Royalty Partners II, L.P.	10-Q	001-34962	August 12, 2011	4.12	
10.1	Form of Director and Executive Officer Indemnification Agreement	S-1/A	333-169210	October 27, 2010	10.1	
10.2#	2006 Equity Incentive Plan, as amended, and forms of option agreements thereunder	S-1	333-169210	September 3, 2010	10.3	
10.3#	2010 Equity Incentive Award Plan and forms of option and restricted stock agreements thereunder	S-1/A	333-169210	October 27, 2010	10.5	
10.4#	2010 Employee Stock Purchase Plan and form of Offering document thereunder	S-1/A	333-169210	October 27, 2010	10.6	
10.5#	Form of Restricted Stock Unit Award Agreement under the 2010 Equity Incentive Award Plan	10-Q	001-34962	August 8, 2013	10.1	
10.6#	Employment Inducement Equity Incentive Award Plan and form of stock option agreement thereunder	8-K	001-34962	December 5, 2013	10.1	
10.7#	Annual Incentive Plan	10-Q	001-34962	May 11, 2015	10.3	
10.8#	Independent Director Compensation Policy as amended and restated effective March 14, 2018	10-Q	001-34962	May 9, 2018	10.1	
10.9#	Amended and Restated Employment Agreement, dated April 27, 2015, by and between the Registrant and Stephen J. Farr, Ph.D.	10-Q	001-34962	August 10, 2015	10.4	
10.10#	Employment Agreement, dated June 29, 2015, by and between the Registrant and Gail M. Farfel, Ph.D.	10-Q	001-34962	August 10, 2015	10.5	
10.11#	Employment Agreement dated December 17, 2013 by and between the Registrant and Bradley S. Galer, M.D.	10-K	001-34962	March 7, 2014	10.44	
10.12#	Employment Agreement dated January 16, 2017, by and between the Registrant and Michael P. Smith	10-Q	001-34962	May 4, 2017	10.2	
10.13#	Employment Agreement dated July 2, 2018, by and between the Registrant and Ashish Sagrolikar	10-Q	001-34962	November 8, 2018	10.1	

Exhibit No.	Description	Incorporated by Reference				Filed Herewith
		Form	File Number	Date of Filing	Exhibit No.	
10.14†	Collaboration and License Agreement dated as of October 23, 2014 by and among The Katholieke Universiteit Leuven, University Hospital Antwerp and Brabant Pharma Limited	10-Q	001-34962	November 6, 2014	10.5	
10.15	Lease dated October 31, 2006 by and between the Registrant and Emery Station Joint Venture, LLC	S-1	333-169210	September 3, 2010	10.1	
10.16	First Amendment to Lease dated July 10, 2007 by and between the Registrant and Emery Station Joint Venture, LLC	S-1	333-169210	September 3, 2010	10.11	
10.17	Second Amendment to Lease dated October 20, 2009 by and between the Registrant and Emery Station Joint Venture, LLC	S-1	333-169210	September 3, 2010	10.12	
10.18	Third Amendment to Office Lease, dated July 20, 2015, by and between the Registrant and Emery Station Joint Venture, LLC	10-Q	001-34962	August 10, 2015	10.8	
10.19	Lease Termination Agreement, dated October 1, 2018, by and between the Registrant and Emery Station Joint Venture, LLC					X
10.20	Office Lease dated August 5, 2014 by and between the Registrant and Kilroy Realty, L.P.	10-Q	001-34962	November 6, 2014	10.6	
10.21	Lease Agreement, dated October 1, 2018, by and between the Registrant and Emery Station West, LLC					X
10.22	Controlled Equity Offering Sales Agreement, dated May 10, 2016, by and between the Registrant and Cantor Fitzgerald & Co.	S-3	333-211265	May 10, 2016	1.2	
21.1	Subsidiaries of the Company	10-K	001-34962	March 10, 2017	21.1	
23.1	Consent of Independent Registered Public Accounting Firm					X
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Public Company Accounting Reform and Investor Protection Act of 2002 (18 U.S.C. §1350, as adopted)					X
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Public Company Accounting Reform and Investor Protection Act of 2002 (18 U.S.C. §1350, as adopted)					X
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Public Company Accounting Reform and Investor Protection Act of 2002 (18 U.S.C. §1350, as adopted)					X
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Public Company Accounting Reform and Investor Protection Act of 2002 (18 U.S.C. §1350, as adopted)					X
101.INS	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	XBRL Taxonomy Extension Schema Document.					X

Exhibit No.	Description	Incorporated by Reference				Filed Herewith
		Form	File Number	Date of Filing	Exhibit No.	
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.					X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.					X

† Confidential treatment has been granted or requested, as applicable, for portions of this exhibit. These portions have been omitted from the Registration Statement and filed separately with the Securities and Exchange Commission

# Indicates management contract or compensatory plan.

Table of Contents

SIGNATURES

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

ZOGENIX, INC.

Date: February 28, 2019

By: /s/ Stephen J. Farr
President and Chief Executive Officer

Date: February 28, 2019

By: /s/ Michael P. Smith
Executive Vice President, Chief Financial Officer, Treasurer and Secretary

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

Signature	Title	Date
/S/ STEPHEN J. FARR, PH.D. **Stephen J. Farr, Ph.D.**	President and Chief Executive Officer (Principal Executive Officer)	February 28, 2019
/S/ MICHAEL P. SMITH **Michael P. Smith**	Executive Vice President, Chief Financial Officer, Treasurer and Secretary (Principal Financial and Accounting Officer)	February 28, 2019
/S/ CAM L. GARNER **Cam L. Garner**	Chairman of the Board	February 28, 2019
/S/ LOUIS C. BOCK **Louis C. Bock**	Director	February 28, 2019
/S/ JAMES B. BREITMEYER, M.D., Ph.D. **James B. Breitmeyer, M.D., Ph.D**	Director	February 28, 2019
/S/ ROGER L. HAWLEY **Roger L. Hawley**	Director	February 28, 2019
/S/ ERLE T. MAST **Erle T. Mast**	Director	February 28, 2019
/S/ RENEE TANNENBAUM, Pharm.D. **Renee Tannenbaum, Pharm.D.**	Director	February 28, 2019
/S/ MARK WIGGINS **Mark Wiggins**	Director	February 28, 2019

Exhibit 10.19

LEASE TERMINATION AGREEMENT

THIS LEASE TERMINATION AGREEMENT (this "**Termination Agreement**") is entered into as of October 1, 2018 (the "**Effective Date**"), by and between Emery Station Joint Venture, LLC, a California limited liability company ("**Landlord**") and Zogenix, Inc., a Delaware corporation ("**Tenant**"), with reference to the following facts:

A. Landlord and Tenant are parties to that certain lease dated as of October 31, 2006 (the "**Original Lease**"), which lease has been previously amended by that certain First Amendment to Lease dated as of July 10, 2007 (the "**First Amendment**"), that certain Second Amendment to Lease dated as of October 20, 2009 (the "**Second Amendment**") (Landlord and Tenant hereby confirming that a prior Second Amendment to Lease that had been dated August 31, 2008 was terminated by Tenant pursuant to Section IV thereof, making the subsequent Second Amendment to Lease dated October 20, 2009 the official and only operative Second Amendment), by that Third Amendment to Lease dated July 16, 2015 (the "**Third Amendment**"), and by that Fourth Amendment to Lease dated April 26, 2018 (the "**Fourth Amendment**"), the Original Lease, as so amended, being referred to herein as the "**Lease**", pursuant to which Landlord leases to Tenant a total of 23,205 rentable square feet (the "**Premises**"), on the fourth (4th) floor of the building commonly known as EmeryStation 1 located at 5858 Horton Street, Emeryville, California (the "**Building**").

B. As set forth in the Lease, the Term of the Lease as it relates to the 22,034 rentable square foot portion of the Premises referred to as the Existing Premises in the Fourth Amendment is scheduled to expire on November 30, 2022 (the "**Stated Expiration Date**"). As set forth in the Lease, the Term of the Lease as it relates to the 1,171 rentable square foot balance of the Premises, commonly referred to as Suite 451 (the "**Suite 451 Space**"), is month-to-month, with each month commencing on the first day of the respective calendar month.

C. Tenant desires to terminate the Lease prior to the Stated Expiration Date. Landlord has agreed to such termination on the terms and conditions contained in this Termination Agreement.

NOW, THEREFORE, in consideration of the above preambles which by this reference are incorporated herein, the mutual covenants and conditions contained herein and other valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Landlord and Tenant agree as follows:

1. Landlord and Tenant hereby agree to extend the Lease Term as it relates to the Suite 451 Space such that it shall expire upon the Early Expiration Date (as such term is defined below). Effective as of the date that Tenant vacates the Premises in compliance with the requirements of Section 11.6 of the Lease (as modified pursuant to Section 4(b) below) (the "**Early Expiration Date**"), which date shall be no later than fifteen (15) days after the earlier to occur of: a) the Rent Commencement Date under Section 1.1(6) of the ESW Lease (as defined in Paragraph 11 below), and b) the Early Occupancy Date under Section 1.1(6) of the ESW Lease (the "**Outside Early Expiration Date**"), and subject to the agreements, representations, warranties and indemnities contained in this Termination Agreement, below, the Lease is terminated and the term of the Lease shall expire with the same force and effect as if the Term were, by the provisions thereof, fixed to expire on the Early Expiration Date. Following Tenant's vacation of the Premises in accordance with this Termination Agreement, Landlord and Tenant shall enter into a commercially reasonable form of letter agreement setting forth the actual Early Expiration Date.

2. Except for obligations that survive the termination of expiration of the Lease, effective as of the Early Expiration Date, Tenant remises, releases, quitclaims and surrenders to Landlord, its successors and assigns, the Lease and all of the estate and rights of Tenant in and to the Lease and the Premises, and Tenant forever releases and discharges Landlord from any and all claims, demands or causes of action whatsoever against Landlord or its successors and assigns arising out of or in connection with the Premises or the Lease and forever releases and discharges Landlord from any obligations to be observed or performed by Landlord under the Lease after the Early Expiration Date. Without limiting the general nature of the foregoing release,

3. As of the Effective Date of this Termination Agreement, Tenant specifically waives any and all rights to any of the TI Allowance and also to the two (2) months of free Monthly Base Rent (as each is defined and set forth in Section 9 of the Third Amendment), and waives any and all rights of extension, renewal, expansion or termination under any provision of the Lease.

4. Subject to the agreements, representations, warranties and indemnities contained in this Termination Agreement, Landlord agrees to accept the surrender of the Lease and the Premises from and after the Early Expiration Date and, effective as of the Early Expiration Date, forever releases and discharges Tenant from any obligations to be observed and performed by Tenant under the Lease after the Early Expiration Date, provided that Tenant has satisfied, performed and fulfilled all of the agreements set forth in this Termination Agreement, and each of the representations and warranties set forth in Section 6 below are true and correct.

5. On or prior to the Early Expiration Date, Tenant shall:

    a. Fulfill all covenants and obligations under the Lease applicable to the period prior to and including the Early Expiration Date.

    b. Completely vacate and surrender the Premises to Landlord in accordance with the terms of the Lease. Without limitation, Tenant shall leave the Premises in a broom-clean condition, with all Hazardous Materials (if any) remediated or removed in compliance with Environmental Laws (including decontamination by an experienced third-party contractor, as evidenced by a written report therefrom, of all surfaces and decommissioning of all areas in which Hazardous Materials were stored or used in accordance with plans and protocols approved in advance by Landlord), and free of all movable furniture and equipment, and shall deliver the keys to the Premises to Landlord or Landlord's designee. To the extent any Hazardous Materials introduced by Tenant remain in the Premises after the Early Expiration Date, Tenant shall remain liable for the removal of same at Tenant's sole cost and expense. Notwithstanding any provisions of the Lease to the contrary, Landlord acknowledges and agrees that Tenant is not required to remove any portion of the Tenant Additions from the Premises.

6. Tenant represents and warrants that (a) Tenant is the rightful owner of all of the Tenant's interest in the Lease; (b) Tenant has not made any disposition, assignment, sublease, or conveyance of the Lease or Tenant's interest therein; (c) Tenant has no knowledge of any fact or circumstance which would give rise to any claim, demand, obligation, liability, action or cause of action arising out of or in connection with Tenant's occupancy of the Premises; (d) no other person or entity has an interest in the Lease, collateral or otherwise; and (e) there are no outstanding contracts for the supply of labor or material and no work has been done or is being done in, to or about the Premises which has not been fully paid for and for which appropriate waivers of mechanic's liens have not been obtained. The foregoing representation and warranty shall be deemed to be remade by Tenant in full as of the Early Expiration Date.

7. Within five days of Tenant vacating the current space and of Tenant satisfying all obligations of Tenant established in the Lease for such vacation and expiration of the Lease Term, Landlord shall return the $156,501.48 security deposit to Tenant.

8. Notwithstanding anything in this Termination Agreement to the contrary, Landlord and Tenant shall each remain liable for all adjustments with respect to Tenant's Share of Operating Expenses and Taxes for that portion of the calendar year up to and including the Early Expiration Date. Such adjustments shall be paid at the time, in the manner and otherwise in accordance with the terms of the Lease, unless otherwise specified herein.

9. If Tenant holds over in the Premises beyond the Outside Early Expiration Date, Landlord and Tenant agree that such shall constitute a holdover by Tenant, in which case the provisions of Section 12 of the Original Lease regarding Holdover shall apply. The Holdover Rent shall be prorated on a per diem basis and on a per square foot basis, from the period commencing with the Outside Expiration Date and ending on the actual Expiration Date. Such holdover amount shall not be in limitation of Tenant's liability for consequential or other damages arising from Tenant's holding over nor shall it be deemed permission for Tenant to holdover in the Premises beyond the Early Expiration Date.

10. Tenant agrees that the terms of the Lease, as modified by this Termination Agreement, are confidential and constitute proprietary information of Landlord, and that disclosure of the terms hereof could adversely affect the ability of Landlord to negotiate with other tenants or potential tenants. Tenant hereby agrees that Tenant and its partners, officers, directors, employees, agents, real estate brokers and sales persons and attorneys shall not disclose the terms of the Lease, as modified by this Termination Agreement, to any other person without Landlord's prior written consent, except to any accountants of Tenant in connection with the preparation of Tenant's financial statements or tax returns, to an assignee of the Lease or subtenant of the Premises, or to an entity (e.g., the SEC)or person to whom disclosure is required by applicable law or in connection with any action brought to enforce the Lease.

11. Notwithstanding anything contained in this Termination Agreement to the contrary, Tenant shall indemnify, defend (with counsel approved by Landlord) and hold Landlord harmless from and against any and all liabilities, obligations, damages, penalties, claims, costs, charges and expenses (including without limitation reasonable attorneys' fees) which may be imposed upon, incurred by, or asserted against Landlord and arising, directly or indirectly, out of or in connection with the use, nonuse, possession, occupancy, condition, operation, maintenance or management of the Premises or any part thereof prior to and including the Early Expiration Date, any act or omission of Tenant or any of its assignees, concessionaires, agents, contractors, employees or invitees, any injury or damage to any person or property occurring in, on or about the Premises or any part thereof prior to and including the Early Expiration Date, or any failure on the part of Tenant to perform or comply with any of the covenants, agreements, terms or conditions contained in the Lease to be observed or performed by Tenant.

12. This Termination Agreement is specifically conditioned upon the full execution of a lease agreement by and between Emery Station West, LLC, a California limited liability company ("ESW LLC"), and Tenant in the building located at 5959 Horton Street, Emeryville, California (the "ESW Lease"), the terms and conditions of such ESW Lease to be satisfactory to both Tenant and ESW LLC in their respective sole and absolute discretions.

13. This Termination Agreement shall be binding upon and inure to the benefit of Landlord and Tenant and their respective successors, assigns and related entities.

IN WITNESS WHEREOF, Landlord and Tenant have executed this Termination Agreement on the day and year first above written.

LANDLORD:

Emery Station West, LLC,
a California limited liability company

By: ES West Associates, LLC
a California limited liability company,
its Managing Member

By: Wareham-NZL, LLC
a California limited liability company,
its Manager

By: /s/ Richard K. Robbins
Richard K. Robbins
Manager

TENANT:

Zogenix, Inc.,
a Delaware corporation

By: /s/ Stephen Farr
Print Name: Stephen Farr
Its: CEO & President

Exhibit 10.21

LEASE

BETWEEN

EMERY STATION WEST, LLC (LANDLORD)

AND

ZOGENIX, INC. (TENANT)

EmeryStation West

Emeryville, California

ARTICLE 1

BASIC LEASE PROVISIONS

1.1 BASIC LEASE PROVISIONS

In the event of any conflict between these Basic Lease Provisions and any other Lease provision, such other Lease provision shall control.

(1) BUILDING AND ADDRESS:

5959 Horton Street
Emeryville, California 94608

(2) LANDLORD AND ADDRESS:

Emery Station West, LLC
1120 Nye Street, Suite 400
San Rafael, California 94901

Notices to Landlord shall be addressed:

Emery Station West, LLC
c/o Wareham Property Group
1120 Nye Street, Suite 400
San Rafael, California 94901

With a copy to:

Shartsis Friese LLP
One Maritime Plaza, 18th Floor
San Francisco, California 94901
Attention: David H. Kremer, Esq.

(3) TENANT AND CURRENT ADDRESS:

Name: Zogenix, Inc., a Delaware corporation

Federal Tax Identification Number: 20-5300780

Tenant shall promptly notify Landlord of any change in the foregoing items.

Notices to Tenant shall be addressed:

Prior to the Commencement Date:

5858 Horton Street, Suite 455
Emeryville, CA 94608
Attn: SVP, Chief of Staff

On and after the Commencement Date:

At the Premises

Attention: SVP, Chief of Staff

(4) DATE OF THIS LEASE: October 1, 2018

(5) LEASE TERM: Commencing on the Rent Commencement Date and continuing through the last day of the ninety-sixth (96th) full calendar month following the Rent Commencement Date; subject to the options set forth in Section 2.6 below.

(6) RENT COMMENCEMENT DATE: June 1, 2019.

Landlord and Tenant hereby acknowledge and agree that Tenant's possession of the Premises during the period commencing with the Commencement Date (as defined hereinafter in this Lease) and ending with the Rent Commencement Date shall be subject to all the terms and conditions of this Lease other than: a) Tenant's obligation to pay Monthly Base Rent, and b) Tenant's obligation to pay Tenant's Share of Operating Expenses and Taxes. Landlord acknowledges that Tenant may be able to complete the Tenant Improvements and occupy the Premises for the purposes of doing business prior to the Rent Commencement Date. The date of any such early occupancy by Tenant shall be referred to herein as the "Early Occupancy Date". The period from the Early Occupancy Date, if applicable, and the Rent Commencement Date shall be referred to herein as the Early Occupancy Period. Landlord and Tenant hereby acknowledge and agree that Tenant's possession of the Premises during any Early Occupancy Period shall be subject to all the terms and conditions of this Lease other than Tenant's obligation to pay Monthly Base Rent, but that Tenant shall be obligated to pay Tenant's Share of Operating Expenses and Taxes during any Early Occupancy Period.

(7) EXPIRATION DATE: The last day of the ninety-sixth (96th) full calendar month following the Rent Commencement Date.

(8) MONTHLY BASE RENT: An amount determined by multiplying the Rentable Area of the Premises (as the same may exist from time) by the Applicable Monthly Base Rate. As used herein, the "Applicable Monthly Base Rate" shall be an amount equal to Three Dollars and Ninety-Two Cents ($3.92) for the twelve (12) month period following the Rent Commencement Date (which twelve (12) month period shall include any partial calendar month following the Commencement Date if the Commencement Date is other than the first (1st) day of a calendar month), which amount shall increase by a compounded three percent (3%) on each annual anniversary thereafter.

(9) RENTABLE AREA: 37,307 square feet.

(10) TENANT IMPROVEMENT ALLOWANCE:

Notwithstanding anything in this Lease to the contrary, Landlord shall provide Tenant a tenant improvement allowance to be utilized to pay for Tenant Improvement Costs (as such are defined in the Workletter attached to this Lease), in the amount of up to $3,096,481.00, calculated to be equal to one hundred-ten dollars ($83.00) per rentable square foot of Premises (the "Tenant Improvement Allowance"). Provided that no Default under the Lease has occurred with respect to Tenant, the Tenant Improvement Allowance shall be drawn down pursuant to the terms of the Workletter.

(11) SECURITY DEPOSIT: $326,063.00.

(12) PREMISES: The leasable area located on the fifth (5th) floor, as outlined on Exhibit A hereto (such portion of the Building collectively hereafter the "Premises"). Tenant acknowledges that the sixth (6th) floor of the Building is subject to negotiations for lease by Landlord to a third-party. If, prior to Landlord's delivery of possession of the fifth (5th) floor to Tenant pursuant to this Lease, the aforementioned lease negotiations by Landlord are completely terminated, Landlord agrees to substitute the sixth (6th) floor as Tenant's as the Premises in lieu of the agreed fifth (5th) floor, in which event all other terms and conditions of this Lease shall remain in full force and effect.

(13) TENANT'S USE OF PREMISES: General Office.

(14) PARKING: Rights to park, on an unreserved basis, up to ninety-three (93) cars, calculated using a ration of two and one-half (2 1/2) unreserved parking rights for each 1,000 square feet of Rentable Area of the Premises.

(15) TENANT BROKERS: None.

ENUMERATION OF EXHIBITS AND RIDER

The Exhibits and Rider set forth below and attached to this Lease are incorporated in this Lease by this reference:

EXHIBIT A Outline of the Premises

EXHIBIT B Workletter Agreement

EXHIBIT B-1 Sustainability Design Guidelines

EXHIBIT B-2 Landlord Work / Warm Shell Description

EXHIBIT C-1 Intentionally deleted

EXHIBIT C-2 Rules and Regulations

RIDER 1 Commencement Date Agreement

1.2 DEFINITIONS

For purposes hereof, in addition to terms defined elsewhere in this Lease, the following terms shall have the following meanings:

AFFILIATE: Any corporation or other business entity that is currently owned or controlled by, owns or controls, or is under common ownership or control with Tenant or Landlord, as the case may be.

BUILDING: The building located at the address specified in Section 1.1(1). The Building may include office, laboratory, medical, retail and other uses.

CABLE: As defined in Section 8.2.

COMMENCEMENT DATE: The date determined in accordance with Article 2.

COMMON AREAS: All areas of the Project made available by Landlord from time to time for the general common use or benefit of the tenants of the Building, and their employees and invitees, or the public, as such areas currently exist and as they may be changed from time to time.

DECORATION: Tenant Alterations which do not require a building permit, are not visible from outside of the Premises, and which do not involve any of the structural elements of the Building, or any of the Building's systems, including its electrical, mechanical, plumbing, security, heating, ventilating, air-conditioning, communication, and fire and life safety systems.

DEFAULT: As defined in Section 11.1.

DEFAULT RATE: Two (2) percentage points above the rate then most recently announced by Bank of America N.T. & S.A. at its San Francisco main office as its base lending reference rate, from time to time announced, but in no event higher than the maximum rate permitted by Law.

EXPIRATION DATE: The date specified in Section 1.1(7).

FORCE MAJEURE: Any accident, casualty, act of God, war or civil commotion, strike or labor troubles, or any cause whatsoever beyond the reasonable control of Landlord, including water shortages, energy shortages or governmental preemption in connection with an act of God, a national emergency, or by reason of Law, or by reason of the conditions of supply and demand which have been or are affected by act of God, war or other emergency.

GREEN BUILDING STANDARDS: One or more of the following: the U.S. EPA's Energy Star® Portfolio Manager, the Green Building Initiative's Green Globes™ building rating system, the U.S. Green Building Council's Leadership in Energy and Environmental Design (LEED®) building rating system, the ASHRAE Building Energy Quotient (BEQ), the Global Real Estate Sustainability Benchmark (GRESB), or other standard for high performance

buildings adopted by Landlord with respect to the Building or the Project, as the same may be revised from time to time.

INDEMNITEES: Collectively, Landlord, any Mortgagee or ground lessor of the Property, the property manager and the leasing manager for the Property and their respective partners, members, directors, officers, agents and employees.

LAND: The parcel(s) of real estate on which the Building and Project are located.

LANDLORD WORK: The construction or installation of the work specifically described in the Workletter Exhibit B-2 attached hereto.

LAWS OR LAW: All laws, ordinances, rules, regulations, other requirements, orders, rulings or decisions adopted or made by any governmental body, agency, department or judicial authority having jurisdiction over the Property, the Premises or Tenant's activities at the Premises and any covenants, conditions or restrictions of record which affect the Property.

LEASE: This instrument and all Exhibits and any Riders attached hereto, as may be amended from time to time.

LEASE YEAR: The twelve month period beginning on the first day of the first month following the Commencement Date (unless the Commencement Date is the first day of a calendar month in which case beginning on the Commencement Date), and each subsequent twelve month, or shorter, period until the Expiration Date.

LEASEHOLD IMPROVEMENTS: As defined in Section 12.1.

MONTHLY BASE RENT: The monthly rent specified in Section 1.1(8). Notwithstanding the terms set forth in Section 1.1(8), Landlord and Tenant hereby acknowledge and agree that, during the first fourteen (14) months of the Lease Term following the Rent Commencement Date (i.e. from June 1, 2019 through July 31, 2020), Monthly Base Rent shall be calculated on the basis of a Rentable Area of 28,000 square feet, not based on the full 37,307 rentable square footage of the Premises, but during said fourteen (14) month period Tenant shall be obligated to pay Tenant's Share of Operating Expenses and Taxes calculated using the full 37,307 rentable square footage of the Premises.

MORTGAGEE: Any holder of a mortgage, deed of trust or other security instrument encumbering the Property.

NATIONAL HOLIDAYS: New Year's Day, Memorial Day, Independence Day, Labor Day, Thanksgiving Day and Christmas Day and other holidays reasonably recognized by the Landlord and the janitorial and other unions servicing the Building in accordance with their contracts.

OPERATING EXPENSES: All costs, expenses and disbursements of every kind and nature which Landlord shall pay or become obligated to pay in connection with the ownership, management, operation, maintenance, replacement and repair of the Property, including, without

limitation, property management fees not to exceed 3.5% of gross revenues; costs and expenses of any capital improvements which shall be amortized over a period reasonably determined by Landlord together with interest thereon at a rate reasonably determined by Landlord; an equitable allocation of management office expenses (including, without limitation, office rent, supplies, equipment, salaries, wages, bonuses and other compensation relating to employees of Landlord or its agents engaged in the management, operation, repair, or maintenance of the EmeryStation Campus); and, if applicable, the cost of operating any shared campus amenities, including but not limited to a fitness center and/or conference center, that are available for use by Tenant (which amenities may be located in the Building or in other buildings in the EmeryStation Campus owned by Landlord or affiliates of Landlord), as reasonably determined by Landlord. Operating Expenses shall not include, (i) costs of alterations of the premises of tenants of the Project, (ii) costs of goods or services to the extent billed directly to other tenants of the Project (other than as reimbursement of general operating expenses), (iii) depreciation charges, (iv) interest and principal payments on loans (except for loans for capital improvements which Landlord may include in Operating Expenses), (v) ground rental payments, (vi) real estate brokerage and leasing commissions, (vii) advertising and marketing expenses, (viii) costs to the extent Landlord has been reimbursed for the same by insurance proceeds, condemnation awards, third party warranties or other third parties (other than tenant's reimbursement of general operating expenses), (ix) expenses incurred in negotiating leases of tenants in the Project or enforcing lease obligations of tenants in the Project, (x) Landlord's general corporate overhead, (xi) costs directly incurred in connection with a sale, financing, refinancing or transfer of all or any portion of the Project; and (xii) costs incurred to comply with Laws relating to the removal and remediation of any Hazardous Material which were in existence at the Project as of the Date of this Lease provided, however, that any costs incurred in the cleanup or remediation of *de minimis* amounts of Hazardous Materials customarily used in office buildings or used to operate motor vehicles and customarily found in parking facilities shall be included as Operating Expenses. If any Operating Expense, though paid in one year, relates to more than one calendar year, at the option of Landlord such expense may be proportionately allocated among such related calendar years. Operating Expenses for the Property that are not, in Landlord's reasonable discretion, allocable solely to either the office, laboratory, or retail portion of the Building shall be equitably allocated by Landlord between/amongst such uses.

PREMISES: The space located in the Building described in Section 1.1(12) and as outlined on Exhibit A attached hereto.

PROJECT or PROPERTY: The Project consists of the mixed-use building located at the street address specified in Section 1.1(1) in Emeryville, California, and associated surface and garage parking as designated by Landlord from time to time, landscaping and improvements, together with the Land, any associated interests in real property, and the personal property, fixtures, machinery, equipment, systems and apparatus located in or used in conjunction with any of the foregoing. Initially, a portion of the parking garage located at 6100 Horton Street shall be designated by Landlord as part of the Project. The Project may also be referred to as the Property.

PROJECT'S SUSTAINABILITY PRACTICES: The operations and maintenance practices for the Building, whether incorporated into the Building's Rules and Regulations,

construction rules and regulations, separate written sustainability policies or otherwise reasonably implemented by Landlord with respect to the Building or the Project, as the same may be revised from time to time, addressing, among other things: energy efficiency; energy measurement and reporting; water usage; recycling, composting, and waste management; indoor air quality; and chemical use.

REAL PROPERTY: The Property excluding any personal property.

RENT: Collectively, Monthly Base Rent, Rent Adjustments and Rent Adjustment Deposits, and all other charges, payments, late fees or other amounts required to be paid by Tenant under this Lease.

RENT ADJUSTMENT: Any amounts owed by Tenant for payment of Operating Expenses and/or Taxes. The Rent Adjustments shall be determined and paid as provided in Article 4.

RENT ADJUSTMENT DEPOSIT: An amount equal to Landlord's estimate of the Rent Adjustment attributable to each month of the applicable calendar year (or partial calendar year) during the Term. On or before the Commencement Date and with each Landlord's Statement (defined in Article 4), Landlord may estimate and notify Tenant in writing of its estimate of the Operating Expenses and of Taxes for such calendar year (or partial calendar year). Prior to the first determination by Landlord of the amount of Operating Expenses and of Taxes for the first calendar year (or partial calendar year), Landlord may estimate such amounts in the foregoing calculation. Landlord shall have the right from time to time during any calendar year to provide a new or revised estimate of Operating Expenses and/or Taxes and to notify Tenant in writing thereof, of corresponding adjustments in Tenant's Rent Adjustment Deposit payable over the remainder of such year, and of the amount or revised amount due allocable to months preceding such change. The last estimate by Landlord shall remain in effect as the applicable Rent Adjustment Deposit unless and until Landlord notifies Tenant in writing of a change, which notice may be given by Landlord from time to time during each year throughout the Term.

RENTABLE AREA OF THE PREMISES: The amount of square footage stipulated and/or determined, from time to time, pursuant to Section 1.1(9).

STANDARD OPERATING HOURS: Monday through Friday from 8:00 A.M. to 6:00 P.M. and Saturdays from 9:00 A.M. to 1:00 P.M., excluding National Holidays.

SUBSTANTIALLY COMPLETE or SUBSTANTIAL COMPLETION: The completion of the Landlord Work or Tenant Work, as the case may be, except for minor insubstantial details of construction, decoration or mechanical adjustments which remain to be done. Substantial Completion shall be deemed to have occurred notwithstanding a requirement to complete "punchlist" or similar minor corrective work. If Landlord shall be delayed in Substantial Completion due to a Tenant Delay, the date of Substantial Completion for purposes of determining the Commencement Date shall be the date when Substantial Completion would have occurred if there had been no Tenant Delay. Tenant acknowledges that the length of any Tenant Delay is to be measured by the duration of the delay in Substantial Completion caused by the

event or conduct constituting Tenant Delay, which may exceed the duration of such event or conduct due to the necessity of rescheduling work or other causes.

TAXES: All federal, state and local governmental taxes, assessments, license fees and charges of every kind or nature, whether general, special, ordinary or extraordinary, which Landlord shall pay or become obligated to pay because of or in connection with the ownership, leasing, management, control, sale, transfer, or operation of the Property or any of its components (including any personal property used in connection therewith) or Landlord's business of owning and operating the Property, which may also include any rental, revenue, general gross receipts or similar taxes levied in lieu of or in addition to general real and/or personal property taxes. For purposes hereof, Taxes for any year shall be Taxes which are assessed for any period of such year, whether or not such Taxes are billed and payable in a subsequent calendar year. There shall be included in Taxes for any year the amount of all fees, costs and expenses (including reasonable attorneys' fees) paid by Landlord during such year in seeking or obtaining any refund or reduction of Taxes. Taxes for any year shall be reduced by the net amount of any tax refund received by Landlord attributable to such year. If a special assessment payable in installments is levied against any part of the Property, Taxes for any year shall include only the installment of such assessment and any interest payable or paid during such year. Taxes shall not include any federal or state inheritance, general income, gift or estate taxes, except that if a change occurs in the method of taxation resulting in whole or in part in the substitution of any such taxes, or any other assessment, for any Taxes as above defined, such substituted taxes or assessments shall be included in the Taxes. Tenant and Landlord acknowledge that Proposition 13 was adopted by the voters of the State of California in the June, 1978 election and that assessments, taxes, fees, levies and charges may be imposed by governmental agencies for such purposes as fire protection, street, sidewalk, road, utility construction and maintenance, refuse removal and for other governmental services which may formerly have been provided without charge to property owners or occupants. It is the intention of the parties that all new and increased assessments, taxes, fees, levies and charges due to any cause whatsoever are to be included within the definition of real property taxes for purposes of this Lease.

TENANT ADDITIONS: Collectively, Landlord Work, Tenant Work and Tenant Alterations.

TENANT ALTERATIONS: Any alterations, improvements, additions, installations or construction in or to the Premises or any Building systems serving the Premises (excluding Landlord Work or Tenant Work); and any supplementary air-conditioning systems installed by Landlord or by Tenant at Landlord's request pursuant to Section 6.1(b).

TENANT DELAY: Any act or omission of Tenant which delays Substantial Completion of the Landlord Work.

TENANT WORK: All work installed or furnished to the Premises by Tenant in connection with Tenant's initial occupancy.

TENANT'S SHARE: The percentage that represents the ratio of the Rentable Area of the Premises to the Rentable Area of the Building, as determined by Landlord from time to time. Tenant acknowledges that the Rentable Area of the Premises or Building may change from re-measurement or otherwise during the Term or as a result of Tenant leasing additional space within the Building. Notwithstanding anything herein to the contrary, Landlord may equitably adjust Tenant's Share for all or part of any item of expense or cost reimbursable by Tenant that relates to a repair, replacement, or service that benefits only the Premises or only a portion of the Building and/or the Project or that varies with the occupancy of the Building and/or the Project, provided such adjustment is done in accordance with sound real estate accounting and management principles, consistently applied.

TERM: The initial term of this Lease commencing on the Commencement Date and expiring on the Expiration Date, and extension of the initial term, if any.

TERMINATION DATE: The Expiration Date or such earlier date as this Lease terminates or Tenant's right to possession of the Premises terminates.

WORKLETTER: The Agreement regarding the manner of completion of Landlord Work and Tenant Work set forth on Exhibit B attached hereto.

ARTICLE 2

PREMISES, TERM, FAILURE TO GIVE POSSESSION, AND PARKING

2.1 LEASE OF PREMISES

(a) Landlord hereby leases to Tenant and Tenant hereby leases from Landlord the Premises for the Term and upon the terms, covenants and conditions provided in this Lease. In the event Landlord delivers possession of the Premises to Tenant prior to the Commencement Date, Tenant shall be subject to all of the terms, covenants and conditions of this Lease as of the date of such possession, except as otherwise expressly provided in this Lease.

(b) The parties acknowledge and agree that the Rentable Area set forth in this Lease has been conclusively determined and is deemed final for the purposes of this Lease and that prior to the Date of Lease, Tenant had the right to cause its Architect to verify and confirm the Rentable Area of the Premises.

2.2 TERM

(a) The Commencement Date shall be the date which Landlord delivers possession of the portion of the Building containing the Premises to Tenant sufficiently complete, in Landlord's reasonable opinion, to allow Tenant to commence construction of the Tenant Work.

(b) Within thirty (30) days following the Commencement Date, Landlord and Tenant shall enter into an agreement (the form of which is attached hereto as Rider 1) confirming the Commencement Date. If Tenant fails to enter into such agreement, then the Commencement Date shall be the date designated by Landlord in such agreement.

2.3 DELIVERY OF POSSESSION

If Landlord shall be unable to give Tenant possession as described above for any reason, then this Lease shall not be void or voidable, nor shall Landlord be subject to any liability therefore. Landlord and Tenant hereby acknowledge and agree that Tenant's access/entry to the Premises prior to Rent Commencement Date shall be subject to all the provisions of this Lease other than the payment of Monthly Base Rent, including, without limitation, Tenant's compliance with the insurance and indemnity requirements of this Lease. In connection with any such early entry, Tenant agrees that it shall not in any way interfere with the progress of any other work being conducted in the Building, either by Landlord and/or Landlord's tenants. Should such early entry interfere with the progress of other work, in Landlord's judgment, then Landlord may demand that Tenant forthwith cease the activities that are causing such interference or vacate the Premises as necessary until such interference would not occur, and Tenant shall immediately comply with such demand.

2.4 CONDITION OF PREMISES

No later than thirty (30) days after the Commencement Date, Tenant shall notify Landlord in writing of any defects in the Landlord Work that are claimed by Tenant or in the materials or workmanship furnished by Landlord in completing the Landlord Work. Except for defects stated in such notice, Tenant shall be conclusively deemed to have accepted the Premises "AS IS" in the condition existing on the date Tenant first takes possession, and to have waived all claims relating to the condition of the Premises. Landlord shall proceed diligently to correct the defects stated in such notice unless Landlord disputes the existence of any such defects. In the event of any dispute as to the existence of any such defects, the decision of Landlord's architect shall be final and binding on the parties. No agreement of Landlord to alter, remodel, decorate, clean or improve the Premises or the Real Property and no representation regarding the condition of the Premises or the Real Property has been made by or on behalf of Landlord to Tenant, except as may be specifically stated in this Lease or in the Workletter.

2.5 PARKING

During the Term, Tenant shall have the right to park up to ninety-three (93) cars of Tenant and its employees ("Tenant's Parking"), such quantity calculated to be two and one-half (2 1/2) vehicle rights for every one thousand (1,000) rentable square feet of Premises Subject to the aforementioned maximum, Tenant shall have the right to adjust the amount of Tenant's Parking not more often than monthly via advance written notice to Landlord (the amount of such notice to be reasonably established by Landlord). All such parking shall initially be located in the parking garage owned by Landlord and located at 6100 Horton Street and shall be leased by Tenant at then quoted rates. In the event Tenant fails at any time to pay the full amount of any such parking charges or reimbursements, then in addition to all other remedies available to Landlord hereunder, Tenant's parking rights shall be reduced to the extent of Tenant's failure to pay for the same and Tenant shall be in Default under. The locations and type of parking shall be designated by Landlord or Landlord's parking operator from time to time. Tenant acknowledges and agrees that the parking stalls serving the Project may, subject to the other provisions of this Section 2.5, include valet parking and a mixture of stalls for compact vehicles as well as

full-size passenger automobiles, and that Tenant shall not use parking stalls for vehicles larger than the striped size of the parking stalls nor shall Tenant park cars overnight. All vehicles utilizing Tenant's parking privileges shall prominently display identification stickers or other markers, and/or have passes or keycards for ingress and egress, as may be required and provided by Landlord or its parking operator from time to time. Tenant shall comply with any and all parking rules and regulations from time to time established by Landlord or Landlord's parking operator, including a requirement that Tenant pay to Landlord or Landlord's parking operator a charge for loss and replacement of passes, keycards, identification stickers or markers, and for any and all loss or other damage caused by persons or vehicles related to use of Tenant's parking privileges. Tenant shall not allow any vehicles using Tenant's parking privileges to be parked, loaded or unloaded except in accordance with this Section, including in the areas and in the manner designated by Landlord or its parking operator for such activities. If any vehicle is using the parking or loading areas contrary to any provision of this Section, Landlord or its parking operator shall have the right, in addition to all other rights and remedies of Landlord under this Lease, to remove or tow away the vehicle without prior notice to Tenant, and the cost thereof shall be paid to Landlord within ten (10) days after notice from Landlord.

2.6 RENEWAL OPTIONS

(a) Tenant shall have the option to renew this Lease ("Renewal Option") with respect to the entirety of the Premises for one (1) additional term of five (5) years (the "Renewal Term"), commencing upon expiration of the initial Term. The Renewal Option must be exercised, if at all, by written notice given by Tenant to Landlord not earlier than twelve (12) months and not later than nine (9) months prior to commencement of the Renewal Term. If Tenant properly exercises the Renewal Option, then references in this Lease to the Term shall be deemed to include the Renewal Term. Tenant's rights under this Section 2.6 shall, at the option of Landlord, be null and void and Tenant shall have no right to renew this Lease if on the date Tenant exercises the Renewal Option or on the date immediately preceding the commencement date of the Renewal Term (i) a Default beyond the applicable cure period shall have occurred and be continuing hereunder, or (ii) the named Tenant hereunder or pursuant to a Permitted Transfer (defined below), a Tenant Affiliate, does not occupy the entire Premises.

(b) If Tenant properly exercises the Renewal Option, then during the Renewal Term all of the terms and conditions set forth in this Lease as applicable to the Premises during the initial Term shall apply during the Renewal Term, including without limitation the obligation to pay Rent Adjustments, except that (i) Tenant shall accept the Premises in their then "as-is" state and condition and Landlord shall have no obligation to make or pay for any improvements to the Premises, and (ii) during the Renewal Term the Monthly Base Rent payable by Tenant shall be equal to ninety-five percent (95%) of the Fair Market Value during the Renewal Term as hereinafter set forth, except that in no event shall Monthly Base Rent during a Renewal Term be less than one hundred percent (100%) of the Monthly Base Rent in effect during the month immediately preceding the Renewal Term.

(c) For purposes of this Section, the term "Fair Market Value" shall mean the rental rate, additional rent adjustment and other charges and increases, if any, for space comparable in size, location and quality of the Premises under primary lease (and not sublease) to new or

renewing tenants, for a comparable term with base rent adjusted for the relative tenant improvement allowance, if applicable, and taking into consideration such amenities as existing improvements and non-removable fixtures in place at the time of such renewal, view, floor on which the Premises is situated and the like, situated in comparable office and laboratory buildings in Emeryville or Berkeley.

(d) If Tenant properly exercises the Renewal Option, then Landlord, by notice to Tenant not later than six (6) months prior to commencement of the Renewal Term, shall indicate Landlord's determination of the Fair Market Value. Tenant, within fifteen (15) days after the date on which Landlord provides such notice of the Fair Market Value shall either (i) give Landlord final binding written notice ("Binding Notice") of Tenant's acceptance of Landlord's determination of the Fair Market Value, or (ii) if Tenant disagrees with Landlords' determination, provide Landlord with written notice of Tenant's election to submit the Fair Market Value to binding arbitration (the "Arbitration Notice"). If Tenant fails to provide Landlord with either a Binding Notice or Arbitration Notice within such fifteen (15) day period, Tenant shall have been deemed to have given the Binding Notice. If Tenant provides or is deemed to have provided Landlord with a Binding Notice, Landlord and Tenant shall enter into the Renewal Amendment (as defined below) upon the terms and conditions set forth herein.

(e) If the parties are unable to agree upon the Fair Market Value for the Premises within ten (10) days after Landlord's receipt of the Arbitration Notice, Fair Market Value as of commencement of the Renewal Term shall be determined as follows:

(1) Within ten (10)) days after the date Tenant delivers the Arbitration Notice, Tenant, at its sole expense, shall obtain and deliver in writing to Landlord a determination of the Fair Market Value for the Premises for a term equal to the Renewal Term from a broker or appraiser ("Tenant's broker") licensed in the State of California and engaged in the science/laboratory markets in Emeryville and Berkeley, California, for at least the immediately preceding five (5) years. If Landlord accepts such determination, Landlord shall provide written notice thereof within ten (10) days after Landlord's receipt of such determination and the Base Rent for the Renewal Term shall be adjusted to an amount equal to the Fair Market Value determined by Tenant's broker. Landlord shall be deemed to have rejected Tenant's determination if Landlord fails to respond within the ten (10) day period.

(2) If Landlord provides notice that it rejects, or is deemed to have rejected, such determination, within twenty (20) days after receipt of the determination of Tenant's broker, Landlord shall designate a broker or appraiser ("Landlord's broker") licensed in the State of California and possessing the qualifications set forth in (1) above. Landlord's broker and Tenant's broker shall name a third broker, similarly qualified, within five (5) days after the appointment of Landlord's broker ("Neutral Broker").

(3) The Neutral Broker shall determine the Fair Market Value for the Premises as of the commencement of the Renewal Term within fifteen (15) days after the appointment of such Neutral Broker by choosing the determination of the Landlord's broker that was set forth in the initial notice delivered by Landlord pursuant to Section 2.6(d) or the Tenant's broker that was

delivered pursuant to Section 2.6(e)(1) which is closest to its own determination of Fair Market Value. The decision of the Neutral Broker shall be binding on Landlord and Tenant.

(f) Landlord shall pay the costs and fees of Landlord's broker in connection with any determination hereunder, and Tenant shall pay the costs and fees of Tenant's broker in connection with such determination as well as the costs and fees of any broker who assists Tenant in the renewal. The costs and fees of the Neutral Broker shall be paid one-half by Landlord and one-half by Tenant.

(g) If the amount of the Fair Market Value has not been determined pursuant to this Section 2.6 as of the commencement of the Renewal Term, then Tenant shall continue to pay the Base Rent in effect during the last month of the initial Term until the amount of the Fair Market Value is determined. When such determination is made, Tenant shall pay any deficiency to Landlord upon demand.

(h) If Tenant is entitled to and properly exercises it's Renewal Option, upon determination of Fair Market Value pursuant to this Section 2.6, Landlord shall prepare an amendment (the "Renewal Amendment") to reflect changes in the Base Rent, Term, Expiration Date and other appropriate terms. The Renewal Amendment shall be sent to Tenant within a reasonable time after determination of Fair Market Value and, provided the same is accurate, Tenant shall execute and return the Renewal Amendment to Landlord within ten (10) days after Tenant's receipt of same, but an otherwise valid exercise of the Renewal Option shall be fully effective whether or not the Renewal Amendment is executed.

2.7 TENANT'S EXISTING LEASE AT 5858 HORTON STREET

Tenant presently leases space in a building commonly known as EmeryStation 1, located at 5858 Horton Street in Emeryville, CA, pursuant to a lease with Landlord Emery Station Joint Venture, LLC ("ESJV") originally dated October 31, 2006 and subsequently amended by First, Second, Third and Fourth Amendments thereto ("Tenant's Existing Lease"). Landlord and Tenant acknowledge and agree that, as a condition to and simultaneous with the execution of this Lease, Landlord, Tenant and ESJV shall enter into documents satisfactory to all three parties, in their respective sole and absolute discretion, which have the effect of assigning Tenant's Existing Lease to Landlord.

ARTICLE 3

RENT

Tenant shall pay to Landlord at the address specified in Section 1.1(2), or to such other persons, or at such other places designated by Landlord, without any prior demand therefor in immediately available funds and without any deduction or offset whatsoever, Rent, including Monthly Base Rent and Rent Adjustments in accordance with Article 4, during the Term. Monthly Base Rent shall be paid monthly in advance on or prior to the first day of each month of the Term, except that the first installment of Monthly Base Rent shall be paid by Tenant to Landlord concurrently with execution of this Lease. Monthly Base Rent shall be prorated for

partial months within the Term. Unpaid Rent shall bear interest at the Default Rate from the date due until paid. Tenant's covenant to pay Rent shall be independent of every other covenant in this Lease.

ARTICLE 4

RENT ADJUSTMENTS AND PAYMENTS

4.1 RENT ADJUSTMENTS

From and after the Commencement Date, Tenant shall pay to Landlord Rent Adjustments with respect to each calendar year (or partial calendar year in the case of the year in which the Commencement Date and the Termination Date occur) as follows as follows:

(a) The Rent Adjustment Deposit representing Tenant's Share of Operating Expenses for the applicable calendar year (or partial calendar year), monthly during the Term with the payment of Monthly Base Rent;

(b) The Rent Adjustment Deposit representing Tenant's Share of Taxes for the applicable calendar year (or partial calendar year), monthly during the Term with the payment of Monthly Base Rent;

(c) Any Rent Adjustments due in excess of the Rent Adjustment Deposits in accordance with Section 4.2. Rent Adjustments due from Tenant to Landlord for any calendar year (or partial calendar year) shall be Tenant's Share of Operating Expenses for such calendar year (or partial calendar year) and Tenant's Share of Taxes for such calendar year (or partial calendar year); and

(d) For purposes of determining Rent Adjustments, if the Building or Property is not fully occupied during all or a portion of any calendar year during the Term, Landlord shall make appropriate adjustments to the variable components of Operating Expenses for such calendar year (or partial calendar year), employing sound accounting and management principles consistently applied, to determine the amount of Operating Expenses that would have been paid or incurred by Landlord had the Building or Property been fully occupied, and the amount so determined shall be deemed to have been the amount of Operating Expenses for such calendar year (or partial calendar year). In the event that the Property is not fully assessed for all or a portion of any calendar year (or partial calendar year) during the Term, then Taxes shall be adjusted to an amount which would have been payable in such calendar year (or partial calendar year) if the Property had been fully assessed.

4.2 STATEMENT OF LANDLORD

On or before April 1 of each calendar year (or as soon thereafter as practical), Landlord will furnish Tenant a statement ("Landlord's Statement") respecting the prior calendar year showing the following:

(a) Operating Expenses and Taxes for such calendar year;

(b) The amount of Rent Adjustments due Landlord for the last calendar year, less credit for Rent Adjustment Deposits paid, if any; and

(c) Any change in the Rent Adjustment Deposit due monthly in the current calendar year, including the amount or revised amount due for months preceding any such change pursuant to Landlord's Statement.

Tenant shall pay to Landlord within ten (10) days after receipt of such statement any amounts for Rent Adjustments then due in accordance with Landlord's Statement. Any amounts due from Landlord to Tenant pursuant to this Section shall, at Landlord's option, either be directly refunded to Tenant by check or otherwise, or be credited to the Rent Adjustment Deposit next coming due. No interest or penalties shall accrue on any amounts that Landlord is obligated to credit or refund to Tenant by reason of this Section 4.2. Landlord's failure to deliver Landlord's Statement or to compute the amount of the Rent Adjustments shall not constitute a waiver by Landlord of its right to deliver such items nor constitute a waiver or release of Tenant's obligations to pay such amounts. The Rent Adjustment Deposit shall be credited against Rent Adjustments due for the applicable calendar year (or partial calendar year). During the last complete calendar year or during any partial calendar year in which this Lease terminates, Landlord may include in the Rent Adjustment Deposit its estimate of Rent Adjustments which may not be finally determined until after the termination of this Lease. Tenant's obligation to pay Rent Adjustments survives the expiration or termination of this Lease. Notwithstanding the foregoing, in no event shall the sum of Monthly Base Rent and the Rent Adjustments be less than the Monthly Base Rent payable.

4.3 BOOKS AND RECORDS

Landlord shall maintain books and records showing Operating Expenses and Taxes in accordance with sound accounting and management practices, consistently applied. Tenant or its representative (which representative shall be a certified public accountant licensed to do business in the state in which the Property is located and whose primary business is certified public accounting and who shall not be paid on a contingency basis) shall have the right, for a period of sixty (60) days following the date upon which Landlord's Statement is delivered to Tenant, to examine the Landlord's books and records with respect to the items in the foregoing statement of Operating Expenses and Taxes during normal business hours, upon written notice, delivered at least three (3) business days in advance. Tenant shall pay for all costs of such examination, provided, however, if such examination results in a discrepancy of more than five percent (5%) in the actual Operating Expenses and Taxes from those shown on the Landlord's Statement, such costs shall be reimbursed by Landlord, not to exceed $1,000.00. If Tenant does not object in writing to Landlord's Statement within ninety (90) days of Tenant's receipt thereof, specifying the nature of the item in dispute and the reasons therefor, then Landlord's Statement shall be considered final and accepted by Tenant and Tenant shall be deemed to have waived its right to dispute Landlord's Statement. If Tenant does dispute any Landlord's Statement, Tenant shall deliver a copy of any such audit to Landlord at the time of notification of the dispute. If Tenant does not provide such notice of dispute and a copy of such audit to Landlord within such ninety day (90) day period, it shall be deemed to have waived such right to dispute Landlord's Statement. Any amount due to Landlord as shown on Landlord's Statement, whether or not

disputed by Tenant as provided herein shall be paid by Tenant when due as provided above, without prejudice to any such written exception. In no event shall Tenant be permitted to examine Landlord's records or to dispute any statement of Operating Expenses and Taxes unless Tenant has paid and continues to pay all Rent when due. Upon resolution of any dispute with respect to Operating Expenses and Taxes, Tenant shall either pay Landlord any shortfall or Landlord shall credit Tenant with respect to any overages paid by Tenant. The records obtained by Tenant shall be treated as confidential and neither Tenant nor any of its representatives or agents (including without limitation any financial or legal consultants) shall disclose or discuss the information set forth in the audit to or with any other person or entity ("Confidentiality Requirement"). Tenant shall indemnify and hold Landlord harmless for any losses or damages arising out of the breach of the Confidentiality Requirement.

4.4 TENANT OR LEASE SPECIFIC TAXES

In addition to Monthly Base Rent, Rent Adjustments, Rent Adjustment Deposits and other charges to be paid by Tenant, Tenant shall pay to Landlord, upon demand, any and all taxes payable by Landlord (other than federal or state inheritance, general income, gift or estate taxes) whether or not now customary or within the contemplation of the parties hereto: (a) upon, allocable to, or measured by the Rent payable hereunder, including any gross receipts tax or excise tax levied by any governmental or taxing body with respect to the receipt of such rent; or (b) upon or with respect to the possession, leasing, operation, management, maintenance, alteration, repair, use or occupancy by Tenant of the Premises or any portion thereof; or (c) upon the measured value of Tenant's personal property located in the Premises or in any storeroom or any other place in the Premises or the Property, or the areas used in connection with the operation of the Property, it being the intention of Landlord and Tenant that, to the extent possible, such personal property taxes shall be billed to and paid directly by Tenant; (d) resulting from any Landlord Work, Tenant Work, Tenant Alterations, or any other improvements to the Premises, whether title thereto is in Landlord or Tenant; or (e) upon this transaction. Taxes paid by Tenant pursuant to this Section 4.4 shall not be included in any computation of Taxes payable pursuant to Sections 4.1 and 4.2.

ARTICLE 5

SECURITY DEPOSIT

Concurrently with the execution of this Lease, Tenant shall pay to Landlord the Security Deposit, in immediately available funds. The Security Deposit may be applied by Landlord to cure, in whole or part, any default of Tenant under this Lease, and upon notice by Landlord of such application, Tenant shall replenish the Security Deposit in full by paying to Landlord within ten (10) days of demand the amount so applied. Landlord's application of the Security Deposit shall not constitute a waiver of Tenant's default to the extent that the Security Deposit does not fully compensate Landlord for all losses, damages, costs and expenses incurred by Landlord in connection with such default and shall not prejudice any other rights or remedies available to Landlord under this Lease or by Law. Landlord shall not pay any interest on the Security Deposit. Landlord shall not be required to keep the Security Deposit separate from its general accounts. The Security Deposit shall not be deemed an advance payment of Rent or a measure

of damages for any default by Tenant under this Lease, nor shall it be a bar or defense of any action that Landlord may at any time commence against Tenant. In the absence of evidence satisfactory to Landlord of an assignment of the right to receive the Security Deposit or the remaining balance thereof, Landlord may return the Security Deposit to the original Tenant, regardless of one or more assignments of this Lease. Upon the transfer of Landlord's interest under this Lease, Landlord's obligation to Tenant with respect to the Security Deposit shall terminate upon transfer to the transferee of the Security Deposit, or any balance thereof. If Tenant shall fully and faithfully comply with all the terms, provisions, covenants, and conditions of this Lease, the Security Deposit, or any balance thereof, shall be returned to Tenant within thirty (30) days after Landlord recovers possession of the Premises. Tenant hereby waives any and all rights of Tenant under the provisions of Section 1950.7 of the California Civil Code or other Law regarding the uses to which security deposits may be applied.

If, upon the expiration of the sixth (6^{th}) Lease Year all of the following are true: a) all Rent due by Tenant under this Lease has been paid, b) Tenant is not in default, and c) Tenant's net worth and liquidity, as calculated pursuant to generally-accepted accounting principles and evidenced by documentation reasonably satisfactory to Landlord, are each not materially less than they were as of the Date of Lease, then Landlord agrees that the Security Deposit amount shall be reduced by fifty percent (50%), to become a revised total of $718,789.00. Failure of any of the above to be true at the end of the sixth lease year shall mean the Security Deposit shall remain unchanged from the amount specified in Section 1.1(11) for the balance of the Lease Term.

ARTICLE 6

SERVICES

6.1 LANDLORD'S GENERAL SERVICES

(a) So long as this Lease is in full force and effect and Tenant has paid all Rent then due, Landlord shall furnish the following services the cost of which services shall be included in Operating Expenses:

(1) heat, ventilation and air-conditioning ("HVAC") in the Premises during Standard Operating Hours as necessary in Landlord's reasonable judgment for the comfortable occupancy of the Premises under normal business office and laboratory operations, and (ii) outside of Tenant's Standard Operating Hours to minimum safe setback levels for office laboratory operations ("After-Hours Setback"), subject to compliance with all applicable voluntary and mandatory regulations and Laws;

(2) tempered and cold water for normal and customary use in the Premises and in lavatories in common with other tenants from the regular supply of the Building;

(3) customary cleaning and janitorial services in the Common Areas five (5) days per week, excluding National Holidays;

(4) washing of the outside windows in the Premises weather permitting at intervals determined by Landlord; and

(5) automatic passenger elevator service in common with other tenants of the Building and freight elevator service subject to reasonable scheduling by Landlord. Tenant shall have access to the Premises seven (7) days per week, twenty-four (24) hours per day, subject to such reasonable measures and systems for access control and/or tenant identification as exist from time to time at the Building, including, for example only, keys or card-keys for entry.

(b) Landlord shall provide a security program for the Building (but not individually for Tenant or the Premises) generally consistent with the standards of comparable office/laboratory buildings in Emeryville. The cost of the security program shall be an Operating Expense. Landlord shall not be liable in any manner to Tenant or any other Tenant Parties for any acts (including criminal acts) of others, or for any direct, indirect, or consequential damages, or any injury or damage to, or interference with, Tenant's business, including, but not limited to, loss of profits, loss of rents or other revenues, loss of business opportunity, loss of goodwill or loss of use, or other loss or damage, bodily injury or death, related to any malfunction, circumvention or other failure of any security program, or for the failure of any security program to prevent bodily injury, death, or property damage, or loss, or to apprehend any person suspected of causing such injury, death, damage or loss.

(c) Upon the Rent Commencement Date, Landlord agrees that in the event of an interruption of power to the Building, Tenant may connect Tenant loads to the emergency generator serving the Building (the "Emergency Generator") on the following conditions: (i) Tenant loads to the Emergency Generator shall in no event exceed Tenant's Share of the kVA capacity of the Emergency Generator Landlord elects to make available for shared use by tenants of the Building; (ii) any use of the Emergency Generator, including the duration of use, shall be subject to the requirements and limitations (if any) imposed by applicable Law; and (iii) in the event of an emergency causing an interruption of power to any portion of the Building, Landlord may, in its reasonable discretion, immediately shed or shut down Tenant loads (an "Emergency Shut Down") to the extent necessary to redirect the power from the Emergency Generator ("Emergency Generator Power") to the Building's emergency/life-safety systems (e.g., elevators, fire-life safety and emergency lighting). To the extent Landlord's load shedding equipment accommodates shedding Tenant loads in stages, then Landlord shall use commercially reasonable good-faith efforts to shed Tenant loads in a priority which Tenant has delivered to Landlord in writing. As a condition to Tenant's right to connect Tenant loads to the Emergency Generator:

(1) Tenant shall install and maintain, at Tenant's sole cost and expense, a meter (the "Meter"), which shall be designed and configured to capture all Tenant loads connected to the Emergency Generator. Any and all costs and expenses incurred by Landlord in connection with the Emergency Generator, including, without limitation, provisions for load-shedding and shunt trips, fuel and maintenance/repair/replacement costs, shall be an Operating Expense; and

(2) Landlord shall have the right to require Tenant to install and maintain a shunt trip device ("Shunt Trip Device") designed and configured to automatically shut down Tenant's connection to the Emergency Generator and use of Emergency Generator Power in the event that

the generator load for the Building exceeds eighty percent (80%) of the Emergency Generator rating.

Tenant shall provide Landlord and Landlord's building management staff (the "Building Management Staff") with access to the Meter installed on the Emergency Generator ("EG Meter") at all times for the purpose of inspection, and if necessary (in the reasonable opinion of the Building Management Staff or Landlord), to perform maintenance or repairs thereto. In the event that Landlord incurs any cost or expense in connection with the inspection, repair or maintenance of the EG Meter, Tenant shall reimburse Landlord for Landlord's reasonable and customary out-of-pocket costs and expenses in connection therewith within thirty (30) days after Tenant's receipt of Landlord's written demand therefor (which demand shall be accompanied by documentation of the costs and expenses which are the subject of such demand). Landlord shall have the right at any time during the Lease Term to install and maintain additional or separate transfer switches, meters, control devices and shunt trip devices in order to monitor and control Tenant's connection to the Emergency Generator and use of the Emergency Generator Power.

Notwithstanding anything to the contrary herein, Tenant acknowledges that the Emergency Generator and any transfer switch may be exercised on a periodic basis, such exercise to be conducted by Landlord or the Building Management Staff at Landlord's reasonable discretion. Tenant further acknowledges that annual maintenance procedures require that the Emergency Generator be taken off-line and that an annual full load test be performed on an annual basis, which test shall be conducted by Landlord or the Building Management Staff at Landlord's reasonable discretion; provided, however, Landlord shall give Tenant not less than five (5) business days' prior written notice thereof. Landlord shall not be liable to Tenant, and Tenant shall not be entitled to any abatement of rent or other recourse in the event that Emergency Generator Power is not available for any reason. Landlord's actual out-of-pocket cost of such exercise and testing shall be included in the maintenance costs, of which Tenant shall pay its proportionate share as set forth above in Paragraph 5(f).

Upon the expiration or earlier termination of the Lease Term, Tenant shall surrender and assign to Landlord the Meter with the Premises. In no event shall Tenant be entitled to any reimbursement from Landlord for costs incurred by Tenant in connection with Tenant's installation and maintenance of the Meter.

The rights granted to Tenant under this Section 6.1(c) are personal to the named Tenant hereunder (and any assignee pursuant to a Permitted Transfer) (each an "Approved User"), and shall only be exercisable by an Approved User so long only one connection exists from the Premises to the Emergency Generator at a time. Any attempt by an Approved User or any of its subtenants or other transferees to make any additional connection from the Premises to the Emergency Generator shall constitute a material breach and default, and Tenant shall reimburse Landlord for all reasonable and customary out-of-pocket costs and expenses incurred by Landlord in connection with curing any such default within ten (10) business days following Tenant's receipt of Landlord's demand therefor accompanied by documentation of such costs and expenses.

(d) So long as this Lease is in full force and effect and Tenant has paid all Rent then due, Landlord shall furnish to the Premises replacement lamps, bulbs, ballasts and starters used in any normal Building lighting installed in the Premises, except that if the replacement or repair of such items is a result of negligence of Tenant, its employees, agents, servants, licensees, subtenants, contractors or invitees, such cost shall be paid by Tenant within ten (10) days after notice from Landlord and shall not be included as part of Operating Expenses.

(e) If Tenant uses heat generating machines or equipment in the Premises to an extent which adversely affects the temperature otherwise maintained by the air-cooling system or whenever the occupancy or electrical load adversely affects the temperature otherwise maintained by the air-cooling system, Landlord reserves the right to install or to require Tenant to install supplementary air-conditioning units to service the Premises. Tenant shall bear all costs and expenses related to the installation, maintenance and operation of such units.

6.2 UTILITIES AND JANITORIAL SERVICES

All utility services used in the production of heating and cooling and air supply and exhaust from the central HVAC systems serving the Building and Premises, including, without limitation, electricity and gas, as well as water and sewer services, shall constitute Operating Expenses. If Landlord so elects, any or all utility services used by Tenant within the Premises, including, without limitation, electricity and gas, shall be paid for by Tenant by separate charge and shall not be included as part of Operating Expenses. Such charges shall be based upon Tenant's usage as measured by a separate meter or sub-meter for the Premises installed by Tenant at Tenant's sole cost and expense, or as reasonably estimated by Landlord and shall be payable by Tenant to Landlord within 15 days after billing by Landlord. In addition, Tenant shall provide its own janitorial services to the Premises, using a janitorial service reasonably acceptable to Landlord or shall make arrangements with Landlord for Landlord, through Landlord's vendors, to perform such Premises cleaning services, and shall pay the costs thereof directly to Landlord. Notwithstanding any provision of this Lease to the contrary, Tenant shall not make any alterations or additions to the electric equipment or systems, in each instance, without the prior written approval of Landlord, which approval shall not be unreasonably withheld, conditioned or delayed so long as such alterations or additions (i) do not exceed the capacity of the wiring, feeders and risers and (ii) are in compliance with the City's building code. Tenant's use of electric current shall at no time exceed the capacity of the wiring, feeders and risers providing electric current to the Premises or the Building. The consent of Landlord to the installation of electric equipment shall not relieve Tenant from the obligation to limit usage of electricity to no more than such capacity.

6.3 ADDITIONAL AND AFTER HOUR SERVICES

At Tenant's written request, Landlord shall furnish additional quantities of any of the services or utilities specified in Section 6.1, if Landlord can reasonably do so, on the terms set forth herein. For services or utilities requested by Tenant and furnished by Landlord, Tenant shall pay to Landlord as a charge therefor Landlord's prevailing rates charged from time to time for such services and utilities. Without limiting the generality of the foregoing, for HVAC service outside of Standard Operating Hours and beyond After-Hours Setback levels. If Tenant

shall fail to make any such payment, Landlord may, upon notice to Tenant and in addition to Landlord's other remedies under this Lease, discontinue any or all of such additional services.

6.4 TELEPHONE SERVICES

All telephone, and communication connections which Tenant may desire shall be subject to Landlord's prior written approval, in Landlord's reasonable discretion, and the location of all wires and the work in connection therewith shall be performed by contractors approved by Landlord, and shall be subject to the direction of Landlord and in compliance with Landlord's then current Building Standards for voice, data and wiring installation. Landlord reserves the right to designate and control the entity or entities providing telephone or other communication cable installation, removal, repair and maintenance in the Building and to restrict and control access to telephone cabinets or panels. In the event Landlord designates a particular vendor or vendors to provide such cable installation, removal, repair and maintenance for the Building, Tenant agrees to abide by and participate in such program. Tenant shall be responsible for and shall pay all costs incurred in connection with the installation of telephone cables and communication wiring in the Premises, including any hook up, access and maintenance fees related to the installation of such wires and cables in the Premises and the commencement of service therein, and the maintenance thereafter of such wire and cables; and there shall be included in Operating Expenses for the Building all installation, removal, hook up or maintenance costs incurred by Landlord in connection with telephone cables and communication wiring serving the Building which are not allocable to any individual users of such service but are allocable to the Building generally. If Tenant fails to maintain all telephone cables and communication wiring in the Premises and such failure affects or interferes with the operation or maintenance of any other telephone cables or communication wiring serving the Building, Landlord or any vendor hired by Landlord may enter into and upon the Premises forthwith and perform such repairs, restorations or alterations as Landlord deems necessary in order to eliminate any such interference (and Landlord may recover from Tenant all of Landlord's costs in connection therewith). If required by Landlord, no later than the Termination Date Tenant shall remove all telephone cables and communication wiring installed by Tenant for and during Tenant's occupancy and surrender the installation in a condition previously approved by Landlord. Tenant agrees that neither Landlord nor any of its agents or employees shall be liable to Tenant, or any of Tenant's employees, agents, customers or invitees or anyone claiming through, by or under Tenant, for any damages, injuries, losses, expenses, claims or causes of action because of any interruption, diminution, delay or discontinuance at any time for any reason in the furnishing of any telephone or other communication service to the Premises and the Building.

6.5 DELAYS IN FURNISHING SERVICES

Tenant agrees that Landlord shall not be in breach of this Lease nor be liable to Tenant for damages or otherwise, for any failure to furnish, or a delay in furnishing, or a change in the quantity or character of any service when such failure, delay or change is occasioned, in whole or in part, by repairs, improvements or mechanical breakdowns, by the act or default of Tenant or other parties or by an event of Force Majeure. No such failure, delay or change shall be deemed to be an eviction or disturbance of Tenant's use and possession of the Premises, or relieve Tenant

from paying Rent or from performing any other obligations of Tenant under this Lease, without any deduction or offset; provided, however, in the case of any such failure or delay is caused by the gross negligence or willful misconduct of Landlord and the same materially interferes with Tenant's ability to conduct business in the Premises, then unless Landlord is diligently pursuing a remedy, Rent shall be abated commencing on the fifth (5th) consecutive business day following such failure or delay and shall continue until such time as the failure or delay that materially interferes with Tenant's ability to conduct business in the Premises is cured. Failure to any extent to make available, or any slowdown, stoppage, or interruption of, the specified utility services resulting from any cause, including changes in service provider or Landlord's compliance with any voluntary or similar governmental or business guidelines now or hereafter published or any requirements now or hereafter established by any governmental agency, board, or bureau having jurisdiction over the operation of the Property shall not render Landlord liable in any respect for damages to either persons, property, or business, nor be construed as an eviction of Tenant or work an abatement of Rent, nor relieve Tenant of Tenant's obligations for fulfillment of any covenant or agreement hereof. Should any equipment or machinery furnished by Landlord break down or for any cause cease to function properly, Landlord shall use reasonable diligence to repair same promptly, but Tenant shall have no claim for abatement of Rent or damages on account of any interruption of service occasioned thereby or resulting therefrom.

6.6 CHOICE OF SERVICE PROVIDER

Tenant acknowledges that Landlord may, at Landlord's sole option, to the extent permitted by applicable law, elect to change, from time to time, the company or companies which provide services (including electrical service, gas service, water, telephone and technical services) to the Building, the Premises and/or its occupants. Notwithstanding anything to the contrary set forth in this Lease, Tenant acknowledges that Landlord has not and does not make any representations or warranties concerning the identity or identities of the company or companies which provide services to the Building and the Premises or its occupants and Tenant acknowledges that the choice of service providers and matters concerning the engagement and termination thereof shall be solely that of Landlord. The foregoing provision is not intended to modify, amend, change or otherwise derogate any provision of this Lease concerning the nature or type of service to be provided or any specific information concerning the amount thereof to be provided. Tenant agrees to cooperate with Landlord and each of its service providers in connection with any change in service or provider.

6.7 SIGNAGE

Initial Building standard signage for Tenant will be installed by Landlord in the directory in the main lobby of the Building at Landlord's sole cost and expense. Any change in such initial signage shall be only with Landlord's prior written consent, shall conform to Building standard signage and shall be at Tenant's sole cost and expense. Tenant may, at its sole cost and subject to Landlord's approval which shall not be unreasonably withheld, inside the Premises.

Landlord hereby agrees not to offer exterior, non-exclusive, top of building signage to any other tenant of the Building who has leased two (2) full floors or less without first offering

such signage rights to Tenant first. Landlord and Tenant hereby agree and acknowledge that if such exterior signage rights are offered by Landlord and accepted by Tenant, that Tenant shall pay Landlord the prevailing market rate for such rights, and Landlord and Tenant also agree that for the cost to design, secure approvals and permits for, fabricate, install, maintain, repair, remove and restore any such exterior signage shall be at Tenant's sole cost and expense.

ARTICLE 7

POSSESSION, USE AND CONDITION OF PREMISES

7.1 POSSESSION AND USE OF PREMISES

(a) Tenant shall occupy and use the Premises only for the uses specified in Section 1.1(12) to conduct Tenant's business. Tenant shall not occupy or use the Premises (or permit the use or occupancy of the Premises) for any purpose or in any manner which: (1) is unlawful or in violation of any Law or Environmental Law; (2) may be dangerous to persons or property or which may increase the cost of, or invalidate, any policy of insurance carried on the Building or covering its operations; (3) is contrary to or prohibited by the terms and conditions of this Lease or the rules of the Building set forth in Article 18; (4) would tend to create or continue a nuisance, or (5) in any manner that will cause the Building or any part thereof not to conform with the Project's Sustainability Practices or the certification of the Building pursuant to the applicable Green Building Standards; provided, however, that in no event shall such practices or certification requirements have the effect of preventing Tenant from conducting its business at the Premises in a manner consistent with the Permitted Use.

(b) Landlord shall provide Tenant with Access Card Keys the cost of which shall be paid by Tenant within ten (10) days of Landlord's demand therefor, and Tenant shall place a deposit for such cards with Landlord to cover lost cards or cards which are not returned at the end of the Term.

(c) Landlord and Tenant acknowledge that the Americans With Disabilities Act of 1990 (42 U.S.C. §12101 et seq.) and regulations and guidelines promulgated thereunder, as all of the same may be amended and supplemented from time to time (collectively referred to herein as the "ADA") establish requirements for business operations, accessibility and barrier removal, and that such requirements may or may not apply to the Premises, the Building and the Project depending on, among other things: (1) whether Tenant's business is deemed a "public accommodation" or "commercial facility", (2) whether such requirements are "readily achievable", and (3) whether a given alteration affects a "primary function area" or triggers "path of travel" requirements. The parties hereby agree that: (a) Landlord shall be responsible for ADA Title III compliance in the Common Areas, except as provided below, (b) Tenant shall be responsible for ADA Title III compliance in the Premises, including any leasehold improvements or other work to be performed in the Premises under or in connection with this Lease, (c) Landlord may perform, or require that Tenant perform, and Tenant shall be responsible for the cost of, ADA Title III "path of travel" requirements triggered by Tenant Additions in the Premises, and (d) Landlord may perform, or require Tenant to perform, and Tenant shall be responsible for the cost of, ADA Title III compliance in the Common Areas necessitated by the

Building being deemed to be a "public accommodation" instead of a "commercial facility" as a result of Tenant's use of the Premises. Tenant shall be solely responsible for requirements under Title I of the ADA relating to Tenant's employees.

(d) Civil Code Section 1938. TENANT HEREBY WAIVES, TO THE FULLEST EXTENT PERMITTED BY LAW, THE PROTECTIONS OF CALIFORNIA CIVIL CODE SECTION 1938. IF SUCH WAIVER IS NOT ENFORCEABLE UNDER CALIFORNIA LAW, THEN THE FOLLOWING PROVISIONS SHALL APPLY. The Premises have not been issued a disability access inspection certificate or undergone inspection by a Certified Access Specialist ("**CASp**"). The following notice is given pursuant to California Civil Code Section 1938: "A Certified Access Specialist (CASp) can inspect the subject premises and determine whether the subject premises comply with all of the applicable construction-related accessibility standards under state law. Although state law does not require a CASp inspection of the subject premises, the commercial property owner or lessor may not prohibit the lessee or tenant from obtaining a CASp inspection of the subject premises for the occupancy or potential occupancy of the lessee or tenant, if requested by the lessee or tenant. The parties shall mutually agree on the arrangements for the time and manner of the CASp inspection, the payment of the fee for the CASp inspection, and the cost of making any repairs necessary to correct violations of construction-related accessibility standards within the premises." Landlord and Tenant hereby agree that if Tenant elects to perform a CASp inspection of the Premises, Tenant will provide written notice to Landlord, and Landlord may elect, in Landlord's sole discretion, to retain a CASp to perform the inspection. If Landlord does not so elect, the time and manner of the CASp inspection is subject to the prior written approval of Landlord. In either event, the payment of the fee for the CASp inspection shall be borne by Tenant. The cost of making any repairs necessary to correct violations of construction-related accessibility standards within the Premises shall be allocated as provided in this Article.

(e) Tenant agrees to cooperate and use commercially reasonable efforts to participate in traffic management programs, and Tenant shall encourage and support van, shuttle service, and carpooling by, and staggered and flexible working hours for, its office workers and service employees to the extent reasonably permitted by the requirements of Tenant's business. Neither this Section or any other provision of this Lease is intended to or shall create any rights or benefits in any other person, firm, company, governmental entity or the public.

(f) Tenant agrees to cooperate with Landlord and to comply with any and all guidelines or controls concerning energy management and usage disclosure imposed upon Landlord by federal or state governmental organizations or by any energy conservation association to which Landlord is a party or which is applicable to the Building, including, without limitation, the requirements of California's Nonresidential Building Energy Use Disclosure Program, as more particularly specified in California Public Resources Code Sections 25402.10 *et seq.* and regulations adopted pursuant thereto. Further, Tenant hereby authorizes (and agrees that Landlord shall have the authority to authorize) any electric or gas utility company providing service to the Building to disclose from time to time so much of the data collected and maintained by it regarding Tenant's energy consumption data as may be necessary to cause the Building to participate in the ENERGY STAR® Portfolio Manager system and similar programs; and Tenant further authorizes Landlord to disclose information concerning

energy use by Tenant, either individually or in combination with the energy use of other tenants, as applicable as Landlord determines to be necessary to comply with applicable Laws pertaining to the Building or Landlord's ownership thereof.

(g) Hazardous Materials.

(1) Definitions. The following terms shall have the following meanings for purposes of this Lease:

(i) "Biohazardous Materials" means any and all substances and materials defined or referred to as "a-medical waste," "biological waste," "biohazardous waste," "biohazardous material" or any other term of similar import under any Hazardous Materials Laws, including (but not limited to) California Health & Safety Code Sections 25105 et seq., and any regulations promulgated thereunder, as amended from time to time.

(ii) "Environmental Condition" means the Release of any Hazardous Materials in, over, on, under, through, from or about the Project (including, but not limited to, the Premises).

(iii) "Environmental Damages" means all claims, suits, judgments, damages, losses, penalties, fines, liabilities, encumbrances, liens, costs and expenses of whatever kind or nature, contingent or otherwise, matured or unmatured, foreseeable or unforeseeable, arising out of or in connection with any Environmental Condition, including, to the extent arising out of an Environmental Condition, without limitation: (A) damages for personal injury, or for injury or damage to the Project or natural resources occurring on or off the Project, including without limitation (1) any claims brought by or on behalf of any person, (2) any loss of, lost use of, damage to or diminution in value of any Project or natural resource, and (3) costs of any investigation, remediation, removal, abatement, containment, closure, restoration or monitoring work required by any federal, state or local governmental agency or political subdivision, or otherwise reasonably necessary to protect the public health or safety, whether on or off the Project; (B) reasonable fees incurred for the services of attorneys, consultants, contractors, experts and laboratories in connection with the preparation of any feasibility studies, investigations or reports or the performance of any work described above: (C) any liability to any third person or governmental agency to indemnify such person or agency for costs expended or liabilities incurred in connection with any items described in clause (A) or (B) above; (D) any fair market or fair market rental value of the Project; and (E) the amount of any penalties, damages or costs a party is required to pay or incur in excess of that which the party otherwise would reasonably have expected to pay or incur absent the existence of the applicable Environmental Condition.

(iv) "Handling" or "Handles", when used with reference to any substance or material, includes (but is not limited to) any receipt, storage, use, generation, Release, transportation, treatment or disposal of such substance or material.

(v) "Hazardous Materials" means any and all chemical, explosive, biohazardous, radioactive or otherwise toxic or hazardous materials or hazardous wastes,

including without limitation any asbestos-containing materials, PCB's, CFCs, petroleum and derivatives thereof, Radioactive Materials, Biohazardous Materials, Hazardous Wastes, any other substances defined or listed as or meeting the characteristics of a hazardous substance, hazardous material, Hazardous Waste, toxic substance, toxic waste, biohazardous material, biohazardous waste, biological waste, medical waste, radiation, radioactive substance, radioactive waste, or other similar term, as applicable, under any law, statute, ordinance, code, rule, regulation, directive, order, condition or other written requirement enacted, promulgated or issued by any public officer or governmental or quasi-governmental authority, whether now in force or hereafter in force at any time or from time to time to protect the environment or human health, and/or any mixed materials, substances or wastes containing more than one of the foregoing categories of materials, substances or wastes.

(vi) "Hazardous Materials Laws" means, collectively, (A) the Comprehensive Environmental Response, Compensation and Liability Act of 1980, 42 U.S.C. Sections 9601-9657, (B) the Hazardous Materials Transportation Act of 1975, 49 U.S.C. Sections 1801-1812, (C) the Resource Conservation and Recovery Act of 1976, 42 U.S.C. Sections 6901-6987 (together with any amendments thereto, any regulations thereunder and any amendments to any such regulations as in effect from time to time, "**RCRA**"), (D) the California Carpenter-Presley-Tanner Hazardous Substance Account Act, California Health & Safety Code Sections 25300 et seq., (E) the Hazardous Materials Release Response Plans and Inventory Act, California Health & Safety Code Sections 25500 et seq., (F) the California Hazardous Waste Control Law, California Health & Safety Code Sections 25100 et seq. (together with any amendments thereto, any regulations thereunder and any amendments to any such regulations as in effect from time to time, the "CHWCL"), (G) California Health & Safety Code Sections 25015-25027.8, (H) any amendments to or successor statutes to any of the foregoing, as adopted or enacted from time to time, (I) any regulations or amendments thereto promulgated pursuant to any of the foregoing from time to time, (J) any Laws relating to Biohazardous Materials, including (but not limited to) any regulations or requirements with respect to the shipping, use, decontamination and disposal thereof, and (K) any other Law now or at any time hereafter in effect regulating, relating to or imposing liability or standards of conduct concerning any Hazardous Materials, including (but not limited to) any requirements or conditions imposed pursuant to the terms of any orders, permits, licenses, registrations or operating plans issued or approved by any governmental or quasi-governmental authority from time to time either on a Project-wide basis or in connection with any Handling of Hazardous Materials in, on or about the Premises or the Project.

(vii) "Hazardous Wastes" means (A) any waste listed as or meeting the identified characteristics of a "hazardous waste" or terms of similar import under RCRA, (B) any waste meeting the identified characteristics of a "hazardous waste", "extremely hazardous waste" or "restricted hazardous waste" under the CHWCL, and/or (C) any and all other substances and materials defined or referred to as a "hazardous waste" or other term of similar import under any Hazardous Materials Laws.

(viii) "Radioactive Materials" means (A) any and all substances and materials the Handling of which requires an approval, consent, permit or license from the Nuclear Regulatory Commission, (B) any and all substances and materials the Handling of which

requires a Radioactive Material License or other similar approval, consent, permit or license from the State of California, and (C) any and all other substances and materials defined or referred to as "radiation," a "radioactive material" or "radioactive waste," or any other term of similar import under any Hazardous Materials Laws, including (but not limited to) Title 26, California Code of Regulations Section 17-30100, and any statutes, regulations or other laws administered, enforced or promulgated by the Nuclear Regulatory Commission.

(ix) "Release" means any accidental or intentional spilling, leaking, pumping, pouring, emitting, discharging, injecting, escaping, leaching, migrating, dumping or disposing into the air, land, surface water, groundwater or the environment (including without limitation the abandonment or discarding of receptacles containing any Hazardous Materials).

(x) "Tenant's Contamination" means any Hazardous Material Release on or about the Property by Tenant and/or any agents, employees, contractors, vendors, suppliers, licensees, subtenants, and invitees of Tenant (individually a "Tenant Party" and collectively, "Tenant Parties").

(xi) "Landlord's Contamination" means any Hazardous Materials which exist in, on, under or in the vicinity of the Project as of the date of this Lease or which migrate onto or beneath the Project after termination of this Lease. Tenant shall not be required to pay any costs with respect to the remediation or abatement of Landlord's Contamination.

(1) Handling of Hazardous Materials. The parties acknowledge that Tenant wishes and intends to use all or a portion of the Premises as a bio-pharmaceutical research and development and otherwise for the conduct by Tenant of its business in accordance with the use specified in Section 1.1(12), that such use, as conducted or proposed to be conducted by Tenant, would customarily include the Handling of Hazardous Materials, and that Tenant shall therefore be permitted to engage in the Handling in the Premises of necessary and reasonable quantities of Hazardous Materials customarily used in or incidental to the operation of a bio pharmaceutical research, development, preparation and dispensing facility and the other business operations of Tenant in the manner conducted or proposed to be conducted by Tenant hereunder ("Permitted Hazardous Materials"), provided that the Handling of such Permitted Hazardous Materials by all Tenant Parties shall at all times comply with and be subject to all provisions of this Lease and all Laws, including all Hazardous Materials Laws as well as be in compliance with Landlord's Chemical Control Area Plan for the Building. Without limiting the generality of the foregoing, Tenant shall comply at all times with all Hazardous Materials Laws applicable to any aspect of Tenant's use of the Premises and the Project and of Tenant's operations and activities in, on and about the Premises and the Project, and shall ensure at all times that Tenant's Handling of Hazardous Materials in, on and about the Premises does not violate (x) the terms of any governmental licenses or permits applicable to the Building (including, but not limited to, the Building Discharge Permit as defined below) or Premises or to Tenant's Handling of any Hazardous Materials therein, or (y) any applicable requirements or restrictions relating to the occupancy classification of the Building and the Premises.

(2) Disposition or Emission of Hazardous Materials. Tenant shall not Release or dispose of any Hazardous Materials, except to the extent authorized by permit, at the Premises

or on the Project, but instead shall arrange for off-site disposal, under Tenant's own name and EPA waste generator number (or other similar identifying information issued or prescribed by any other governmental authority with respect to Radioactive Materials, Biohazardous Materials or any other Hazardous Materials) and at Tenant's sole expense, in compliance with all applicable Hazardous Materials Laws, with the Laboratory Rules and Regulations (defined below) and with all other applicable Laws and regulatory requirements.

(3) Information Regarding Hazardous Materials. Tenant shall maintain and make available to Landlord the following information and/or documentation upon demand:

(i) An inventory of all Hazardous Materials that Tenant receives, uses, handles, generates, transports, stores, treats or disposes of from time to time, or at the time of preparation of such inventory proposes or expects to use, handle, generate, transport, store, treat or dispose of from time to time, in connection with its operations at the Premises. Such inventory shall include, but shall separately identify, any Hazardous Wastes, Biohazardous Materials and Radioactive Materials covered by the foregoing description. If such inventory includes any Biohazardous Materials, Tenant shall also disclose in writing to Landlord the Biosafety Level designation associated with the use of such materials.

(ii) Copies of all then existing permits, licenses, registrations and other similar documents issued by any governmental or quasi-governmental authority that authorize any Handling of Hazardous Materials in, on or about the Premises or the Project by any Tenant Party.

(iii) All Material Safety Data Sheets ("MSDSs"), if any, required to be completed with respect to operations of Tenant at the Premises from time to time in accordance with Title 26, California Code of Regulations Section 8-5194 or 42 U.S.C. Section 11021, or any amendments thereto, and any Hazardous Materials Inventory Sheets that detail the MSDSs.

(iv) All hazardous waste manifests (as defined in Title 26, California Code of Regulations Section 22-66481), if any, that Tenant is required to complete from time to time in connection with its operations at the Premises.

(v) A copy of any "Hazardous Materials Business Plan" required from time to time with respect to Tenant's operations at the Premises pursuant to California Health & Safety Code Sections 25500 et seq., and any regulations promulgated thereunder, as amended from time to time, or in connection with Tenant's application for a business license from the City of Emeryville. If applicable law does not require Tenant to prepare a Hazardous Materials Business Plan, Tenant shall furnish to Landlord at the times and in the manner set forth above the information that would customarily be contained in a Hazardous Materials Business Plan, including (but not limited to) information regarding Tenant's Hazardous Materials inventories. The parties acknowledge that a Hazardous Materials Business Plan would ordinarily include an emergency response plan, and that regardless of whether applicable Law requires Tenant or other tenants in the Building to prepare Hazardous Materials Business Plans, Landlord in its discretion may elect to prepare a coordinated emergency response plan for the entire Building and/or for multiple Buildings on the Project.

(vi) Any "Contingency Plans and Emergency Procedures" required of Tenant from time to time, in connection with its operations at the Premises, pursuant to applicable Law, Title 26, California Code of Regulations Sections 22-67140 et seq., and any amendments thereto, and any "Training Programs and Records" required under Title 26, California Code of Regulations Section 22-66493, and any amendments thereto from time to time. Landlord in its discretion may elect to prepare a Contingency Plan and Emergency Procedures for the entire Building and/or for multiple Buildings on the Project, in which event, if applicable law does not require Tenant to prepare a Contingency Plan and Emergency Procedures for its operations at the Premises, Tenant shall furnish to Landlord at the times and in the manner set forth above the information that would customarily be contained in a Contingency Plan and Emergency Procedures.

(vii) Copies of any biennial or other periodic reports furnished or required to be furnished to the California Department of Health Services from time to time, under applicable law, pursuant to Title 26, California Code of Regulations Section 22-66493 and any amendments thereto, relating to any Hazardous Materials.

(viii) Copies of any industrial wastewater discharge permits issued to or held by Tenant from time to time in connection with its operations at the Premises (the parties presently anticipate, however, that because of the existence of the Building Discharge Permit in Landlord's name as described above. Tenant will not be required to maintain a separate, individual discharge permit).

(ix) Copies of any other lists, reports, studies, or inventories of Hazardous Materials or of any subcategories of materials included in Hazardous Materials that Tenant is otherwise required to prepare and file from time to time with any governmental or quasi-governmental authority in connection with Tenant's operations at the Premises, including (but not limited to) reports filed by Tenant with the federal Food & Drug Administration or any other regulatory authorities primarily in connection with the presence (or lack thereof) of any "select agents" or other Biohazardous Materials on the Premises, together with proof of filing thereof.

(x) Any other information reasonably requested by Landlord in writing from time to time in connection with (A) Landlord's monitoring (in Landlord's reasonable discretion) and enforcement of Tenant's obligations under this Section and of compliance with applicable Laws in connection with any Handling or Release of Hazardous Materials in the Premises or Building or on or about the Project by any Tenant Party, (B) any inspections or enforcement actions by any governmental authority pursuant to any Hazardous Materials Laws or any other Laws relating to the presence or Handling of Hazardous Materials in the Premises or Building or on or about the Project by any Tenant Party, and/or (C) Landlord's preparation (in Landlord's discretion) and enforcement of any reasonable rules and procedures relating to the presence or Handling by Tenant or any Tenant Party of Hazardous Materials in the Premises or Building or on or about the Project, including (but not limited to) any contingency plans or emergency response plans as described above. Except as otherwise required by Law, Landlord shall keep confidential any information supplied to Landlord by Tenant pursuant to the foregoing, provided, however, that the foregoing shall not apply to any information filed with

any governmental authority or available to the public at large. Landlord may provide such information to its lenders, consultants or investors provided such entities agree to keep such information confidential.

(1) Indemnification; Notice of Release. Tenant shall be responsible for and shall indemnify, defend and hold Landlord harmless from and against all Environmental Damages to the extent arising out of or otherwise relating to, (i) any Handling of Hazardous Materials by any Tenant Party in, on or about the Premises or the Project in violation of this Section, (ii) any breach of Tenant's obligations under this Section or of any Hazardous Materials Laws by any Tenant Party, or (iii) the existence of any Tenant Contamination in, on or about the Premises or the Project to the extent caused by any Tenant Party, including without limitation any removal, cleanup or restoration work and materials necessary to return the Project or any improvements of whatever nature located on the Project to the condition existing prior to the Handling of Hazardous Materials in, on or about the Premises or the Project by any Tenant Party. In the event of any Tenant Contamination in, on or about the Premises or any other portion of the Project or any adjacent lands, Tenant shall promptly remedy the problem in accordance with all applicable Hazardous Materials Laws and Laws, shall give Landlord oral notice of any such non-standard or non-customary Release promptly after Tenant becomes aware of such Release, followed by written notice to Landlord within five (5) days after Tenant becomes aware of such Release, and shall furnish Landlord with concurrent copies of any and all notices, reports and other written materials filed by any Tenant Party with any governmental authority in connection with such Release. Tenant shall have no obligation to remedy any Hazardous Materials contamination which was not caused or released by a Tenant Party.

(2) Governmental Notices. Tenant shall promptly provide Landlord with copies of all notices received by Tenant relating to any actual or alleged presence or Handling by any Tenant Party of Hazardous Materials in, on or about the Premises or any other portion of the Project, including, without limitation, any notice of violation, notice of responsibility or demand for action from any federal, state or local governmental authority or official in connection with any actual or alleged presence or Handling by any Tenant Party of Hazardous Materials in or about the Premises or any other portion of the Project.

(3) Inspection by Landlord. In addition to, and not in limitation of, Landlord's rights under this Lease, upon reasonable prior request by Landlord, Tenant shall grant Landlord and its consultants, as well as any governmental authorities having jurisdiction over the Premises or over any aspect of Tenant's use thereof, reasonable access to the Premises at reasonable times to inspect Tenant's Handling of Hazardous Materials in, on and about the Premises, and Landlord shall not thereby incur any liability to Tenant or be deemed guilty of any disturbance of Tenant's use or possession of the Premises by reason of such entry; provided, however, that Landlord shall use reasonable efforts to minimize interference with Tenant's use of the Premises caused by such entry. Landlord shall comply with any security precaution reasonably imposed by Tenant during any entry onto the Premises and shall minimize to the extent reasonably possible any interference with Tenant's use of the Premises caused by such entry. Notwithstanding Landlord's rights of inspection and review of documents, materials and physical conditions under this Section with respect to Tenant's Handling of Hazardous Materials, Landlord shall have no duty or obligation to perform any such inspection or review or to monitor

in any way any documents, materials, physical conditions or compliance with Laws in connection with Tenant's Handling of Hazardous Materials, and no third Party shall be entitled to rely on Landlord to conduct any such inspection, review or monitoring by reason of the provisions of this Section.

(4) Monitoring by Landlord. Landlord reserves the right to monitor, in Landlord's reasonable discretion and at Landlord's cost (the reasonable cost of which shall be recoverable as an Operating Expense (except in the case of a breach of any of Tenant's obligations under this Section, in which event such monitoring costs may be charged back entirely to Tenant and shall be reimbursed by Tenant to Landlord within ten (10) days after written demand by Landlord from time to time, accompanied by supporting documentation reasonably evidencing the costs for which such reimbursement is claimed), at such times and from time to time as Landlord in its reasonable discretion may determine, through consultants engaged by Landlord or otherwise as Landlord in its reasonable discretion may determine, (x) all aqueous and atmospheric discharges and emissions from the Premises during the Term by a Tenant Party, (y) Tenant's compliance and the collective compliance of all tenants in the Building with requirements and restrictions relating to the occupancy classification of the Building (including, but not limited to, Hazardous Materials inventory levels of Tenant and all other tenants in the Building), and (z) Tenant's compliance with all other requirements of this Section.

(5) Discovery of Discharge. If Landlord, Tenant or any governmental or quasi-governmental authority discovers any Release from the Premises during the Term by a Tenant Party in violation of this Section that, in Landlord's reasonable determination, jeopardizes the ability of the Building or the Project to meet applicable Laws or otherwise adversely affects the Building's or the Project's compliance with applicable discharge or emission standards, or if Landlord discovers any other breach of Tenant's obligations under this Section, then upon receipt of written notice from Landlord or at such earlier time as Tenant obtains actual knowledge of the applicable discharge, emission or breach, Tenant at its sole expense shall within a reasonable time (x) in the case of a Release in violation of this Lease, cease the applicable discharge or emission and remediate any continuing effects of the discharge or emission until such time, if any, as Tenant demonstrates to Landlord's reasonable satisfaction that the applicable discharge or emission is in compliance with all applicable Laws and any other applicable regulatory commitments and obligations to the satisfaction of the appropriate governmental agency with jurisdiction over the Release, and (y) in the case of any other breach of Tenant's obligations under this Section, take such corrective measures as Landlord may reasonably request in writing in order to cure or eliminate the breach as promptly as practicable and to remediate any continuing effects of the breach.

(6) Post-Occupancy Study. No later than thirty (30) days prior to the Termination Date, Tenant at its sole cost and expense, shall obtain and deliver to Landlord an environmental study, performed by an expert reasonably satisfactory to Landlord, evaluating, the presence or absence of any Tenant Contamination in, on and about the Premises and the Project. Such study shall be based on a reasonable and prudent level of tests and investigations of the Premises and surrounding portions of the Project (if appropriate) which tests shall be conducted no earlier than fifteen (15) days prior to the Termination Date. Liability for any remedial actions required or recommended on the basis of such study shall be allocated in accordance with the

applicable provisions of this Lease. To the extent any such remedial actions are the responsibility of Tenant, Tenant at its sole expense shall promptly commence and diligently pursue to completion the required remedial actions.

(7) Emergency Response Plans. If Landlord in its reasonable discretion adopts any emergency response plan and/or any Contingency Plan and Emergency Procedures for the Building or for multiple Buildings on the Project as contemplated above, Landlord shall provide copies of any such plans and procedures to Tenant and, so long as such plans and procedures are reasonable, Tenant shall comply with all of the requirements of such plans and procedures to the extent applicable to Tenant and/or the Premises. If Landlord elects to adopt or materially modify any such plans or procedures that apply to the Building during the Term, Landlord shall consult with Tenant, and Tenant shall cooperate, in the preparation of such plans, procedures or modifications in efforts to accurately reflect and maintain consistency with Tenant's operations in the Premises, but Landlord alone shall determine, in its good faith reasonable discretion, the appropriate scope of such consultation and nothing in this paragraph shall be construed to give Tenant any right of approval or disapproval over Landlord's adoption or modification of any such plans or procedures.

(8) Radioactive Materials. Without limiting any other applicable provisions of this Section, if Tenant Handles or proposes to Handle any Radioactive Materials in or about the Premises, Tenant shall provide Landlord with copies of Tenant's licenses or permits for such Radioactive Materials and with copies of all radiation protection programs and procedures required under applicable Laws or otherwise adopted by Tenant from time to time in connection with Tenant's Handling of such Radioactive Materials. In addition, Tenant shall comply with any and all rules and procedures issued by Landlord in its good faith discretion from time to time with respect to the Handling of Radioactive Materials on the Project (such as, by way of example but not limitation, rules implementing a label defacement program for decayed waste destined for common trash and/or rules relating to transportation and storage of Radioactive Materials on the Project), provided that such rules and procedures shall be reasonable and not in conflict with any applicable Laws.

(9) Deemed Holdover Occupancy. Notwithstanding any other provisions of this Lease, Tenant expressly agrees as follows:

(i) If Tenant Handles any Radioactive Materials in or about the Premises or the Project during the Term, then for so long as any license or permit relating to such Radioactive Materials remains open or valid following the Termination Date, and another entity handling Radioactive Materials which is a prospective tenant of Landlord is legally prohibited from occupying a portion of the Premises for a use similar to Tenant's use, then Tenant shall be deemed to be occupying that portion of the Premises on a holdover basis without Landlord's consent (notwithstanding such otherwise applicable termination or expiration of the Term) and shall be required to continue to pay Rent and other charges in accordance with Article 13 solely for that portion of the Premises effected by the radioactive materials license, until such time as all such Radioactive Materials licenses and permits have been fully closed out in accordance with the requirements of this Lease and with all applicable Hazardous Materials Laws and other Laws.

(ii) If Tenant Handles any Hazardous Materials in or about the Premises or the Project during the Term and, on or before the Termination Date, has failed to remove from the Premises or the Project all known Hazardous Materials Handled by a Tenant Party or has failed to complete any remediation or removal of Tenant's Contamination and/or to have fully remediated in compliance with the requirements of this Lease and with all applicable Hazardous Materials Laws and any other applicable Laws, the Tenant's Handling and/or Release (if applicable) of any such Hazardous Materials during the Term, then for so long as such circumstances continue to exist, Tenant shall be deemed to be occupying the Premises on a holdover basis without Landlord's consent (notwithstanding such otherwise applicable termination or expiration of the Term) and shall be required to continue to pay Rent and other charges in accordance with Article 13 until such time as all such circumstances have been fully resolved in accordance with the requirements of this Lease and with all applicable Hazardous Materials Laws and other Laws.

(1) Survival of Obligations. Each party's obligations under this Section shall survive the Termination Date and shall survive any conveyance by Landlord of its interest in the Premises. The provisions of this Section and any exercise by either party of any of the rights and remedies contained herein shall be without prejudice to any other rights and remedies that such party may have under this Lease or under applicable Law with respect to any Environmental Conditions and/or any Hazardous Materials. Either party's exercise or failure to exercise, at any time or from time to time, any or all of the rights granted in this Section shall not in any way impose any liability on such party or shift from the other party to such party any responsibility or obligation imposed upon the other party under this Lease or under Hazardous Materials Laws, Environmental Conditions and/or compliance with Laws.

(2) Laboratory Rules and Regulations. Tenant agrees for itself and for its subtenants, employees, agents, and invitees to comply with the laboratory rules and regulations ("Laboratory Rules and Regulations") attached to this Lease as Exhibit C-1 and with all reasonable modifications and additions thereto which Landlord may make from time to time.

7.2 LANDLORD ACCESS TO PREMISES; APPROVALS

(a) Tenant shall permit Landlord to erect, use and maintain pipes, ducts, wiring and conduits in and through the Premises, so long as Tenant's use, layout or design of the Premises is not materially affected or altered. Landlord or Landlord's agents shall have the right to enter upon the Premises to perform janitorial and other routine services or in the event of an emergency, or to inspect the Premises, to conduct safety and other testing in the Premises, and to make such repairs, alterations, improvements or additions to the Premises or the Building or other parts of the Property as Landlord may deem necessary or desirable (including all alterations, improvements and additions in connection with a change in service provider or providers). Janitorial and cleaning services shall be performed after Standard Operating Hours. Any entry or work by Landlord may be during Standard Operating Hours and Landlord may use reasonable efforts to ensure that any entry or work shall not materially interfere with Tenant's occupancy of the Premises.

(b) Advance notice shall not be required for entry to perform routine janitorial and cleaning services or for entry in the event of an emergency or urgent situation, as reasonably determined by Landlord, but any other entry or work by Landlord shall be upon at least one (1) business day's prior notice to Tenant, which notice may be delivered orally or by e-mail to Tenant's on-site manager at the Premises. If Tenant shall not be personally present to permit an entry into the Premises when for any reason an entry therein shall be necessary or permissible, Landlord (or Landlord's agents), after attempting to notify Tenant (unless Landlord believes an emergency situation exists), may enter the Premises without rendering Landlord or its agents liable therefor, and without relieving Tenant of any obligations under this Lease.

(c) Landlord may enter the Premises for the purpose of conducting such inspections, tests and studies as Landlord may deem desirable or necessary to confirm Tenant's compliance with all Laws and Hazardous Materials Laws or for other purposes necessary in Landlord's reasonable judgment to ensure the sound condition of the Property and the systems serving the Property. Landlord's rights under this Section 7.2(c) are for Landlord's own protection only, and Landlord has not, and shall not be deemed to have assumed, any responsibility to Tenant or any other party as a result of the exercise or non-exercise of such rights, for compliance with Laws or Hazardous Materials Laws or for the accuracy or sufficiency of any item or the quality or suitability of any item for its intended use.

(d) Landlord may do any of the foregoing, or undertake any of the inspection or work described in the preceding paragraphs without such action constituting an actual or constructive eviction of Tenant, in whole or in part, or giving rise to an abatement of Rent by reason of loss or interruption of business of Tenant, or otherwise.

(e) The review, approval or consent of Landlord with respect to any item required or permitted under this Lease is for Landlord's own protection only, and Landlord has not, and shall not be deemed to have assumed, any responsibility to Tenant or any other party, as a result of the exercise or non-exercise of such rights, for compliance with Laws or Hazardous Materials Laws or for the accuracy or sufficiency of any item or the quality or suitability of any item for its intended use.

7.3 QUIET ENJOYMENT

Landlord covenants, in lieu of any implied covenant of quiet possession or quiet enjoyment, that so long as Tenant is in compliance with the covenants and conditions set forth in this Lease, Tenant shall have the right to quiet enjoyment of the Premises without hindrance or interference from Landlord or those claiming through Landlord, and subject to the covenants and conditions set forth in this Lease and to the rights of any Mortgagee or ground lessor.

7.4 TENANT ACKNOWLEDGMENTS REGARDING PROPERTY

(a) The Property is situated in the City of Emeryville ("City") in a mixed-use area that includes, among other possible uses permitted by the City, residential, commercial, manufacturing, industrial and laboratory/research uses. In recognition of such mixed-use character of area in which the Property is located, as a condition of the approval of the

development of the Building on the Property, the City has required that Landlord disclose to tenants of the Building that:

(1) industrial and laboratory/research uses located in nearby buildings have the potential to emit noise at levels and during hours of the day that persons may find disturbing;

(2) nearby manufacturing, industrial and laboratory/research uses may generate odor;

(3) at times there may be substantial truck traffic in the area;

(4) there is a mainline railroad in the vicinity of the Property that operates 24 hours per day, seven days per week, with associated train horns and other sounds and vibration;

(5) future development in the vicinity of the Property may block views from the Building; and

(6) the site on which the Building is built formerly contained hazardous materials; under the direction of the Environmental Protection Agency and the State Department of Toxic Substances Control (the "Agencies"), remediation and abatement measures have been undertaken to address potential health risks associated with such hazardous materials; and the documents relating to the remediation and abatement measures at the Property are on file at Landlord's property management office and at the offices of the Agencies (the parties acknowledge that this clause (6) constitutes the notice required by Cal. Health and Safety Code Section 25359.7).

Tenant acknowledges the foregoing disclosures required to be made by Landlord regarding the mixed-use character of the area in which the Property is located.

(b) As required by the terms of that certain Covenant and Environmental Restriction on Property referenced hereinbelow, the following notice regarding the land upon which the 6100 Horton Street parking garage is situated is provided:

> "The land described herein [i.e., the land upon which the Parking Garage is located] contains polychlorinated biphenyls (PCBs) in soil and volatile organic compounds in groundwater under the Burdened Property referred to as "Emery Station West Parking Garage", and is subject to a deed restriction dated as of August 11, 2016, and recorded on August 19, 2016, in the Official Records of Alameda County, California, as Document No. 2016210925, which Covenant and Restriction imposes certain covenants, conditions, and restrictions on usage of the property described herein. This statement is not a declaration that a hazard exists."

(c) Provided that Tenant is not in Default hereunder, during the Lease Term, Landlord shall provide Tenant and its employees reasonable access to any shared lockers and showers serving the Building and other properties owned by Landlord or Landlord's Affiliates, such access to be free of charge other that for charges customarily charged to all tenants and employees.

7.5 TRANSPORTATION DEMAND MANAGEMENT PROGRAM

Landlord may elect or may be required to develop and implement a Transportation Demand Management ("TDM") program for the Building in order to reduce the traffic-related impacts resulting from development of the Property. One element of any such TDM program will require tenants of the Building to adopt programs and offer incentives to their employees to reduce auto use and support the increase of alternative modes of transit. The following are examples of such programs and incentives:

• Alternative commute subsidies and/or parking cash-out, where employees are provided with a subsidy if they use transit or commute by alternative modes;

• Opportunities to purchase commuter checks which allow employees to purchase transit tickets at discounted rates from their before-tax income; and

• Compressed work weeks and flex time where employees adjust their work schedules to reduce peak hour trips to/from the Building.

In order to support any such TDM program for the Building, Tenant agrees that it shall adopt programs and offer incentives to its employees in order to reduce auto use and support the increase of alternative modes of transit. The specifics of Tenant's programs and incentives shall be tailored to the needs of Tenant's workforce and shall be determined by Tenant in its good faith efforts to meet the goals of the TDM program. Upon request by Landlord from time to time, but not more often than once per calendar year, Tenant shall provide to Landlord a written report summarizing the programs and incentives being offered by Tenant to achieve the goals of the TDM program.

ARTICLE 8

MAINTENANCE

8.1 LANDLORD'S MAINTENANCE

Subject to the provisions of Articles 4 and 14, Landlord shall, as an Operating Expense, maintain and make necessary repairs to the foundations, roofs, exterior walls, and the structural elements of the Building, the electrical, plumbing, heating, ventilating, air-conditioning, mechanical, communication, security and the fire and life safety systems of the Building and those corridors, washrooms and lobbies which are Common Areas of the Building, except that: (a) Landlord shall not be responsible for the maintenance or repair of any floor or wall coverings in the Premises or any of such systems which are located within the Premises and are supplemental or special to the Building's standard systems; and (b) the cost of performing any of said maintenance or repairs whether to the Premises or to the Building caused by the negligence of Tenant, its employees, agents, servants, licensees, subtenants, contractors or invitees, shall be paid by Tenant, subject to the waivers set forth in Section 16.4. Landlord shall not be liable to Tenant for any expense, injury, loss or damage resulting from work done in or upon, or in connection with the use of, any adjacent or nearby building, land, street or alley.

8.2 TENANT'S MAINTENANCE

Tenant shall periodically inspect the Premises to identify any conditions that are dangerous or in need of maintenance or repair. Tenant shall promptly provide Landlord with notice of any such conditions. Tenant shall, at its sole cost and expense, perform all maintenance and repairs to the Premises that are not Landlord's express responsibility under this Lease, and keep the Premises in good condition and repair, reasonable wear and tear excepted. Tenant's repair and maintenance obligations include, without limitation, repairs to: (a) floor covering; (b) interior partitions; (c) doors; (d) the interior side of demising walls; (e) electronic, phone and data cabling, wiring and related equipment that is installed by or for the exclusive benefit of Tenant (collectively, "Cable"); (f) supplemental air conditioning units, kitchens, including hot water heaters, plumbing, and similar facilities exclusively serving Tenant; and (g) Tenant Alterations. To the extent Landlord is not reimbursed by insurance proceeds, Tenant shall reimburse Landlord for the cost of repairing damage to the Building caused by the acts of Tenant, Tenant Related Parties and their respective contractors and vendors. All maintenance and repairs, including, but not limited to, janitorial and cleaning services, pest control and waste management and recycling performed by or on behalf of Tenant must comply with the Project's Sustainability Practices and the applicable Green Building Standards. If Tenant fails to make any repairs to the Premises for more than fifteen (15) days after notice from Landlord (although notice shall not be required in an emergency), Landlord may make the repairs, and Tenant shall pay the reasonable cost of the repairs, together with an administrative charge in an amount equal to 15% of the cost of the repairs. Tenant hereby waives all right to make repairs at the expense of Landlord or in lieu thereof to vacate the Premises and its other similar rights as provided in California Civil Code Sections 1932(1), 1941 and 1942 or any other Laws (whether now or hereafter in effect). In addition to the foregoing, Tenant shall be responsible for all costs in connection with repairing all special tenant fixtures and improvements, including garbage disposals, showers, plumbing, and appliances.

ARTICLE 9

ALTERATIONS AND IMPROVEMENTS

9.1 TENANT ALTERATIONS

(a) The following provisions shall apply to the completion of any Tenant Alterations:

(1) Tenant shall not, except as provided herein, without the prior written consent of Landlord, which consent shall not be unreasonably withheld, make or cause to be made any Tenant Alterations in or to the Premises or any Property systems serving the Premises. Prior to making any Tenant Alterations, Tenant shall give Landlord ten (10) days' prior written notice (or such earlier notice as would be necessary pursuant to applicable Law) to permit Landlord sufficient time to post appropriate notices of non-responsibility. Subject to all other requirements of this Article 9, Tenant may undertake Decoration work without Landlord's prior written consent. Tenant shall furnish Landlord with the names and addresses of all contractors and subcontractors and copies of all contracts. All Tenant Alterations shall be completed at such time and in such manner as Landlord may from time to time designate, and only by contractors

or mechanics approved by Landlord, which approval shall not be unreasonably withheld; provided, however, that Landlord may, in its sole discretion, specify the engineers and contractors to perform all work relating to the Building's systems (including the mechanical, heating, plumbing, security, ventilating, air-conditioning, electrical, communication and the fire and life safety systems in the Building). The contractors, mechanics and engineers who may be used are further limited to those whose work will not cause or threaten to cause disharmony or interference with Landlord or other tenants in the Building and their respective agents and contractors performing work in or about the Building. Landlord may further condition its consent upon Tenant furnishing to Landlord and Landlord approving prior to the commencement of any work or delivery of materials to the Premises related to the Tenant Alterations such of the following as specified by Landlord: architectural plans and specifications, opinions from Landlord's engineers stating that the Tenant Alterations will not in any way adversely affect the Building's systems, necessary permits and licenses, certificates of insurance, and such other documents in such form reasonably requested by Landlord. Landlord may, in the exercise of reasonable judgment, request that Tenant provide Landlord with appropriate evidence of Tenant's ability to complete and pay for the completion of the Tenant Alterations such as a performance bond or letter of credit. Upon completion of the Tenant Alterations, Tenant shall deliver to Landlord an as-built mylar and digitized (if available) set of plans and specifications for the Tenant Alterations.

(2) Tenant shall pay the cost of all Tenant Alterations and the cost of decorating the Premises and any work to the Property occasioned thereby. Upon completion of Tenant Alterations, Tenant shall furnish Landlord with contractors' affidavits and full and final waivers of lien and receipted bills covering all labor and materials expended and used in connection therewith and such other documentation reasonably requested by Landlord or Mortgagee.

(3) Tenant agrees to complete all Tenant Alterations (i) in accordance with all Laws, Hazardous Materials Laws, all requirements of applicable insurance companies and in accordance with Landlord's standard construction rules and regulations, (ii) in a good and workmanlike manner with the use of good grades of materials, and (iii) in accordance with the requirements of the Project's Sustainability Practices and comply with the applicable Green Building Standards. Tenant shall notify Landlord immediately if Tenant receives any notice of violation of any Law in connection with completion of any Tenant Alterations and shall immediately take such steps as are necessary to remedy such violation. In no event shall such supervision or right to supervise by Landlord nor shall any approvals given by Landlord under this Lease constitute any warranty by Landlord to Tenant of the adequacy of the design, workmanship or quality of such work or materials for Tenant's intended use or of compliance with the requirements of Section 9.1(a)(3)(i) and (ii) above or impose any liability upon Landlord in connection with the performance of such work.

(b) All Tenant Additions, whether installed by Landlord or Tenant, shall without compensation or credit to Tenant, become part of the Premises and the property of Landlord at the time of their installation and shall remain in the Premises, unless pursuant to Article 12, Tenant may remove them or is required to remove them at Landlord's request.

9.2 LIENS

Tenant shall not permit any lien or claim for lien of any mechanic, laborer or supplier or any other lien to be filed against the Building, the Land, the Premises, or any other part of the Property arising out of work performed, or alleged to have been performed by, or at the direction of, or on behalf of Tenant. If any such lien or claim for lien is filed, Tenant shall within ten (10) days of receiving notice of such lien or claim (a) have such lien or claim for lien released of record or (b) deliver to Landlord a bond in form, content, amount, and issued by surety, satisfactory to Landlord, indemnifying, protecting, defending and holding harmless the Indemnitees against all costs and liabilities resulting from such lien or claim for lien and the foreclosure or attempted foreclosure thereof. If Tenant fails to take any of the above actions, Landlord, in addition to its rights and remedies under Article 11, without investigating the validity of such lien or claim for lien, may pay or discharge the same and Tenant shall, as payment of additional Rent hereunder, reimburse Landlord upon demand for the amount so paid by Landlord, including Landlord's expenses and attorneys' fees.

ARTICLE 10

ASSIGNMENT AND SUBLETTING

10.1 ASSIGNMENT AND SUBLETTING

(a) Subject to Landlord's recapture right set forth in Section 10.2, without the prior written consent of Landlord, which consent of Landlord shall not be unreasonably withheld, conditioned or delayed, Tenant may not sublease, assign, mortgage, pledge, hypothecate or otherwise transfer or permit the transfer of this Lease or the encumbering of Tenant's interest therein in whole or in part, by operation of Law or otherwise or permit the use or occupancy of the Premises, or any part thereof, by anyone other than Tenant. Tenant agrees that the provisions governing sublease and assignment set forth in this Article 10 shall be deemed to be reasonable. If Tenant desires to enter into any sublease of the Premises or assignment of this Lease, Tenant shall deliver written notice thereof to Landlord ("Tenant's Notice"), together with the identity of the proposed subtenant or assignee and the proposed principal terms thereof and financial and other information sufficient for Landlord to make an informed judgment with respect to such proposed subtenant or assignee at least forty-five (45) days prior to the commencement date of the term of the proposed sublease or assignment. If Tenant proposes to sublease less than all of the Rentable Area of the Premises, the space proposed to be sublet and the space retained by Tenant must each be a marketable unit as reasonably determined by Landlord and otherwise in compliance with all Laws. Landlord shall notify Tenant in writing of its approval or disapproval of the proposed sublease or assignment or its decision to exercise its rights under Section 10.2 within fifteen (15) days after receipt of Tenant's Notice (and all required information). Failure by Landlord to respond to Tenant's Notice within such fifteen (15) day period shall be deemed disapproval thereof. In no event may Tenant sublease any portion of the Premises or assign this Lease to any other tenant of the Project; and in no event may Tenant publicly offer or advertise all or any portion of the Premises for assignment or sublease at a rental rate less than that then sought by Landlord for a direct lease (non-sublease) of comparable space in the Project. Tenant shall submit for Landlord's approval (which approval shall not be unreasonably withheld) any

advertising which Tenant or its agents intend to use with respect to the space proposed to be sublet.

(b) With respect to Landlord's consent to an assignment or sublease, Landlord may take into consideration any factors that Landlord may deem relevant, and the reasons for which Landlord's denial shall be deemed to be reasonable shall include, without limitation, the following:

(i) the business reputation or creditworthiness of any proposed subtenant or assignee is not acceptable to Landlord; or

(ii) in Landlord's reasonable judgment the proposed assignee or sublessee would diminish the value or reputation of the Project or Landlord; or

(iii) any proposed assignee's or sublessee's use of the Premises would violate Section 7.1 of this Lease or would violate the provisions of any other leases of tenants in the Project; or

(iv) the proposed sublessee or assignee is a current occupant of the Project or a bona fide prospective tenant of Landlord in the Project as demonstrated by a written proposal dated within six (6) months prior to the date of Tenant's request and Landlord has vacancy in the Project of a similar size and finish as the space subject to such proposed sublease or assignment; or

(v) the proposed sublessee or assignee would materially increase the estimated pedestrian and vehicular traffic to and from the Premises and the Project above that deemed typical by Landlord for office/lab use in the Project; or

(vi) a Default by Tenant under this Lease shall be continuing.

(c) Any sublease or assignment shall be expressly subject to the terms and conditions of this Lease. Any subtenant or assignee shall execute such documents as Landlord may reasonably require to evidence such subtenant or assignee's assumption of the obligations and liabilities of Tenant under this Lease. Tenant shall deliver to Landlord a copy of all agreements executed by Tenant and the proposed subtenant and assignee with respect to the Premises. Landlord's approval of a sublease, assignment, hypothecation, transfer or third party use or occupancy shall not constitute a waiver of Tenant's obligation to obtain Landlord's consent to further assignments or subleases, hypothecations, transfers or third party use or occupancy.

(d) For purposes of this Article 10, an assignment shall be deemed to include a change in the majority control of Tenant, resulting from any transfer, sale or assignment of shares of stock of Tenant occurring by operation of Law or otherwise if Tenant is a corporation whose shares of stock are not traded publicly. If Tenant is a partnership, any change in the partners of Tenant shall be deemed to be an assignment.

(e) For purposes of this Lease, a "Permitted Transferee" shall mean any Person which: (i) is an Affiliate; or (ii) is the corporation or other entity (the "Successor") resulting

from a merger, consolidation or non-bankruptcy reorganization with Tenant; or (iii) is otherwise a deemed assignee due to a change of control under Section 10.1(d) above; or (iv) purchases substantially all the assets of Tenant as a going concern (the "Purchaser"). Notwithstanding anything to the contrary in Sections 10.1(a) and (b) and 10.3, provided there is no uncured Default under this Lease, Tenant shall have the right, without the prior written consent of Landlord, to assign this Lease to a Permitted Transferee or to sublease the Premises or any part thereof to a Permitted Transferee provided that: (1) Landlord receives thirty (30) days' prior written notice of an assignment or sublease (including a proposed transaction described in subparts (i), (ii), (iii) or (iv) of this Section 10.1(e)); (2) with respect to an assignment of this Lease or a sublease of more than half the Premises to an entity described in subparts (ii) or (iv) of this Section 10.1(e), the Permitted Transferee's net worth and liquidity are each not less than Tenant's net worth immediately prior to such assignment or subletting; (3) with respect to an assignment of this Lease or a sublease of more than half the Premises to an entity described in subparts (i) or (iii) of this Section 10.1(e), Tenant (as the assignor or sublandlord) continues in existence with a net worth not less than Tenant's net worth immediately prior to such assignment or subletting; (4) the Permitted Transferee expressly assumes (except a Permitted Transferee which is a deemed assignee under subpart (iii) of this Section 10.1(e) or which is a sublessee in the event of a sublease under this Section 10.1(e)) in writing reasonably satisfactory to Landlord all of the obligations of Tenant under this Lease and delivers such assumption to Landlord no later than fifteen (15) days prior to the effective date of the assignment; (5) Landlord receives no later than five (5) days before the effective date a fully executed copy of the applicable assignment or sublease agreement between Tenant and the Permitted Transferee; (6) promptly after Landlord's written request, Tenant and the Permitted Transferee provide such reasonable documents and information which Landlord reasonably requests for the purpose of substantiating whether or not the assignment or sublease is to a Permitted Transferee; and (7) such transfer is not being entered into for the primary purpose of avoiding the requirement for Landlord's prior consent or the provisions of Sections 10.2 or 10.3. All determinations of net worth and liquidity for purposes of this Subsection shall exclude any value attributable to goodwill or going concern value.

(f) With respect to any sublease hereunder, Tenant hereby irrevocably assigns to Landlord, effective upon any such sublease, all rent and other payments due from subtenant under the sublease, provided however, that Tenant shall have a license to collect such rent and other payments until the occurrence of a Default by Tenant under any of the provisions of this Lease. At any time after such Default, at Landlord's option, Landlord shall have the right to give notice to the subtenant of such assignment. Landlord shall credit Tenant with any rent received by Landlord under such assignment but the acceptance of any payment on account of rent from the subtenant as the result of any such default shall in no manner whatsoever serve to release Tenant from any liability under the terms, covenants, conditions, provisions or agreement under this Lease. No such payment of rent or any other payment by the subtenant directly to Landlord and/or acceptance of such payment(s) by Landlord, regardless of the circumstances or reasons therefor, shall in any manner whatsoever be deemed an attornment by the subtenant to Landlord in the absence of a specific written agreement signed by Landlord to such an effect.

10.2 RECAPTURE

Excluding any assignment or sublease contemplated in Section 10.1(e), Landlord shall have the option to exclude from the Premises covered by this Lease ("recapture") the space proposed to be sublet or subject to assignment, effective as of the proposed commencement date of such sublease or proposed effective date of such assignment. If Landlord elects to recapture, Tenant shall surrender possession of the space proposed to be subleased or subject to the assignment to Landlord on the effective date of recapture of such space from the Premises, such date being the Termination Date for such space. Effective as of the date of recapture of any portion of the Premises pursuant to this section, the Monthly Base Rent, Rentable Area of the Premises and Tenant's Share shall be adjusted accordingly.

10.3 EXCESS RENT

Tenant shall pay Landlord on or before the first day of each month during the term of the sublease or assignment, fifty percent (50%) of the amount by which the sum of all rent and other consideration (direct or indirect) due from the subtenant or assignee for such month exceeds: a) that portion of the Monthly Base Rent and Rent Adjustments due under this Lease for said month which is allocable to the space sublet or assigned, and b) the following costs and expenses for the subletting or assignment of such space: (i) brokerage commissions and attorneys' fees and expenses, (ii) the actual costs paid in making any improvements or substitutions in the Premises required by any sublease or assignment; and (iii) "free rent" periods, costs of any inducements or concessions given to subtenant or assignee, moving costs, and other amounts in respect of such subtenant's or assignee's other leases or occupancy arrangements. All such costs and expenses shall be amortized over the term of the sublease or assignment pursuant to sound accounting principles.

10.4 TENANT LIABILITY

In the event of any sublease or assignment, whether or not with Landlord's consent, Tenant shall not be released or discharged from any liability, whether past, present or future, under this Lease, including any liability arising from the exercise of any renewal or expansion option, to the extent such exercise is expressly permitted by Landlord. Tenant's liability shall remain primary, and in the event of default by any subtenant, assignee or successor of Tenant in performance or observance of any of the covenants or conditions of this Lease, Landlord may proceed directly against Tenant without the necessity of exhausting remedies against said subtenant, assignee or successor. After any assignment, Landlord may consent to subsequent assignments or subletting of this Lease, or amendments or modifications of this Lease with assignees of Tenant, without notifying Tenant, or any successor of Tenant, and without obtaining its or their consent thereto, and such action shall not relieve Tenant or any successor of Tenant of liability under this Lease. If Landlord grants consent to such sublease or assignment, Tenant shall pay all reasonable attorneys' fees and expenses incurred by Landlord with respect to such assignment or sublease. In addition, if Tenant has any options to extend the Term or to add other space to the Premises, such options shall not be available to any subtenant or assignee, directly or indirectly without Landlord's express written consent, which may be withheld in Landlord's sole discretion.

10.5 ASSUMPTION AND ATTORNMENT

If Tenant shall assign this Lease as permitted herein, the assignee shall expressly assume all of the obligations of Tenant hereunder in a written instrument satisfactory to Landlord and furnished to Landlord not later than fifteen (15) days prior to the effective date of the assignment. If Tenant shall sublease the Premises as permitted herein, Tenant shall, at Landlord's option, within fifteen (15) days following any request by Landlord, obtain and furnish to Landlord the written agreement of such subtenant to the effect that the subtenant will attorn to Landlord and will pay all sublease rent directly to Landlord.

10.6 PROCESSING EXPENSES

Tenant shall pay to Landlord, as Landlord's cost of processing each proposed assignment or subletting (whether or not the same is ultimately approved by Landlord or consummated by Tenant), an amount equal to the sum of (i) Landlord's reasonable attorneys' and other professional fees, plus (ii) the sum of $2,500.00 for the cost of Landlord's administrative, accounting and clerical time (collectively, "Processing Costs"). Notwithstanding anything to the contrary herein, Landlord shall not be required to process any request for Landlord's consent to an assignment or subletting until Tenant has paid to Landlord the amount of Landlord's estimate of the Processing Costs. When the actual amount of the Processing Costs is determined, it shall be reconciled with Landlord's estimate, and any payments or refunds required as a result thereof shall promptly thereafter be made by the parties.

10.7 EFFECT OF IMPERMISSIBLE TRANSFER

Any assignment or sublease effected without Landlord's consent in violation of this Article 10 shall, at Landlord's option, be a non-curable Default under Section 11.1 without the necessity of any notice and grace period.

ARTICLE 11

DEFAULT AND REMEDIES

11.1 EVENTS OF DEFAULT

The occurrence or existence of any one or more of the following shall constitute a "Default" by Tenant under this Lease:

(i) Tenant fails to pay any installment or other payment of Rent including Rent Adjustment Deposits or Rent Adjustments within five (5) days after the date when due;

(ii) Tenant fails to observe or perform any of the other covenants, conditions or provisions of this Lease or the Workletter and fails to cure such default within fifteen (15) days after written notice thereof to Tenant, unless the default involves a hazardous condition, which shall be cured forthwith or unless the failure to perform is a Default for which this Lease specifies there is no cure or grace period;

(iii) Tenant fails to maintain any insurance policy required hereunder, and fails to cure such default within five (5) days after written notice thereof to Tenant;

(iv) Tenant vacates or abandons the Premises for a period of ten (10) consecutive days or any vacation or abandonment of the Premises by Tenant which would cause any insurance policy to be invalidated or otherwise lapse, in each of forgoing cases irrespective of whether or not Tenant is then in monetary default under this Lease;

(v) an assignment or sublease, or attempted assignment or sublease, of this Lease or the Premises by Tenant contrary to the provisions of Article 10, unless such assignment or sublease is expressly conditioned upon Tenant having received Landlord's consent thereto;

(vi) the interest of Tenant in this Lease is levied upon under execution or other legal process;

(vii) a petition is filed by or against Tenant to declare Tenant bankrupt or seeking a plan of reorganization or arrangement under any Chapter of the Bankruptcy Act, or any amendment, replacement or substitution therefor, or to delay payment of, reduce or modify Tenant's debts, which in the case of an involuntary action is not discharged within thirty (30) days;

(viii) Tenant is declared insolvent by Law or any assignment of Tenant's property is made for the benefit of creditors;

(ix) a receiver is appointed for Tenant or Tenant's property, which appointment is not discharged within thirty (30) days;

(x) any action taken by or against Tenant to reorganize or modify Tenant's capital structure in a materially adverse way which in the case of an involuntary action is not discharged within thirty (30) days;

(xi) upon the dissolution of Tenant; or

(xii) upon the third occurrence during any consecutive 12-month period during the Term that Tenant fails to pay Rent when due or has breached a particular covenant of this Lease (whether or not such failure or breach is thereafter cured within any stated cure or grace period or statutory period).

11.2 LANDLORD'S REMEDIES

(a) A Default shall constitute a breach of this Lease for which Landlord shall have the rights and remedies set forth in this Section 11.2 and all other rights and remedies set forth in this Lease or now or hereafter allowed by Law, whether legal or equitable, and all rights and remedies of Landlord shall be cumulative and none shall exclude any other right or remedy now or hereafter allowed by applicable Law.

(b) With respect to a Default, at any time Landlord may terminate Tenant's right to possession by written notice to Tenant stating such election. Any written notice required pursuant to Section 11.1 shall constitute notice of unlawful detainer pursuant to California Code of Civil Procedure Section 1161 if, at Landlord's sole discretion, it states Landlord's election that Tenant's right to possession is terminated after expiration of any period required by Law or any longer period required by Section 11.1. Upon the expiration of the period stated in Landlord's written notice of termination (and unless such notice provides an option to cure within such period and Tenant cures the Default within such period), Tenant's right to possession shall terminate and this Lease shall terminate, and Tenant shall remain liable as hereinafter provided. Upon such termination in writing of Tenant's right to possession, Landlord shall have the right, subject to applicable Law, to re-enter the Premises and dispossess Tenant and the legal representatives of Tenant and all other occupants of the Premises by unlawful detainer or other summary proceedings, or as otherwise permitted by Law, regain possession of the Premises and remove their property (including their trade fixtures, personal property and Required Removables pursuant to Article 12), but Landlord shall not be obligated to effect such removal, and such property may, at Landlord's option, be stored elsewhere, sold or otherwise dealt with as permitted by Law, at the risk of, expense of and for the account of Tenant, and the proceeds of any sale shall be applied pursuant to Law. Landlord shall in no event be responsible for the value, preservation or safekeeping of any such property. Tenant hereby waives all claims for damages that may be caused by Landlord's removing or storing Tenant's personal property pursuant to this Section or Section 12.1, and Tenant hereby indemnifies, and agrees to defend, protect and hold harmless, the Indemnitees from any and all loss, claims, demands, actions, expenses, liability and cost (including attorneys' fees and expenses) arising out of or in any way related to such removal or storage. Upon such written termination of Tenant's right to possession and this Lease, Landlord shall have the right to recover damages for Tenant's Default as provided herein or by Law, including the following damages provided by California Civil Code Section 1951.2:

(1) the worth at the time of award of the unpaid Rent which had been earned at the time of termination;

(2) the worth at the time of award of the amount by which the unpaid Rent which would have been earned after termination until the time of award exceeds the amount of such Rent loss that Tenant proves could reasonably have been avoided;

(3) the worth at the time of award of the amount by which the unpaid Rent for the balance of the term of this Lease after the time of award exceeds the amount of such Rent loss that Tenant proves could be reasonably avoided; and

(4) any other amount necessary to compensate Landlord for all the detriment proximately caused by Tenant's failure to perform its obligations under this Lease or which in the ordinary course of things would be likely to result therefrom, including, without limitation, Landlord's unamortized costs of tenant improvements, leasing commissions and legal fees incurred in connection with entering into this Lease.

The word "rent" as used in this Section 11.2 shall have the same meaning as the defined term Rent in this Lease. The "worth at the time of award" of the amount referred to in clauses (1) and (2) above is computed by allowing interest at the Default Rate. The worth at the time of award of the amount referred to in clause (3) above is computed by discounting such amount at the discount rate of the Federal Reserve Bank of San Francisco at the time of award plus one percent (1%). For the purpose of determining unpaid Rent under clause (3) above, the monthly Rent reserved in this Lease shall be deemed to be the sum of the Monthly Base Rent, monthly storage space rent, if any, and the amounts last payable by Tenant as Rent Adjustments for the calendar year in which Landlord terminated this Lease as provided hereinabove.

(c) Even if Tenant is in Default and/or has abandoned the Premises, this Lease shall continue in effect for so long as Landlord does not terminate Tenant's right to possession by written notice as provided in Section 11.2(b) above, and Landlord may enforce all its rights and remedies under this Lease, including the right to recover Rent as it becomes due under this Lease. In such event, Landlord shall have all of the rights and remedies of a landlord under California Civil Code Section 1951.4 (lessor may continue Lease in effect after Tenant's Default and abandonment and recover Rent as it becomes due, if Tenant has the right to sublet or assign, subject only to reasonable limitations), or any successor statute. During such time as Tenant is in Default, if Landlord has not terminated this Lease by written notice and if Tenant requests Landlord's consent to an assignment of this Lease or a sublease of the Premises, subject to Landlord's option to recapture pursuant to Section 10.2, Landlord shall not unreasonably withhold its consent to such assignment or sublease. Tenant acknowledges and agrees that in the absence of written notice pursuant to Section 11.2(b) above terminating Tenant's right to possession, no other act of Landlord shall constitute a termination of Tenant's right to possession or an acceptance of Tenant's surrender of the Premises, including acts of maintenance or preservation or efforts to re-let the Premises or the appointment of a receiver upon initiative of Landlord to protect Landlord's interest under this Lease or the withholding of consent to a subletting or assignment, or terminating a subletting or assignment, if in accordance with other provisions of this Lease.

(d) In the event that Landlord seeks an injunction with respect to a breach or threatened breach by Tenant of any of the covenants, conditions or provisions of this Lease, Tenant agrees to pay the premium for any bond required in connection with such injunction.

(e) Tenant hereby waives any and all rights to relief from forfeiture, redemption or reinstatement granted by Law (including California Civil Code of Procedure Sections 1174 and 1179) in the event of Tenant being evicted or dispossessed for any cause or in the event of Landlord obtaining possession of the Premises by reason of Tenant's Default or otherwise;

(f) Notwithstanding any other provision of this Lease, a notice to Tenant given under this Article and Article 24 of this Lease or given pursuant to California Code of Civil Procedure Section 1161, and any notice served by mail, shall be deemed served, and the requisite waiting period deemed to begin under said Code of Civil Procedure Section upon mailing (except as may be required under Code of Civil Procedure Section 1161 et seq.), without any additional waiting requirement under Code of Civil Procedure Section 1011 et seq. or by other Law. For purposes of Code of Civil Procedure Section 1162, Tenant's "place of residence", "usual place of

business", "the property" and "the place where the property is situated" shall mean and be the Premises, whether or not Tenant has vacated same at the time of service.

(g) The voluntary or other surrender or termination of this Lease, or a mutual termination or cancellation thereof, shall not work a merger and shall terminate all or any existing assignments, subleases, subtenancies or occupancies permitted by Tenant, except if and as otherwise specified in writing by Landlord.

(h) No delay or omission in the exercise of any right or remedy of Landlord upon any default by Tenant, and no exercise by Landlord of its rights pursuant to Section 26.16 to perform any duty which Tenant fails timely to perform, shall impair any right or remedy or be construed as a waiver. No provision of this Lease shall be deemed waived by Landlord unless such waiver is in writing signed by Landlord. The waiver by Landlord of any breach of any provision of this Lease shall not be deemed a waiver of any subsequent breach of the same or any other provision of this Lease.

11.3 ATTORNEY'S FEES

In the event any party brings any suit or other proceeding with respect to the subject matter or enforcement of this Lease, the prevailing party (as determined by the court, agency or other authority before which such suit or proceeding is commenced) shall, in addition to such other relief as may be awarded, be entitled to recover attorneys' fees, expenses and costs of investigation as actually incurred, including court costs, expert witness fees, costs and expenses of investigation, and all attorneys' fees, costs and expenses in any such suit or proceeding (including in any action or participation in or in connection with any case or proceeding under the Bankruptcy Code, 11 United States Code Sections 101 et seq., or any successor statutes, in establishing or enforcing the right to indemnification, in appellate proceedings, or in connection with the enforcement or collection of any judgment obtained in any such suit or proceeding).

11.4 BANKRUPTCY

The following provisions shall apply in the event of the bankruptcy or insolvency of Tenant:

(a) In connection with any proceeding under Chapter 7 of the Bankruptcy Code where the trustee of Tenant elects to assume this Lease for the purposes of assigning it, such election or assignment, may only be made upon compliance with the provisions of (b) and (c) below, which conditions Landlord and Tenant acknowledge to be commercially reasonable. In the event the trustee elects to reject this Lease then Landlord shall immediately be entitled to possession of the Premises without further obligation to Tenant or the trustee.

(b) Any election to assume this Lease under Chapter 11 or 13 of the Bankruptcy Code by Tenant as debtor-in-possession or by Tenant's trustee (the "Electing Party") must provide for:

The Electing Party to cure or provide to Landlord adequate assurance that it will cure all monetary defaults under this Lease within fifteen (15) days from the date of assumption and that

it will cure all nonmonetary defaults under this Lease within thirty (30) days from the date of assumption. Landlord and Tenant acknowledge such condition to be commercially reasonable.

(c) If the Electing Party has assumed this Lease or elects to assign Tenant's interest under this Lease to any other person, such interest may be assigned only if the intended assignee has provided adequate assurance of future performance (as herein defined), of all of the obligations imposed on Tenant under this Lease.

For the purposes hereof, "adequate assurance of future performance" means that Landlord has ascertained that each of the following conditions has been satisfied:

(i) The assignee has submitted a current financial statement, certified by its chief financial officer, which shows a net worth and working capital in amounts sufficient to assure the future performance by the assignee of Tenant's obligations under this Lease; and

(ii) Landlord has obtained consents or waivers from any third parties that may be required under a lease, mortgage, financing arrangement, or other agreement by which Landlord is bound, to enable Landlord to permit such assignment.

(d) Landlord's acceptance of rent or any other payment from any trustee, receiver, assignee, person, or other entity will not be deemed to have waived, or waive, the requirement of Landlord's consent, Landlord's right to terminate this Lease for any transfer of Tenant's interest under this Lease without such consent, or Landlord's claim for any amount of Rent due from Tenant.

11.5 LANDLORD'S DEFAULT

Landlord shall be in default hereunder in the event Landlord has not commenced and pursued with reasonable diligence the cure of any failure of Landlord to meet its obligations hereunder within thirty (30) days after the receipt by Landlord of written notice from Tenant of the alleged failure to perform. Failure to provide the requisite notice and cure period by Tenant under this paragraph shall be an absolute defense by Landlord against any claims for failure to perform any of its obligations. In no event shall Tenant have the right to terminate or rescind this Lease as a result of Landlord's default as to any covenant or agreement contained in this Lease. Tenant hereby waives such remedies of termination and rescission and hereby agrees that Tenant's remedies for default hereunder and for breach of any promise or inducement shall be limited to a suit for damages and/or injunction. In addition, Tenant hereby covenants that, prior to the exercise of any such remedies, it will give any Mortgagee notice and a reasonable time to cure any default by Landlord.

ARTICLE 12

SURRENDER OF PREMISES

12.1 IN GENERAL

Upon the Termination Date, Tenant shall surrender and vacate the Premises immediately and deliver possession thereof to Landlord in a clean, good and tenantable condition as existed on the Commencement Date, ordinary wear and tear, and damage caused by Landlord excepted. Tenant shall deliver to Landlord all keys to the Premises. All improvements in and to the Premises, including any Tenant Alterations (collectively, "Leasehold Improvements") shall remain upon the Premises at the end of the Term without compensation to Tenant. Landlord, however, by written notice to Tenant at least 30 days prior to the Termination Date, may require Tenant, at its expense, to remove (a) any Cable, and (b) any Landlord Work or Tenant Alterations that, in Landlord's reasonable judgment, are of a nature that would require removal and repair costs that are materially in excess of the removal and repair costs associated with standard laboratory and office improvements, as applicable (collectively referred to as "Required Removables"). Required Removables shall include, without limitation, internal stairways, raised floors, personal baths and showers, vaults, rolling file systems and structural alterations and modifications. The designated Required Removables shall be removed by Tenant before the Termination Date. Tenant's removal and disposal of items pursuant to this Paragraph 12 must comply with the Project's Sustainability Practices and the applicable Green Building Standards. Tenant shall repair damage caused by the installation or removal of Required Removables. If Tenant fails to perform its obligations in a timely manner, Landlord may perform such work at Tenant's expense. Tenant, at the time it requests approval for a proposed Tenant Alteration, may request in writing that Landlord advise Tenant whether the proposed Tenant Alteration or any portion of the proposed Tenant Alteration is a Required Removable. Within 10 days after receipt of Tenant's request, Landlord shall advise Tenant in writing as to which portions of the proposed Tenant Alterations are Required Removables. If any of the Tenant Additions which were installed by Tenant involved the lowering of ceilings, raising of floors or the installation of specialized wall or floor coverings or lights, then Tenant shall also be obligated to return such surfaces to their condition prior to the commencement of this Lease. Tenant shall also be required to close any staircases or other openings between floors. In the event possession of the Premises is not delivered to Landlord when required hereunder, or if Tenant shall fail to remove those items described above, Landlord may (but shall not be obligated to), at Tenant's expense, remove any of such property and store, sell or otherwise deal with such property, and undertake, at Tenant's expense, such restoration work as Landlord deems necessary or advisable.

12.2 LANDLORD'S RIGHTS

All property which may be removed from the Premises by Landlord shall be conclusively presumed to have been abandoned by Tenant and Landlord may deal with such property as provided in Section 11.2(b), including the waiver and indemnity obligations provided in that Section. Tenant shall also reimburse Landlord for all costs and expenses incurred by Landlord in removing any Tenant Additions and in restoring the Premises to the condition required by this Lease.

ARTICLE 13

HOLDING OVER

In the event that Tenant holds over in possession of the Premises after the Termination Date, for each month or partial month Tenant holds over possession of the Premises. Tenant shall pay Landlord 150% of the monthly Rent payable for the first two (2) month immediately preceding the holding over (including increases for Rent Adjustments which Landlord may reasonably estimate) and 200% for any months beyond said initial two (2) months. Tenant shall also pay all damages, but not including consequential damages, sustained by Landlord by reason of such holding over. The provisions of this Article shall not constitute a waiver by Landlord of any re-entry rights of Landlord, and Tenant's continued occupancy of the Premises shall be as a tenancy in sufferance.

ARTICLE 14

DAMAGE BY FIRE OR OTHER CASUALTY

14.1 SUBSTANTIAL UNTENANTABILITY

(a) If any fire or other casualty (whether insured or uninsured) renders all or a substantial portion of the Premises or the Building untenantable, Landlord shall, with reasonable promptness after the occurrence of such damage, estimate the length of time that will be required to substantially complete the repair and restoration and shall, by notice advise Tenant of such estimate ("Landlord's Notice"). If Landlord estimates that the amount of time required to substantially complete such repair and restoration will exceed one hundred eighty (180) days from the date such damage occurred, then Landlord, or Tenant if all or a substantial portion of the Premises is rendered untenantable, shall have the right to terminate this Lease as of the date of such damage by delivering written notice to the other at any time within twenty (20) days after delivery of Landlord's Notice, provided that if Landlord so chooses, Landlord's Notice may also constitute such notice of termination.

(b) Unless this Lease is terminated as provided in the preceding subparagraph, Landlord shall proceed with reasonable promptness to repair and restore the Premises to its condition as existed prior to such casualty, subject to reasonable delays for insurance adjustments and Force Majeure delays, and also subject to zoning Laws and building codes then in effect. Landlord shall have no liability to Tenant, and Tenant shall not be entitled to terminate this Lease if such repairs and restoration are not in fact completed within the time period estimated by Landlord so long as Landlord shall proceed with reasonable diligence to complete such repairs and restoration.

(c) Tenant acknowledges that Landlord shall be entitled to the full proceeds of any insurance coverage, whether carried by Landlord or Tenant, for damages to the Premises, except for those proceeds of Tenant's insurance of its own personal property and equipment which would be removable by Tenant at the Termination Date. All such insurance proceeds shall be payable to Landlord whether or not the Premises are to be repaired and restored, provided,

however, if this Lease is not terminated and the parties proceed to repair and restore Tenant Additions at Tenant's cost, to the extent Landlord received proceeds of Tenant's insurance covering Tenant Additions, such proceeds shall be applied to reimburse Tenant for its cost of repairing and restoring Tenant Additions.

(d) Notwithstanding anything to the contrary herein set forth: (i) Landlord shall have no duty pursuant to this Section to repair or restore any portion of any Tenant Additions or to expend for any repair or restoration of the Premises or Building in amounts in excess of insurance proceeds paid to Landlord and available for repair or restoration; and (ii) Tenant shall not have the right to terminate this Lease pursuant to this Section if any damage or destruction was caused by the act or neglect of Tenant, its agent or employees. Whether or not this Lease is terminated pursuant to this Article 14, in no event shall Tenant be entitled to any compensation or damages for loss of the use of the whole or any part of the Premises or for any inconvenience or annoyance occasioned by any such damage, destruction, rebuilding or restoration of the Premises or the Building or access thereto.

(e) Any repair or restoration of the Premises performed by Tenant shall be in accordance with the provisions of Article 9 hereof.

14.2 INSUBSTANTIAL UNTENANTABILITY

If the Premises or the Building is damaged by a casualty but neither is rendered substantially untenantable and Landlord estimates that the time to substantially complete the repair or restoration will not exceed one hundred eighty (180) days from the date such damage occurred, then Landlord shall proceed to repair and restore the Building or the Premises other than Tenant Additions, with reasonable promptness, unless such damage is to the Premises and occurs during the last six (6) months of the Term, in which event either Tenant or Landlord shall have the right to terminate this Lease as of the date of such casualty by giving written notice thereof to the other within twenty (20) days after the date of such casualty. Notwithstanding the aforesaid, Landlord's obligation to repair shall be limited in accordance with the provisions of Section 14.1 above.

14.3 RENT ABATEMENT

Except for the negligence or willful act of Tenant or its agents, employees, contractors or invitees, if all or any part of the Premises are rendered untenantable by fire or other casualty and this Lease is not terminated, Monthly Base Rent and Rent Adjustments shall abate for that part of the Premises which is untenantable on a per diem basis from the date of the casualty until Landlord has Substantially Completed the repair and restoration work in the Premises which it is required to perform, provided, that as a result of such casualty, Tenant does not occupy the portion of the Premises which is untenantable during such period.

14.4 WAIVER OF STATUTORY REMEDIES

The provisions of this Lease, including this Article 14, constitute an express agreement between Landlord and Tenant with respect to any and all damage to, or destruction of, the

Premises or the Property or any part of either, and any Law, including Sections 1932(2), 1933(4), 1941 and 1942 of the California Civil Code, with respect to any rights or obligations concerning damage or destruction shall have no application to this Lease or to any damage to or destruction of all or any part of the Premises or the Property or any part of either, and are hereby waived.

ARTICLE 15

EMINENT DOMAIN

15.1 TAKING OF WHOLE OR SUBSTANTIAL PART

In the event the whole or any substantial part of the Building or of the Premises is taken or condemned by any competent authority for any public use or purpose (including a deed given in lieu of condemnation) and is thereby rendered untenantable, this Lease shall terminate as of the date title vests in such authority, and Monthly Base Rent and Rent Adjustments shall be apportioned as of the Termination Date. Notwithstanding anything to the contrary herein set forth, in the event the taking is temporary (for less than the remaining Term of this Lease), Landlord may elect either (i) to terminate this Lease or (ii) permit Tenant to receive the entire award attributable to the Premises in which case Tenant shall continue to pay Rent and this Lease shall not terminate.

15.2 TAKING OF PART

In the event a part of the Building or the Premises is taken or condemned by any competent authority (or a deed is delivered in lieu of condemnation) and this Lease is not terminated, this Lease shall be amended to reduce or increase, as the case may be, the Monthly Base Rent and Tenant's Share to reflect the Rentable Area of the Premises or Building, as the case may be, remaining after any such taking or condemnation. Landlord, upon receipt and to the extent of the award in condemnation (or proceeds of sale) shall make necessary repairs and restorations to the Premises (exclusive of Tenant Additions) and to the Building to the extent necessary to constitute the portion of the Building not so taken or condemned as a complete architectural and economically efficient unit. Notwithstanding the foregoing, if as a result of any taking, or a governmental order that the grade of any street or alley adjacent to the Building is to be changed and such taking or change of grade makes it necessary or desirable to substantially remodel or restore the Building or prevents the economical operation of the Building, Landlord shall have the right to terminate this Lease upon ninety (90) days' prior written notice to Tenant.

15.3 COMPENSATION

Landlord shall be entitled to receive the entire award (or sale proceeds) from any such taking, condemnation or sale without any payment to Tenant, and Tenant hereby assigns to Landlord, Tenant's interest, if any, in such award; provided, however, Tenant shall have the right separately to pursue against the condemning authority a separate award in respect of the loss, if any, to Tenant Additions paid for by Tenant without any credit or allowance from Landlord so long as there is no diminution of Landlord's award as a result.

ARTICLE 16

INSURANCE

16.1 TENANT'S INSURANCE

Tenant, at Tenant's expense, agrees to maintain in force, with a company or companies acceptable to Landlord, during the Term: (a) Commercial General Liability Insurance on a primary basis and without any right of contribution from any insurance carried by Landlord covering the Premises on an occurrence basis against all claims for personal injury, bodily injury, death and property damage, including contractual liability covering the indemnification provisions in this Lease, and such insurance shall be for such limits that are reasonably required by Landlord from time to time but not less than a combined single limit of Five Million Dollars ($5,000,000.00); (b) Workers' Compensation and Employers' Liability Insurance to the extent required by and in accordance with the Laws of the State of California; (c) "All Risks" property insurance in an amount adequate to cover the full replacement cost of all Tenant Additions, equipment, installations, fixtures and contents of the Premises in the event of loss; (d) in the event a motor vehicle is to be used by Tenant in connection with its business operation from the Premises, Comprehensive Automobile Liability Insurance coverage with limits of not less than One Million Dollars ($1,000,000.00) combined single limit coverage against bodily injury liability and property damage liability arising out of the use by or on behalf of Tenant, its agents and employees in connection with this Lease, of any owned, non-owned or hired motor vehicles; and (e) such other insurance or coverages as Landlord reasonably requires.

16.2 FORM OF POLICIES

Each policy referred to in Section 16.1 shall satisfy the following requirements. Each policy shall (i) name Landlord and the Indemnitees as additional insureds (except Workers' Compensation and Employers' Liability Insurance), (ii) be issued by one or more responsible insurance companies licensed to do business in the State of California reasonably satisfactory to Landlord, (iii) where applicable, provide for deductible amounts satisfactory to Landlord and not permit co-insurance, (iv) shall provide that such insurance may not be canceled or amended without thirty (30) days' prior written notice to Landlord, and (v) each policy of "All-Risks" property insurance shall provide that the policy shall not be invalidated should the insured waive in writing prior to a loss, any or all rights of recovery against any other party for losses covered by such policies. Tenant shall deliver to Landlord, certificates of insurance and at Landlord's request, copies of all policies and renewals thereof to be maintained by Tenant hereunder, not less than ten (10 days prior to Tenant's entry into the Premises and not less than ten (10) days prior to the expiration date of each policy. If Tenant fails to carry the insurance required under this Article 16 or fails to provide certificates of renewal as and when required hereunder, Landlord may, but shall not be obligated to acquire such insurance on Tenant's behalf or Tenant's sole cost and expense.

16.3 LANDLORD'S INSURANCE

Landlord agrees to purchase and keep in full force and effect during the Term hereof, including any extensions or renewals thereof, insurance under policies issued by insurers of recognized responsibility, qualified to do business in the State of California on the Building in amounts not less than the greater of eighty percent (80%) of the then full replacement cost (without depreciation) of the Building (above foundations and excluding Tenant Additions), or an amount sufficient to prevent Landlord from becoming a co-insurer under the terms of the applicable policies, against fire and such other risks as may be included in standard forms of all risk coverage insurance reasonably available from time to time. Landlord agrees to maintain in force during the Term, Commercial General Liability Insurance covering the Building on an occurrence basis against all claims for personal injury, bodily injury, death, and property damage. Such insurance shall be for a combined single limit of not less than Three Million and No/100 Dollars ($3,000,000.00). Neither Landlord's obligation to carry such insurance nor the carrying of such insurance shall be deemed to be an indemnity by Landlord with respect to any claim, liability, loss, cost or expense due, in whole or in part, to Tenant's negligent acts or omissions or willful misconduct. Without obligation to do so, Landlord may, in its sole discretion from time to time, carry insurance in amounts greater and/or for coverage additional to the coverage and amounts set forth above.

16.4 WAIVER OF SUBROGATION

(a) Landlord agrees that, if obtainable at no, or minimal, additional cost, and so long as the same is permitted under the laws of the State of California, it will include in its "All Risks" policies appropriate clauses pursuant to which the insurance companies (i) waive all right of subrogation against Tenant with respect to losses payable under such policies and/or (ii) agree that such policies shall not be invalidated should the insured waive in writing prior to a loss any or all right of recovery against any party for losses covered by such policies.

(b) Tenant agrees to include, if obtainable at no, or minimal, additional cost, and so long as the same is permitted under the laws of the State of California, in its "All Risks" insurance policy or policies on Tenant Additions, whether or not removable, and on Tenant's furniture, furnishings, fixtures and other property removable by Tenant under the provisions of this Lease appropriate clauses pursuant to which the insurance company or companies (i) waive the right of subrogation against Landlord and/or any tenant of space in the Building with respect to losses payable under such policy or policies and/or (ii) agree that such policy or policies shall not be invalidated should the insured waive in writing prior to a loss any or all right of recovery against any party for losses covered by such policy or policies. If Tenant is unable to obtain in such policy or policies either of the clauses described in the preceding sentence, Tenant shall, if legally possible and without necessitating a change in insurance carriers, have Landlord named in such policy or policies as an additional insured. If Landlord shall be named as an additional insured in accordance with the foregoing, Landlord agrees to endorse promptly to the order of Tenant, without recourse, any check, draft, or order for the payment of money representing the proceeds of any such policy or representing any other payment growing out of or connected with said policies, and Landlord does hereby irrevocably waive any and all rights in and to such proceeds and payments.

(c) Provided that Landlord's right of full recovery under its policy or policies aforesaid is not adversely affected or prejudiced thereby, Landlord hereby waives any and all right of recovery which it might otherwise have against Tenant, its servants, agents and employees, for loss or damage occurring to the Real Property and the fixtures, appurtenances and equipment therein, to the extent the same is covered by Landlord's insurance, notwithstanding that such loss or damage may result from the negligence or fault of Tenant, its servants, agents or employees. Provided that Tenant's right of full recovery under its aforesaid policy or policies is not adversely affected or prejudiced thereby, Tenant hereby waives any and all right of recovery which it might otherwise have against Landlord, its servants, and employees and against every other tenant of the Real Property who shall have executed a similar waiver as set forth in this Section 16.4(c) for loss or damage to Tenant Additions, whether or not removable, and to Tenant's furniture, furnishings, fixtures and other property removable by Tenant under the provisions hereof to the extent the same is coverable by Tenant's insurance required under this Lease, notwithstanding that such loss or damage may result from the negligence or fault of Landlord, its servants, agents or employees, or such other tenant and the servants, agents or employees thereof.

(d) Landlord and Tenant hereby agree to advise the other promptly if the clauses to be included in their respective insurance policies pursuant to subparagraphs (a) and (b) above cannot be obtained on the terms hereinbefore provided and thereafter to furnish the other with a certificate of insurance or copy of such policies showing the naming of the other as an additional insured, as aforesaid. Landlord and Tenant hereby also agree to notify the other promptly of any cancellation or change of the terms of any such policy that would affect such clauses or naming. All such policies which name both Landlord and Tenant as additional insureds shall, to the extent obtainable, contain agreements by the insurers to the effect that no act or omission of any additional insured will invalidate the policy as to the other additional insureds.

16.5 NOTICE OF CASUALTY

Tenant shall give Landlord notice in case of a fire or accident in the Premises promptly after Tenant is aware of such event.

ARTICLE 17

WAIVER OF CLAIMS AND INDEMNITY

17.1 WAIVER OF CLAIMS

To the extent permitted by Law, Tenant hereby releases the Indemnitees from, and waives all claims for, damage to person or property sustained by Tenant or any occupant of the Premises or the Property resulting directly or indirectly from any existing or future condition, defect, matter or thing in and about the Premises or the Property or any part of either or any equipment or appurtenance therein, or resulting from any accident in or about the Premises or the Property, or resulting directly or indirectly from any act or neglect of any tenant or occupant of the Property or of any other person, including Landlord's agents and servants, except to the extent caused by the gross negligence or willful and wrongful act of any of the Indemnitees. To the

extent permitted by Law, Tenant hereby waives any consequential damages, compensation or claims for inconvenience or loss of business, rents, or profits as a result of such injury or damage, whether or not caused by the gross negligence or willful and wrongful act of any of the Indemnitees. If any such damage, whether to the Premises or the Property or any part of either, or whether to Landlord or to other tenants in the Property, results from any act or neglect of Tenant, its employees, servants, agents, contractors, invitees or customers, Tenant shall be liable therefor and Landlord may, at Landlord's option, repair such damage and Tenant shall, upon demand by Landlord, as payment of additional Rent hereunder, reimburse Landlord within ten (10) days of demand for the total cost of such repairs, in excess of amounts, if any, paid to Landlord under insurance covering such damages. Tenant shall not be liable for any such damage caused by its acts or neglect if Landlord or a tenant has recovered the full amount of the damage from proceeds of insurance policies and the insurance company has waived its right of subrogation against Tenant.

17.2 INDEMNITY BY TENANT

To the extent permitted by Law, Tenant hereby indemnifies, and agrees to protect, defend and hold the Indemnitees harmless, against any and all actions, claims, demands, liability, costs and expenses, including attorneys' fees and expenses for the defense thereof, arising from Tenant's occupancy of the Premises, from the undertaking of any Tenant Additions or repairs to the Premises, from the conduct of Tenant's business on the Premises, or from any breach or default on the part of Tenant in the performance of any covenant or agreement on the part of Tenant to be performed pursuant to the terms of this Lease, or from any willful act or negligence of Tenant, its agents, contractors, servants, employees, customers or invitees, in or about the Premises or the Property or any part of either. In case of any action or proceeding brought against the Indemnitees by reason of any such claim, upon notice from Landlord, Tenant covenants to defend such action or proceeding by counsel chosen by Landlord, in Landlord's sole discretion. Landlord reserves the right to settle, compromise or dispose of any and all actions, claims and demands related to the foregoing indemnity. The foregoing indemnity shall not operate to relieve Indemnitees of liability to the extent such liability is caused by the willful and wrongful act of Indemnitees. Further, the foregoing indemnity is subject to and shall not diminish any waivers in effect in accordance with Section 16.4 by Landlord or its insurers to the extent of amounts, if any, paid to Landlord under its "All-Risks" property insurance. This Article 17 shall survive the expiration or earlier termination of this Lease.

17.3 WAIVER OF CONSEQUENTIAL DAMAGES

To the extent permitted by law, Tenant hereby waives and releases the Indemnitees from any consequential damages, compensation or claims for inconvenience or loss of business, rents or profits as a result of any injury or damage, whether or not caused by the willful and wrongful act of any of the Indemnitees.

ARTICLE 18

RULES AND REGULATIONS

18.1 RULES

Tenant agrees for itself and for its subtenants, employees, agents, and invitees to comply with the rules and regulations listed on Exhibit C-2 attached hereto and with all reasonable modifications and additions thereto which Landlord may make from time to time.

18.2 ENFORCEMENT

Nothing in this Lease shall be construed to impose upon Landlord any duty or obligation to enforce the rules and regulations as set forth on Exhibit C-2 or as hereafter adopted, or the terms, covenants or conditions of any other lease as against any other tenant, and Landlord shall not be liable to Tenant for violation of the same by any other tenant, its servants, employees, agents, visitors or licensees. Landlord shall use reasonable efforts to enforce the rules and regulations of the Project in a uniform and non-discriminatory manner.

ARTICLE 19

LANDLORD'S RESERVED RIGHTS

Landlord shall have the following rights exercisable without notice to Tenant and without liability to Tenant for damage or injury to persons, property or business and without being deemed an eviction or disturbance of Tenant's use or possession of the Premises or giving rise to any claim for offset or abatement of Rent: (1) to change the Building's name or street address upon thirty (30) days' prior written notice to Tenant; (2) to install, affix and maintain all signs on the exterior and/or interior of the Building; (3) to designate and/or approve prior to installation, all types of signs, window shades, blinds, drapes, awnings or other similar items, and all internal lighting that may be visible from the exterior of the Premises; (4) upon reasonable notice to Tenant, to display the Premises to prospective purchasers and lenders at reasonable hours at any time during the Term and to prospective tenants at reasonable hours during the last twelve (12) months of the Term; (5) to grant to any party the exclusive right to conduct any business or render any service in or to the Building, provided such exclusive right shall not operate to prohibit Tenant from using the Premises for the purpose permitted hereunder; (6) to change the arrangement and/or location of entrances or passageways, doors and doorways, corridors, elevators, stairs, washrooms or public portions of the Building, and to close entrances, doors, corridors, elevators or other facilities, provided that such action shall not materially and adversely interfere with Tenant's access to the Premises or the Building; (7) to have access for Landlord and other tenants of the Building to any mail chutes and boxes located in or on the Premises as required by any applicable rules of the United States Post Office; and (8) to close the Building after Standard Operating Hours, except that Tenant and its employees and invitees shall be entitled to admission at all times, under such regulations as Landlord prescribes for security purposes.

ARTICLE 20

RELOCATION OF TENANT

At any time during the Term, Landlord may substitute for the Premises, other premises in the Project, in which event the New Premises shall be deemed to be the Premises for all purposes under this Lease, provided that (i) the New Premises shall be substantially similar to the Premises in area, configuration and functionality; (ii) if Tenant is then occupying the Premises, Landlord shall pay the actual and reasonable expenses of physically moving Tenant, its property and equipment to the New Premises; (iii) Landlord shall give Tenant not less than ninety (90) days' prior written notice of such substitution; and (iv) Landlord, at its expense, shall improve the New Premises with improvements substantially similar to those in the Premises at the time of such substitution, if the Premises are then improved.

ARTICLE 21

ESTOPPEL CERTIFICATE

21.1 TENANT ESTOPPEL

Within ten (10) days after request therefor by Landlord, Mortgagee or any prospective mortgagee or owner, Tenant agrees as directed in such request to execute an Estoppel Certificate in recordable form, binding upon Tenant, certifying (i) that this Lease is unmodified and in full force and effect (or if there have been modifications, a description of such modifications and that this Lease as modified is in full force and effect); (ii) the dates to which Rent has been paid; (iii) that Tenant is in the possession of the Premises, if that is the case; (iv) that Landlord is not in default under this Lease (or if Tenant believes there are any such defaults, a full and complete explanation thereof); (v) that Tenant has no offsets or defenses to the performance of its obligations under this Lease (or if Tenant believes there are any offsets or defenses, a full and complete explanation thereof); (vi) that the Premises have been completed in accordance with the terms and provisions hereof or the Workletter, that Tenant has accepted the Premises and the condition thereof and of all improvements thereto and has no claims against Landlord or any other party with respect thereto (or stating such exceptions thereto as applicable); (vii) that if an assignment of rents or leases has been served upon the Tenant by a Mortgagee, Tenant will acknowledge receipt thereof and agree to be bound by the provisions thereof; (viii) that Tenant will give to the Mortgagee copies of all notices required or permitted to be given by Tenant to Landlord; and (ix) to any other information reasonably requested.

21.2 ENFORCEMENT

In the event that Tenant fails to timely deliver an Estoppel Certificate, then such failure shall be a Default for which there shall be no cure or grace period. In addition to any other remedy available to Landlord, Landlord may impose a charge equal to $500.00 for each day that Tenant fails to deliver an Estoppel Certificate and Tenant shall be deemed to have irrevocably appointed Landlord as Tenant's attorney-in-fact to execute and deliver such Estoppel Certificate.

21.3 LANDLORD ESTOPPEL

Within ten (10) business days after request therefor by Tenant, Landlord shall also certify that (i) that this Lease is unmodified and in full force and effect (or if there have been modifications, a description of such modifications and that this Lease as modified is in full force and effect); (ii) the dates to which Rent has been paid; (iii) whether or not to the best knowledge of Landlord without any duty to investigate, Tenant is in default in the performance of any covenant, agreement or condition contained in this Lease and, if so, specifying each such default of which Landlord may have knowledge.

ARTICLE 22

REAL ESTATE BROKERS

Tenant represents that Tenant has not dealt with any real estate broker, sales person, or finder in connection with this Lease, and no such person initiated or participated in the negotiation of this Lease, or showed the Premises to Tenant. Tenant hereby agrees to indemnify, protect, defend and hold Landlord and the Indemnitees, harmless from and against any and all liabilities and claims for commissions and fees arising out of a breach of the foregoing representation as well as from any claim or claims for any commission or fee by any broker or other party claiming to represent Tenant in connection with any future extensions or renewals hereof. In consideration of Landlord's having no obligation to pay a commission or fee to any broker or other representative of Tenant, Landlord hereby agrees to increase the amount of the Tenant Improvement Allowance otherwise stated in Section 1.1(10) by four hundred forty-seven thousand, six hundred and eighty-four dollars ($447,684.00).

ARTICLE 23

MORTGAGEE PROTECTION

23.1 SUBORDINATION AND ATTORNMENT

This Lease is and shall be expressly subject and subordinate at all times to (i) any ground or underlying lease of the Real Property, now or hereafter existing, and all amendments, extensions, renewals and modifications to any such lease, and (ii) the lien of any mortgage or trust deed now or hereafter encumbering fee title to the Real Property and/or the leasehold estate under any such lease, and all amendments, extensions, renewals, replacements and modifications of such mortgage or trust deed and/or the obligation secured thereby, unless such ground lease or ground lessor, or mortgage, trust deed or Mortgagee, expressly provides or elects that this Lease shall be superior to such lease or mortgage or trust deed. If any such mortgage or trust deed is foreclosed (including any sale of the Real Property pursuant to a power of sale), or if any such lease is terminated, upon request of the Mortgagee or ground lessor, as the case may be, Tenant shall attorn to the purchaser at the foreclosure sale or to the ground lessor under such lease, as the case may be, provided, however, that such purchaser or ground lessor shall not be (i) bound by any payment of Rent for more than one month in advance except payments in the nature of

security for the performance by Tenant of its obligations under this Lease; (ii) subject to any offset, defense or damages arising out of a default of any obligations of any preceding Landlord; or (iii) bound by any amendment or modification of this Lease made without the written consent of the Mortgagee or ground lessor; or (iv) liable for any security deposits not actually received in cash by such purchaser or ground lessor. This subordination shall be self-operative and no further certificate or instrument of subordination need be required by any such Mortgagee or ground lessor. In confirmation of such subordination, however, Tenant shall execute promptly any reasonable certificate or instrument that Landlord, Mortgagee or ground lessor may request. Tenant hereby constitutes Landlord as Tenant's attorney-in-fact to execute such certificate or instrument for and on behalf of Tenant upon Tenant's failure to do so within fifteen (15) days of a request to do so. Upon request by such successor in interest, Tenant shall execute and deliver reasonable instruments confirming the attornment provided for herein. The terms of this paragraph shall survive any termination of this Lease by reason of foreclosure.

During the thirty (30) day period following the Date of this Lease, Landlord shall use commercially reasonable efforts to obtain a subordination, non-disturbance and attornment agreement (a "SNDA") from the current Mortgagee on such party's standard form; provided, however, in no event shall Landlord be in default of this Lease if, despite Landlord's exercise of commercially reasonable efforts, Landlord is unable to obtain a SNDA for Tenant from any such Mortgagee. Additionally, notwithstanding anything herein to the contrary, Tenant's obligation to subordinate this Lease to any future ground lease or mortgage as provided above is conditioned upon Landlord providing a SNDA from such future Mortgagee on the standard form provided by such Mortgagee.

23.2 MORTGAGEE PROTECTION

Tenant agrees to give any Mortgagee or ground lessor, by registered or certified mail, a copy of any notice of default served upon Landlord by Tenant, provided that prior to such notice Tenant has received notice (by way of service on Tenant of a copy of an assignment of rents and leases, or otherwise) of the address of such Mortgagee or ground lessor. Tenant further agrees that if Landlord shall have failed to cure such default within the time provided for in this Lease, then the Mortgagee or ground lessor shall have an additional thirty (30) days after receipt of notice thereof within which to cure such default or if such default cannot be cured within that time, then such additional notice time as may be necessary, if, within such thirty (30) days, any Mortgagee or ground lessor has commenced and is diligently pursuing the remedies necessary to cure such default (including the commencement of foreclosure proceedings or other proceedings to acquire possession of the Real Property, if necessary to effect such cure). Such period of time shall be extended by any period within which such Mortgagee or ground lessor is prevented from commencing or pursuing such foreclosure proceedings or other proceedings to acquire possession of the Real Property by reason of Landlord's bankruptcy. Until the time allowed as aforesaid for Mortgagee or ground lessor to cure such defaults has expired without cure, Tenant shall have no right to, and shall not, terminate this Lease on account of default. This Lease may not be modified or amended so as to reduce the Rent or shorten the Term, or so as to adversely affect in any other respect to any material extent the rights of Landlord, nor shall this Lease be canceled or surrendered, without the prior written consent, in each instance, of the ground lessor or the Mortgagee.

ARTICLE 24

NOTICES

(a) All notices, demands or requests provided for or permitted to be given pursuant to this Lease must be in writing and shall be personally delivered, sent by Federal Express or other reputable overnight courier service, or mailed by first class, registered or certified United States mail, return receipt requested, postage prepaid.

(b) All notices, demands or requests to be sent pursuant to this Lease shall be deemed to have been properly given or served by delivering or sending the same in accordance with this Section, addressed to the parties hereto at their respective addresses listed in Section 1.1.

(c) Notices, demands or requests sent by mail or overnight courier service as described above shall be effective upon deposit in the mail or with such courier service. However, except with respect to a notice given under Code of Civil Procedure Section 1161 et seq., the time period in which a response to any such notice, demand or request must be given shall commence to run from (i) in the case of delivery by mail, the date of receipt on the return receipt of the notice, demand or request by the addressee thereof, or (ii) in the case of delivery by Federal Express or other overnight courier service, the date of acceptance of delivery by an employee, officer, director or partner of Landlord or Tenant. Rejection or other refusal to accept or the inability to deliver because of changed address of which no notice was given, as indicated by advice from Federal Express or other overnight courier service or by mail return receipt, shall be deemed to be receipt of notice, demand or request sent. Notices may also be served by personal service upon any officer, director or partner of Landlord or Tenant, and shall be effective upon such service.

(d) By giving to the other party at least thirty (30) days' written notice thereof, either party shall have the right from time to time during the term of this Lease to change their respective addresses for notices, statements, demands and requests, provided such new address shall be within the United States of America.

ARTICLE 25

OFAC

Landlord advises Tenant hereby that the purpose of this Article is to provide to the Landlord information and assurances to enable Landlord to comply with the law relating to OFAC.

Tenant hereby represents, warrants and covenants to Landlord, either that (i) Tenant is regulated by the SEC, FINRA or the Federal Reserve (a "Regulated Entity") or (ii) neither Tenant nor any person or entity that directly or indirectly (a) controls Tenant or (b) has an ownership interest in Tenant of twenty-five percent (25%) or more, appears on the list of Specially Designated Nationals and Blocked Persons ("OFAC List") published by the Office of Foreign Assets Control ("OFAC") of the U.S. Department of the Treasury.

If, in connection with this Lease, there is one or more Guarantors of Tenant's obligations under this Lease, then Tenant further represents, warrants and covenants either that (i) any such Guarantor is a Regulated Entity or (ii) neither Guarantor nor any person or entity that directly or indirectly (a) controls such Guarantor or (b) has an ownership interest in such Guarantor of twenty-five percent (25%) or more, appears on the OFAC List.

Tenant covenants that during the term of this Lease to provide to Landlord information reasonably requested by Landlord including without limitation, organizational structural charts and organizational documents which Landlord may deem to be necessary ("Tenant OFAC Information") in order for Landlord to confirm Tenant's continuing compliance with the provisions of this Article. Tenant represents and warrants that the Tenant OFAC Information it has provided or to be provided to Landlord or Landlord's Broker in connection with the execution of this Lease is true and complete.

ARTICLE 26

MISCELLANEOUS

26.1 LATE CHARGES

(a) All payments required hereunder (other than the Monthly Base Rent, Rent Adjustments, and Rent Adjustment Deposits, which shall be due as hereinbefore provided) to Landlord shall be paid within ten (10) days after Landlord's demand therefor. All such amounts (including Monthly Base Rent, Rent Adjustments, and Rent Adjustment Deposits) not paid when due shall bear interest from the date due until the date paid at the Default Rate in effect on the date such payment was due.

(b) In the event Tenant is more than five (5) days late in paying any installment of Rent due under this Lease, Tenant shall pay Landlord a late charge equal to five percent (5%) of the delinquent installment of Rent. The parties agree that (i) such delinquency will cause Landlord to incur costs and expenses not contemplated herein, the exact amount of which will be difficult to calculate, including the cost and expense that will be incurred by Landlord in processing each delinquent payment of rent by Tenant, (b) the amount of such late charge represents a reasonable estimate of such costs and expenses and that such late charge shall be paid to Landlord for each delinquent payment in addition to all Rent otherwise due hereunder. The parties further agree that the payment of late charges and the payment of interest provided for in subparagraph (a) above are distinct and separate from one another in that the payment of interest is to compensate Landlord for its inability to use the money improperly withheld by Tenant, while the payment of late charges is to compensate Landlord for its additional administrative expenses in handling and processing delinquent payments.

(c) Payment of interest at the Default Rate and/or of late charges shall not excuse or cure any default by Tenant under this Lease, nor shall the foregoing provisions of this Article or any such payments prevent Landlord from exercising any right or remedy available to Landlord upon Tenant's failure to pay Rent when due, including the right to terminate this Lease.

26.2 NO JURY TRIAL; VENUE; JURISDICTION

To the fullest extent permitted by law, including laws enacted after the Commencement Date, each party hereto (which includes any assignee, successor, heir or personal representative of a party) shall not seek a jury trial, hereby waives trial by jury, and hereby further waives any objection to venue in the County in which the Project is located, and agrees and consents to personal jurisdiction of the courts of the State of California, in any action or proceeding or counterclaim brought by any party hereto against the other on any matter whatsoever arising out of or in any way connected with this Lease, the relationship of Landlord and Tenant, Tenant's use or occupancy of the Premises, or any claim of injury or damage, or the enforcement of any remedy under any statute, emergency or otherwise, whether any of the foregoing is based on this Lease or on tort law. No party will seek to consolidate any such action in which a jury has been waived with any other action in which a jury trial cannot or has not been waived. It is the intention of the parties that these provisions shall be subject to no exceptions. The provisions of this Section shall survive the expiration or earlier termination of this Lease.

26.3 NO DISCRIMINATION

Tenant agrees for Tenant and Tenant's heirs, executors, administrators, successors and assigns and all persons claiming under or through Tenant, and this Lease is made and accepted upon and subject to the following conditions: that there shall be no discrimination against or segregation of any person or group of persons on account of race, color, creed, religion, sex, marital status, national origin or ancestry (whether in the leasing, subleasing, transferring, use, occupancy, tenure or enjoyment of the Premises or otherwise) nor shall Tenant or any person claiming under or through Tenant establish or permit any such practice or practices of discrimination or segregation with reference to the use or occupancy of the Premises by Tenant or any person claiming through or under Tenant.

26.4 FINANCIAL STATEMENTS

Within ten (10) days after written request from Landlord from time to time during the Term, Tenant shall provide Landlord with current financial statements setting forth Tenant's financial condition and net worth for the most recent quarter, including balance sheets and statements of profits and losses. Such statements shall be prepared by an independent accountant and certified by Tenant's president, chief executive officer or chief financial officer. Landlord shall keep such financial information confidential and shall only disclose such information to Landlord's lenders, consultants, purchasers or investors, or other agents (who shall be subject to the same confidentiality obligations) on a need to know basis in connection with the administration of this Lease. Notwithstanding the foregoing, Tenant shall have no obligation to deliver any financial statements if Tenant is a publicly traded entity or an entity that is otherwise required to file financial statements with any governmental entity that are publicly available and Tenant is in compliance with such public reporting requirement.

26.5 OPTION

This Lease shall not become effective as a lease or otherwise until executed and delivered by both Landlord and Tenant. The submission of this Lease to Tenant does not constitute a reservation of or option for the Premises, but when executed by Tenant and delivered to Landlord, this Lease shall constitute an irrevocable offer by Tenant in effect for fifteen (15) days to lease the Premises on the terms and conditions herein contained.

26.6 TENANT AUTHORITY

Tenant represents and warrants to Landlord that it has full authority and power to enter into and perform its obligations under this Lease, that the person executing this Lease is fully empowered to do so, and that no consent or authorization is necessary from any third party. Landlord may request that Tenant provide Landlord evidence of Tenant's authority.

26.7 ENTIRE AGREEMENT

This Lease, the Exhibits, and Riders attached hereto contain the entire agreement between Landlord and Tenant concerning the Premises and there are no other agreements, either oral or written, and no other representations or statements, either oral or written, on which Tenant has relied. This Lease shall not be modified except by a writing executed by Landlord and Tenant.

26.8 MODIFICATION OF LEASE FOR BENEFIT OF MORTGAGEE

If Mortgagee of Landlord requires a modification of this Lease which shall not result in any increased cost or expense to Tenant or in any other substantial and adverse change in the rights and obligations of Tenant hereunder, then Tenant agrees that this Lease may be so modified.

26.9 EXCULPATION

Tenant agrees, on its behalf and on behalf of its successors and assigns, that any liability or obligation under this Lease shall only be enforced against Landlord's equity interest in the Property up to a maximum of Five Million Dollars ($5,000,000.00) and in no event against any other assets of Landlord, or Landlord's members, officers or directors or partners, and that any liability of Landlord with respect to this Lease shall be so limited and Tenant shall not be entitled to any judgment in excess of such amount. Notwithstanding anything to the contrary contained herein, in no event shall Landlord be liable to Tenant for consequential, punitive or special damages with respect to this Lease.

26.10 ACCORD AND SATISFACTION

No payment by Tenant or receipt by Landlord of a lesser amount than any installment or payment of Rent due shall be deemed to be other than on account of the amount due, and no endorsement or statement on any check or any letter accompanying any check or payment of Rent shall be deemed an accord and satisfaction, and Landlord may accept such check or payment without prejudice to Landlord's right to recover the balance of such installment or

payment of Rent or pursue any other remedies available to Landlord. No receipt of money by Landlord from Tenant after the termination of this Lease or Tenant's right of possession of the Premises shall reinstate, continue or extend the Term. Receipt or acceptance of payment from anyone other than Tenant, including an assignee of Tenant, is not a waiver of any breach of Article 10, and Landlord may accept such payment on account of the amount due without prejudice to Landlord's right to pursue any remedies available to Landlord.

26.11 LANDLORD'S OBLIGATIONS ON SALE OF BUILDING

In the event of any sale or other transfer of the Building, Landlord shall be entirely freed and relieved of all agreements and obligations of Landlord hereunder accruing or to be performed after the date of such sale or transfer, and any remaining liability of Landlord with respect to this Lease shall be limited to the dollar amount specified in Section 26.9 and Tenant shall not be entitled to any judgment in excess of such amount. Landlord shall have the right to assign this Lease to an entity comprised of the principals of Landlord or any Landlord Affiliate. Upon such assignment and assumption of the obligations of Landlord hereunder, Landlord shall be entirely freed and relieved of all obligations hereunder.

26.12 BINDING EFFECT

Subject to the provisions of Article 10, this Lease shall be binding upon and inure to the benefit of Landlord and Tenant and their respective heirs, legal representatives, successors and permitted assigns.

26.13 CAPTIONS

The Article and Section captions in this Lease are inserted only as a matter of convenience and in no way define, limit, construe, or describe the scope or intent of such Articles and Sections.

26.14 TIME; APPLICABLE LAW; CONSTRUCTION

Time is of the essence of this Lease and each and all of its provisions. This Lease shall be construed in accordance with the Laws of the State of California. If any term, covenant or condition of this Lease or the application thereof to any person or circumstance shall, to any extent, be invalid or unenforceable, the remainder of this Lease, or the application of such term, covenant or condition to persons or circumstances other than those as to which it is held invalid or unenforceable, shall not be affected thereby and each item, covenant or condition of this Lease shall be valid and be enforced to the fullest extent permitted by Law. Wherever the term "including" or "includes" is used in this Lease, it shall have the same meaning as if followed by the phrase "but not limited to". The language in all parts of this Lease shall be construed according to its normal and usual meaning and not strictly for or against either Landlord or Tenant.

26.15 ABANDONMENT

In the event Tenant vacates or abandons the Premises but is otherwise in compliance with all the terms, covenants and conditions of this Lease, Landlord shall (i) have the right to enter into the Premises in order to show the space to prospective tenants, (ii) have the right to reduce the services provided to Tenant pursuant to the terms of this Lease to such levels as Landlord reasonably determines to be adequate services for an unoccupied premises, and (iii) during the last six (6) months of the Term, have the right to prepare the Premises for occupancy by another tenant upon the end of the Term. Tenant expressly acknowledges that in the absence of written notice pursuant to Section 11.2(b) or pursuant to California Civil Code Section 1951.3 terminating Tenant's right to possession, none of the foregoing acts of Landlord or any other act of Landlord shall constitute a termination of Tenant's right to possession or an acceptance of Tenant's surrender of the Premises, and this Lease shall continue in effect.

26.16 LANDLORD'S RIGHT TO PERFORM TENANT'S DUTIES

If Tenant fails timely to perform any of its duties under this Lease, Landlord shall have the right (but not the obligation), to perform such duty on behalf and at the expense of Tenant without prior notice to Tenant, and all sums expended or expenses incurred by Landlord in performing such duty shall be deemed to be additional Rent under this Lease and shall be due and payable upon demand by Landlord.

26.17 SECURITY SYSTEM

Landlord shall not be obligated to provide or maintain any security patrol or security system. Landlord shall not be responsible for the quality of any such patrol or system which may be provided hereunder or for damage or injury to Tenant, its employees, invitees or others due to the failure, action or inaction of such patrol or system.

26.18 NO LIGHT, AIR OR VIEW EASEMENTS

Any diminution or shutting off of light, air or view by any structure which may be erected on lands of or adjacent to the Project shall in no way affect this Lease or impose any liability on Landlord.

26.19 RECORDATION

Neither this Lease, nor any notice nor memorandum regarding the terms hereof, shall be recorded by Tenant. Any such unauthorized recording shall be a Default for which there shall be no cure or grace period. Tenant agrees to execute and acknowledge, at the request of Landlord, a memorandum of this Lease, in recordable form.

26.20 SURVIVAL

The waivers of the right of jury trial, the other waivers of claims or rights, the releases and the obligations of Tenant under this Lease to indemnify, protect, defend and hold harmless Landlord and/or Indemnitees shall survive the expiration or termination of this Lease, and so

shall all other obligations or agreements which by their terms survive expiration or termination of this Lease.

26.21 TENANT'S CONTRACTORS, SUBCONTRACTORS AND VENDORS

Notwithstanding anything to the contrary set forth in this Lease, Tenant hereby agrees that all of its contractors and subcontractors at any tier performing any construction, repair, refurbishment or restoration or providing janitorial or other services ("Work") within the Premises, including, without limitation, tenant improvements, build-out, alterations, additions, improvements, renovations, repairs, remodeling, painting and installations of fixtures, mechanical, electrical, plumbing, data, security, telecommunication, low voltage or elevator equipment or systems or other equipment, or with respect to any other construction work in, on or to the Building are required to be approved in advance by Landlord. Landlord may disapprove of any such contractors, subcontractors or other vendors who (i) are not bound by and signatory to a collective bargaining agreement with a labor organization, and/or (ii) do not observe area standards for wages and other terms and conditions of employment, including fringe benefits. Further, Tenant shall comply with any reasonable contractor selection and payment policy promulgated by Landlord from time to time. Upon the request of Landlord, each such contractor, subcontractor and vendor shall provide written certification that all work performed by such party was performed in compliance with this policy.

26.22 COUNTERPARTS

This Lease may be executed in any number of counterparts, each of which shall be deemed an original, but all of which, together, shall constitute one and the same instrument. Telecopied signatures or signatures transmitted by electronic mail in so-called "pdf" format or via DocuSign or similar electronic means may be used in place of original signatures on this Lease. Landlord and Tenant intend to be bound by the signatures on the telecopied or e-mailed document, are aware that the other party will rely on the telecopied or e-mailed signatures, and hereby waive any defenses to the enforcement of the terms of this Lease based on such telecopied or e-mailed signatures. Promptly following request by either party, the other party shall provide the requesting party with original signatures on this Lease.

26.23 EXHIBITS AND RIDERS

All exhibits, riders and/or addenda referred to in this Lease as an exhibit, rider, or addenda hereto, or attached hereto, are hereby incorporated into and made a part of this Lease.

[Signatures on Following Page]

IN WITNESS WHEREOF, this Lease has been executed as of the date set forth in Section 1.1(4) hereof.

TENANT:

Zogenix, Inc.,
a Delaware corporation

By: /s/ Stephen Farr
Print Name: Stephen Farr
Its: CEO & President

By: _____
Print Name: _____
Its: _____

LANDLORD:

Emery Station West, LLC,
a California limited liability company

By: ES West Associates, LLC
a California limited liability company,
its Managing Member

By: Wareham-NZL, LLC
a California limited liability company,
its Manager

By: /s/ Richard K. Robbins
Richard K. Robbins
Manager

EXHIBIT A

OUTLINE OF PREMISES

EXHIBIT B

WORKLETTER

THIS WORK AGREEMENT (this "Work Agreement") is attached to and made a part of that certain Lease (the "Lease") between EMERY STATION WEST, LLC, a California limited liability company ("Landlord"), and ZOGENIX, INC., a Delaware corporation ("Tenant"). All capitalized terms used but not defined herein shall have the respective meanings given such terms in the Lease. This Work Agreement sets forth the terms and conditions relating to the construction of Tenant Improvements (defined below) in the Premises.

SECTION 1

ALLOWANCE; TENANT IMPROVEMENTS

1.1 Allowance. Tenant shall be entitled to the Tenant Improvement Allowance (as such is set forth in Articles 1 and 22 of the Lease) to help defray Tenant's total costs relating to the design, permitting and construction of Tenant's improvements which are permanently affixed to the Premises (the "Tenant Improvements"). In no event will Landlord be obligated to make disbursements pursuant to this Work Agreement in a total amount which exceeds the Tenant Improvement Allowance. Tenant agrees that is shall commence and complete the Tenant Improvements promptly following the Date of Lease. Tenant must complete all Tenant Improvements and have submitted Payment Request Supporting Documentation (defined below) for such work no later than December 31, 2019 in order to be entitled to receive the Tenant Improvement Allowance for such work.

1.2 Disbursement of the Tenant Improvement Allowance.

(a) Tenant Improvement Allowance Items. Except as otherwise set forth in this Work Agreement, the Tenant Improvement Allowance shall be disbursed by Landlord only for the following items and costs (collectively the "Tenant Improvement Allowance Items"):

(i) Payment of the fees of the Architect and the Building Consultants (as those terms are defined below) and payment of fees and costs reasonably incurred by Landlord for the review of the Construction Drawings (defined below) by Landlord or by Landlord's third party consultants;

(ii) The payment of plan check, permit and license fees relating to the Tenant Improvements;

(iii) The cost of construction of the Tenant Improvements, including, without limitation, after hours charges, testing and inspection costs, freight elevator usage, trash removal costs, and contractors' fees and general conditions;

(iv) The cost of any changes to the Building when such changes are required by the Construction Drawings, such cost to include all direct architectural and/or engineering fees and expenses incurred in connection therewith;

(v) The cost of any changes to the Construction Drawings (defined below) or Tenant Improvements required by applicable building codes (collectively, "Code"); and

(vi) The Coordination Fee (defined below).

(b) Disbursement of Tenant Improvement Allowance. During the design and construction of the Tenant Improvements, Landlord shall make monthly disbursements of the Tenant Improvement Allowance to reimburse Tenant for Tenant Improvement Allowance Items and shall authorize the release of funds as follows, and otherwise in accordance with Landlord's standard disbursement process.

(i) On or before the fifth (5th) day of each calendar month (or such other date as Landlord may designate), Tenant shall deliver to Landlord: (A) a request for payment from Contractor (defined below) approved by Tenant and the Architect (hereafter defined), in a form to be provided or approved in advance by Landlord, including a schedule of values and showing the percentage of completion, by trade, of the Tenant Improvements, which details the portion of the work completed and the portion not completed; (B) invoices from all of Tenant's Agents (defined below) for labor rendered and materials delivered to the Phase I Premises and Phase II Premises; (C) executed conditional mechanic's lien releases from all of Tenant's Agents who have lien rights with respect to the subject request for payment (along with unconditional mechanics' lien releases with respect to payments made pursuant to Tenant's prior submission hereunder) in compliance with all applicable laws; and (D) all other information reasonably requested by Landlord (collectively, the "Payment Request Supporting Documentation").

(ii) Within forty-five (45) days after Tenant's delivery to Landlord of all Payment Request Supporting Documentation, Landlord shall deliver to Tenant payment in an amount equal to the lesser of: (x) the amount so requested by Tenant, as set forth above, less (i) the applicable Over-Tenant Improvement Allowance Amount (defined in Section 3.2(a) below and (ii) a ten percent (10%) retention (the aggregate amount of such retentions to be known as the "Final Retention"), and (y) the balance of any remaining available portion of the Tenant Improvement Allowance (not including the Final Retention), provided that if Landlord, in good faith, disputes any item in a request for payment based on non-compliance of any work with the Approved Working Drawings (defined below) or due to any substandard work and delivers a written objection to such item setting forth with reasonable particularity Landlord's reasons for its dispute (a "Draw Dispute Notice") within ten (10) business days following Tenant's submission of its Payment Request Supporting Documentation, Landlord may deduct the amount of such disputed item from the payment. Landlord and Tenant shall, in good faith, endeavor to diligently resolve any such dispute. Landlord's payment of such amounts shall not be deemed Landlord's approval or acceptance of the work furnished or materials supplied as set forth in Tenant's payment request.

(iii) Subject to the provisions of this Work Agreement, following the final completion of construction of the Tenant Improvements, Landlord shall deliver to Tenant a check made payable to Tenant, or a check or checks made payable to another party or parties as reasonably requested by Tenant, in the amount of the Final Retention, provided that (A) Tenant

delivers to Landlord properly executed unconditional mechanics' lien releases from all of Tenant's Agents in compliance with all applicable laws, as reasonably determined by Landlord; (B) Landlord has determined in good faith that no substandard work exists which adversely affects the mechanical, electrical, plumbing, heating, ventilating and air conditioning, life-safety or other systems of the Building, the curtain wall of the Building, the structure or exterior appearance of the Building; (C) Architect delivers to Landlord a certificate, in a form reasonably acceptable to Landlord, certifying that the construction of the Tenant Improvements has been finally completed; (D) Tenant supplies Landlord with evidence that all governmental approvals required for an occupant to legally occupy the Premises has been obtained; and (E) Tenant has fulfilled its Completion Obligations (defined below) and has otherwise complied with Landlord's standard "close-out" requirements regarding city approvals, closeout tasks, closeout documentation regarding the general contractor, financial close-out matters, and Tenant's vendors.

SECTION 2

CONSTRUCTION DRAWINGS

2.1 Selection of Architect; Construction Drawings. Tenant shall retain an architect approved in writing, in advance by Landlord, such approval not to be unreasonably withheld (the "Architect") to prepare the Construction Drawings. Tenant shall retain engineering consultants approved in writing, in advance by Landlord, such approval not to be unreasonably withheld (the "Building Consultants") to prepare all plans and engineering working drawings and perform all work relating to mechanical, electrical and plumbing ("MEP"), HVAC/Air Balancing, life-safety, structural, sprinkler and riser work. Landlord acknowledges its' pre-approval of the following Building Consultants:

MEP:	Interface Engineering
Structural:	Rutherford and Chekene; and Murphy, Burr, Curry.

The plans and drawings to be prepared by Architect and the Building Consultants hereunder (i.e., both the Space Plan and the Working Drawings, as each term is defined below) shall be known collectively as the "Construction Drawings." All Construction Drawings shall comply with the drawing format and specifications determined or approved by Landlord and shall be subject to Landlord's prior written approval, not to be unreasonably withheld, conditioned or delayed. All MEP drawings must be fully engineered and cannot be prepared on a "design-build" basis. Landlord's review of the Construction Drawings shall be for its sole purpose and shall not obligate Landlord to review the same, for quality, design, Code compliance or other like matters. Accordingly, notwithstanding that any Construction Drawings are reviewed by Landlord or its space planner, architect, engineers and consultants, and notwithstanding any advice or assistance which may be rendered to Tenant by Landlord or Landlord's space planner, architect, engineers, and consultants, Landlord shall have no liability whatsoever in connection therewith and shall not be responsible for any omissions or errors contained in the Construction Drawings.

2.2 Space Plan. Tenant shall supply Landlord for Landlord's review and approval with four (4) copies signed by Tenant of its space plan for the Premises (the "Space Plan") before any architectural working drawings or engineering drawings have been commenced. The Space Plan shall include a layout and designation of all laboratory facilities, offices, rooms and other partitioning, their intended use, and equipment to be contained therein. Landlord may request clarification or more specific drawings for special use items not included in the Space Plan. Landlord shall advise Tenant within ten (10) business days after Landlord's receipt of the Space Plan (or, if applicable, such additional information requested by Landlord pursuant to the provisions of the immediately preceding sentence) if the same is approved or is unsatisfactory or incomplete in any respect. Upon any disapproval by Landlord, Tenant shall promptly cause the Space Plan to be revised to correct any deficiencies or other matters Landlord may reasonably require.

2.3 Working Drawings. After the Space Plan has been approved by Landlord, Tenant shall supply the Architect and the Building Consultants with a complete listing of standard and non-standard equipment and specifications, including, without limitation, B.T.U. calculations, electrical requirements and special electrical receptacle requirements, to enable the Architect and the Building Consultants to complete the Working Drawings and shall cause the Architect and the Engineers to promptly complete the architectural and engineering drawings, and Architect shall compile a fully coordinated set of drawings, including but not limited to architectural, structural, mechanical, electrical, plumbing, fire sprinkler and life safety in a form which is complete to allow subcontractors to bid on the work and to obtain all applicable permits (collectively, the "Working Drawings") and shall submit the same to Landlord for Landlord's review and approval. Tenant shall supply Landlord with four (4) copies signed by Tenant of the Working Drawings. Landlord shall advise Tenant within fifteen (15) business days after Landlord's receipt of the Working Drawings if Landlord, in good faith, determines that the same are approved or are unsatisfactory or incomplete. If Tenant is so advised, Tenant shall promptly revise the Working Drawings to correct any deficiencies or other matters Landlord may reasonably require.

2.4 Landlord's Approval. Tenant acknowledges that it shall be deemed reasonable for Landlord to disapprove the Space Plan and any subsequent Working Drawings unless, at a minimum, the same are prepared on the basis that they will only utilize the appropriate pro-rated share of building systems capacity made available by Landlord for tenant usage in the building (including, but not limited to, Heating Ventilation and Air Conditioning equipment, electrical power, fire sprinkler, emergency electrical power), (b) the Tenant Improvements as specified and designed comply with the requirements of the Project's Sustainability Practices and the applicable Green Building Standards, and (c) the sprinkler systems shall be designed in compliance with the specifications provided by FM Global. Additionally, Landlord's approval of any matter under this Work Agreement may be withheld if Landlord reasonably determines that the same would violate any provision of the Lease or this Work Agreement or would adversely affect the mechanical, electrical, plumbing, heating, ventilating and air conditioning, life-safety or other systems of the Building, the curtain wall of the Building, the structure or exterior appearance of the Building.

SECTION 3

CONSTRUCTION OF THE TENANT IMPROVEMENTS

3.1 Tenant's Selection of Contractors.

(a) The Contractor. Tenant shall retain a general contractor approved in writing, in advance by Landlord, such approval not to be unreasonably withheld, to construct the Tenant Improvements ("Contractor").

(b) Tenant's Agents . All subcontractors, laborers, materialmen, and suppliers used by Tenant (such subcontractors, laborers, materialmen, and suppliers, and the Contractor to be known collectively as "Tenant's Agents") must be approved in writing by Landlord, in Landlord's sole discretion (Landlord will approve or disapprove Tenant's Agents within ten (10) Business Days following Tenant's written request), provided that Landlord will require Tenant to retain the Building Consultants. All of Tenant's Agents shall be licensed in the State of California, capable of being bonded and union-affiliated in compliance with all then existing master labor agreements.

3.2 Construction of Tenant Improvements by Tenant's Agents.

(a) Construction Contract. Prior to Tenant's execution of the construction contract and general conditions with Contractor (the "Contract"), Tenant shall submit the Contract to Landlord for its approval, which approval shall not be unreasonably withheld or delayed. Prior to the commencement of the construction of the Tenant Improvements, Tenant shall provide Landlord with a schedule of values consisting of a detailed breakdown, by trade, of the final costs to be incurred or which have been incurred, for all Tenant Improvement Allowance Items in connection with the design and construction of the Tenant Improvements, which costs form the basis for the amount of the Contract ("Final Costs"). Prior to the commencement of construction of the Tenant Improvements, Landlord and Tenant shall identify the amount equal to the difference between the amount of the Final Costs and the amount of the Tenant Improvement Allowance (less any portion thereof already disbursed by Landlord, or in the process of being disbursed by Landlord, on or before the commencement of construction of the Tenant Improvements), the "Over-Allowance Amount", and Landlord will reimburse Tenant on a monthly basis, as described in Section 1.2(b)(ii) above, for a percentage of each amount requested by the Contractor or otherwise to be disbursed under this Work Agreement, which percentage shall be equal to the Tenant Improvement Allowance divided by the amount of the Final Costs (after deducting from the Final Costs any amounts expended in connection with the preparation of the Construction Drawings, and the cost of all other Tenant Improvement Allowance Items incurred prior to the commencement of construction of the Tenant Improvements), and Tenant shall be solely responsible for any Over-Allowance Amount. If, after the Final Costs have been initially determined, the costs relating to the design and construction of the Tenant Improvements shall change, any additional costs for such design and construction in excess of the Final Costs shall be added to the Over-Allowance Amount and the Final Costs, and Landlord's reimbursement percentage, shall be recalculated in accordance with the terms of the immediately preceding sentence. Notwithstanding anything set forth herein to the contrary, construction of the Tenant Improvements shall not commence until Tenant has procured and delivered to Landlord a copy of all Permits for the applicable Tenant Improvements.

(b) Construction Requirements.

(i) Landlord's General Conditions for Tenant's Agents and Tenant Improvement Work . Construction of the Tenant Improvements shall comply with the following: (A) the Tenant Improvements shall be constructed in strict accordance with the Approved Working Drawings and Landlord's then-current published construction guidelines; (B) Tenant's Agents shall submit schedules of all work relating to the Tenant Improvements to Landlord and Landlord shall, within five (5) business days of receipt thereof, inform Tenant's Agents of any changes which are necessary thereto, and Tenant's Agents shall adhere to such corrected schedule; and (C) Tenant shall abide by all rules made by Landlord's Building manager with respect to the use of contractor parking, materials delivery, freight, loading dock and service elevators, any required shutdown of utilities (including life-safety systems), storage of materials, coordination of work with the contractors of Landlord, and any other matter in connection with this Work Agreement, including, without limitation, the construction of the Tenant Improvements. Tenant shall pay an oversight and supervisory fee (the "Coordination Fee") to Landlord in an amount equal to one percent (1.0%) of the Final Costs.

(ii) Indemnity. Tenant's indemnity of Landlord as set forth in the Lease shall also apply with respect to any and all costs, losses, damages, injuries and liabilities related in any way to any act or omission of Tenant or Tenant's Agents, or anyone directly or indirectly employed by any of them, or in connection with Tenant's non-payment of any amount arising out of the Tenant Improvements and/or Tenant's disapproval of all or any portion of any request for payment. Such indemnity by Tenant, as set forth in the Lease, shall also apply with respect to any and all costs, losses, damages, injuries and liabilities related in any way to Landlord's performance of any ministerial acts reasonably necessary (A) to permit Tenant to complete the Tenant Improvements, and (B) to enable Tenant to obtain any related building permit or certificate of occupancy.

(iii) Requirements of Tenant's Agents. Each of Tenant's Agents shall guarantee to Tenant and for the benefit of Landlord that the portion of the Tenant Improvements for which it is responsible shall be free from any defects in workmanship and materials for a period of not less than one (1) year from the date of completion thereof. Each of Tenant's Agents shall be responsible for the replacement or repair, without additional charge, of all work done or furnished in accordance with its contract that shall become defective within one (1) year after the completion of the work performed by such contractor or subcontractor. The correction of such work shall include, without additional charge, all additional expenses and damages incurred in connection with the removal or replacement of all or any part of the Tenant Improvements, and/or the Building and/or common areas that are damaged or disturbed thereby. All such warranties or guarantees as to materials or workmanship of or with respect to the Tenant Improvements shall be contained in the Contract or subcontract and shall be written such that such guarantees or warranties shall inure to the benefit of both Landlord and Tenant, as their respective interests may appear, and can be directly enforced by either. Tenant covenants to give to Landlord any assignment or other assurances as may be necessary to effect such right of direct enforcement.

(c) Insurance Requirements.

(i) General Coverages. All of Tenant's Agents shall carry employer's liability and worker's compensation insurance covering all of their respective employees, and shall also carry commercial general liability insurance, including personal and bodily injury, property damage and completed operations liability, all with limits, in form and with companies as are required to be carried by Tenant as set forth in the Lease.

(ii) Special Coverages. Tenant or Contractor shall carry "Builder's All Risk" insurance in an amount approved by Landlord covering the construction of the Tenant Improvements, and such other insurance as Landlord may require, it being understood and agreed that the Tenant Improvements shall be insured by Tenant pursuant to the Lease immediately upon completion thereof. Such insurance shall be in amounts and shall include such extended coverage endorsements as may be reasonably required by Landlord, and shall be in form and with companies as are required to be carried by Tenant as set forth in the Lease.

(iii) General Terms. Certificates for all of the foregoing insurance coverage shall be delivered to Landlord before the commencement of construction of the Tenant Improvements and before the Contractor's equipment is moved onto the site. All such policies of insurance must contain a provision that the company writing said policy will endeavor to give Landlord thirty (30) days' prior written notice of any cancellation of such insurance. In the event that the Tenant Improvements are damaged by any cause during the course of the construction thereof, Tenant shall immediately repair the same at Tenant's sole cost and expense. Tenant's Agents shall maintain all of the foregoing insurance coverage in force until the Tenant Improvements are fully completed and accepted by Landlord, except for any Products and Completed Operations Coverage insurance required by Landlord, which is to be maintained for one (1) year following completion of the work and acceptance by Landlord and Tenant. All policies carried hereunder shall insure Landlord, Wareham Property Group as Landlord's manager, and Tenant, as their interests may appear, as well as Tenant's Agents. All insurance, except Workers' Compensation, maintained by Tenant's Agents shall preclude subrogation claims by the insurer against anyone insured thereunder. Such insurance shall provide that it is primary insurance as respects Landlord and Tenant and that any other insurance maintained by Landlord or Tenant is excess and noncontributing with the insurance required hereunder. The requirements for the foregoing insurance shall not derogate from the provisions for indemnification of Landlord by Tenant under the Lease and/or this Work Agreement.

(d) Governmental Compliance. The Tenant Improvements shall comply in all respects with the following: (i) the Code and other federal, state, city and/or quasi-governmental laws, codes, ordinances and regulations, as each may apply according to the rulings of the controlling public official, agent or other person or entity; (ii) applicable standards of the American Insurance Association (formerly, the National Board of Fire Underwriters) and the National Electrical Code; (iii) building material manufacturer's specifications, and (iv) the Project's Sustainability Practices and the applicable Green Building Standards.

(e) Inspection by Landlord. Landlord shall have the right to inspect the Tenant Improvements at all times, provided however, that Landlord's failure to inspect the Tenant Improvements shall in no event constitute a waiver of any of Landlord's rights hereunder nor shall Landlord's inspection of the Tenant Improvements constitute Landlord's approval of the same. Should Landlord disapprove any portion of the Tenant Improvements, Landlord shall

notify Tenant in writing of such disapproval and shall specify the items disapproved. Any defects or deviations in, and/or disapproval by Landlord of, the Tenant Improvements shall be rectified by Tenant at no expense to Landlord, provided however, that in the event Landlord determines that a defect or deviation exists or disapproves of any matter in connection with any portion of the Tenant Improvements and such defect, deviation or matter might adversely affect the mechanical, electrical, plumbing, heating, ventilating and air conditioning or life-safety systems of the Building, the structure or exterior appearance of the Building or any other tenant's use of such other tenant's leased premises, Landlord may take such action as Landlord deems necessary, at Tenant's expense and without incurring any liability on Landlord's part, to correct any such defect, deviation and/or matter, including, without limitation, causing the cessation of performance of the construction of the Tenant Improvements until such time as the defect, deviation and/or matter is corrected to Landlord's satisfaction.

(f) Meetings. Tenant shall hold periodic meetings at a reasonable time with the Architect and the Contractor regarding the progress of the preparation of the Construction Drawings and the construction of the Tenant Improvements, which meetings shall be held at a location designated or reasonably approved by Landlord, and Landlord and/or its agents shall receive prior written notice of, and shall have the right to attend, all such meetings. Upon Landlord's request, certain of Tenant's Agents shall attend such meetings. In addition, minutes shall be taken at all such meetings, and Landlord will be included in the distribution list for such minutes. One such meeting each month shall include the review of Contractor's current request for payment.

3.3 Notice of Completion; Copy of Record Set of Plans. Following completion of construction of the Tenant Improvements, Landlord shall cause a Notice of Completion to be recorded in the office of the Recorder of Alameda County and shall furnish a copy thereof to Tenant. Within thirty (30) days following the completion of construction, (i) Tenant shall cause the Architect and Contractor (A) to update the Approved Working Drawings as necessary to reflect all changes made to the Approved Working Drawings during the course of construction, (B) to certify to the best of their knowledge that the updated drawings are true and correct, which certification shall survive the expiration or termination of the Lease, and (C) to deliver to Landlord such updated drawings in accordance with Landlord's then-current CAD Requirements, and (ii) Tenant shall deliver to Landlord a copy of all warranties, guaranties, and operating manuals and information relating to the improvements, equipment, and systems in the Premises. Tenant's obligations set forth in this Section are collectively referred to as the "Completion Obligations."

SECTION 4

LANDLORD WORK

Landlord shall deliver the Premises in "warm shell" condition and in conformance with the base building standards as set forth on Exhibit B-1 hereto (the "Landlord Work"). The Landlord Work shall comply in all respects with the Code and other federal, state, city and/or quasi-governmental laws, codes, ordinances and regulations, as each may apply according to the rulings of the controlling public official, agent or other person or entity; the applicable standards of the American Insurance Association (formerly, the National Board of Fire Underwriters), and

the National Electrical Code. Subject to the foregoing, Tenant shall accept the Premises in its then existing, "AS-IS" condition.

SECTION 5

MISCELLANEOUS

5.1 Tenant's Representative. Tenant has designated _____ as its sole representative with respect to the matters set forth in this Work Agreement, until further notice to Landlord, who shall have full authority and responsibility to act on behalf of Tenant as required in this Work Agreement.

5.2 Landlord's Representative. Landlord has designated _____ as its sole representative with respect to the matters set forth in this Work Agreement, who, until further notice to Tenant, shall have full authority and responsibility to act on behalf of Landlord as required in this Work Agreement.

5.3 Tenant's Default. Notwithstanding any provision to the contrary contained in the Lease, if a Default by Tenant under the Lease (including, without limitation, this Work Agreement) has occurred at any time on or before the substantial completion of the Tenant Improvements, then (i) in addition to all other rights and remedies granted to Landlord pursuant to the Lease, Landlord shall have the right to withhold payment of all or any portion of the Tenant Improvement Allowance, and (ii) all other obligations of Landlord under the terms of this Work Agreement shall be forgiven until such time as such default is cured pursuant to the terms of the Lease.

EXHIBIT B-1

THE SUSTAINABILITY DESIGN GUIDELINES

EXHIBIT B-2

LANDLORD WORK / WARM-SHELL DESCRIPTION

OCCUPANCY

- Tower designed to accommodate "B" and "L" occupancies.

SITEWORK/PARKING

- Exterior hardscape and landscape including site lighting, curbs, sidewalks and drive aisles, miscellaneous site furnishings and stormwater bio-filtration system.
- Hardscape and landscaping on podium rooftop (tower's base), accessible from tower.
- Connection from podium roof terrace to pedestrian bridge.
- Landlord-provided Generac emergency generator with enclosure for life-safety and tenant purpose back-up power (l 600kW / 2000 kV A/60Hz).
- Immediate connection to area commuter trains, buses and free EmeryGoRound shuttle.
- Ample visitor/transient parking in podium with tenant employee parking in adjacent 6100 Horton St Garage structure, including provisions for electric vehicle charging.
- Outdoor bike racks and large indoor, secured bike storage.
- Significant on-site public art.

STRUCTURE

- Structural slab on grade supported by auger piles, pile caps and grade beams.
- Steel superstructure for podium and commercial tower above.
- Lateral system using moment frames and buckling-restrained brace frames (BRB's). Seismic importance of 1.0.
- Floors of concrete slab on metal deck. Floor load of l 00 lbs/SF, reducible.
- Structural roof (l 00 lbs per SF, reducible), and central mechanical penthouse.
- Floor-to-floor height of 14' l 0" with top (9th) floor at 15' 0". Designed to allow robust lab MEP above a minimum finished ceiling height of l 0'0".
- Floor vibration: 3rd floor 14,000 micro-inches/second, Floors 4-9 18,000 microinches/second.

EXTERIOR SKIN

- Glass (curtainwall, storefront and ribbon window systems), metal panels and precast panels.
- Head of ribbon windows at 9'-0" above finished floor, sills at 3'-0."
- Metal panels for penthouse and screened mechanical area.
- Accessible private exterior terraces on Floors 4-6.

COMMON AREAS/FACILITIES

- Double-height ground floor lobby, complete with main greeting/security desk, and all interior finishes, FF&E and art.
- Ground floor main electrical room, and fire control room with main fire alarm panel.

- Covered loading dock with roll-down door, at-grade area for shipping/receiving, and hydraulic scissor lift.
- Trash room.
- 750 GPM Patterson fire pump and 60,000 gallon fire water storage tank.
- Telecom main point of entry (MPOE) room. At grade with pathway to stacked tower riser closets on every floor. Open access to main telco providers (AT&T, Comcast and Paxio Fiber).
- One service/freight elevator with capacity of 5,000 lbs. (sized to accommodate an 8 ft. chemical fume hood). This elevator is accessible from loading dock and services all floors plus roof and penthouse.
- Three destination dispatch passenger elevators serving the commercial tower with capacity of 3,500 lbs. Fourth pit for potential future elevator.
- Two exit stair towers completed including drywall enclosure finished and painted on interior, stair treads, handrails, lighting, and stairway pressurization/smoke evacuation.

FULL FLOOR TENANT AREAS:

- Central, fully finished men's and women's restrooms on each floor.
- Janitor closet on every floor.
- Electrical closet with access to main bus duct riser on every floor. Closets have been sized to allow some amount of future tenant transformers.
- IDF riser closet on every floor.
- Tenant and employee access to nearby shared campus conference facility and workout room.
- Exterior cladding and framing ready for tenant insulation and drywall.

MECHANICAL

- Floor heights and structural beam depths allow for 22" duct height while still maintaining a I O'O" finished ceiling, with higher ceilings possible. Indicative duct layout drawings can be shared upon request.
- Stand-alone split system serves the main lobby and ground floor back of house areas.
- Completed vertical shafts sized to accommodate supply air mains, exhaust duct mains, and chilled and heating water risers.
- 74"x24" supply air duct stub-out at each shaft (typ. x3) per floor
- 66"x24" general lab exhaust sub-duct stub-out at each shaft (typ. x3) per floor
- 4" process condenser water stub-out at each floor
- 4" heat hot water stub-out at each floor
- Central equipment (air handlers, exhaust fans, chillers, boilers, pumps, cooling tower, and associated equipment) designed to supply I 00% outside air of l .6 CFM per square foot of tenant area.
- (3) 100,000 CFM GovernAir custom air handling units
- (4) 60,000 CFM Lorin Cook lab exhaust fans
- (2) 750 ton Trane water cooled chillers
- (1) 400 ton heat exchanger for process cooling
- (1) 1875 GPM BAC cooling tower
- (4) 5,600 MBH Aerco output boilers.
- Central Building Management System (BMS) to control core HVAC.

- Pre-identified future louver area on each floor allows for potential additional on-floor air handler for greater capacities, if necessary.
- High-rise smoke evacuation system as required by code for base building shell.
- Core restrooms on every floor served by dedicated bathroom exhaust riser with rooftop exhaust fan. Transfer/make-up air will be provided as part of Tenant Improvement.

ELECTRICAL

• PG&E transformer at 1 00kV A, 480Y /2 77V.
• Transformer serves installed main switchboard rated at 4,000 amp, 480Y/277V.
• 3000 amp, 277/480V 3P, 4W bus duct runs from main electrical room up to penthouse and connecting all on-floor tenant electrical rooms. Tenants have their pro-rata share of access to this electrical riser. Assuming a typical 60/40 lab to office mix for any tenant, this electrical system allows for power and lighting at 5.2W/sq.ft. in office areas and of 6.2W/sq.ft. in lab areas. Please note that the Mechanical system electrical needs have been accommodated outside/on top of of these amounts.
• Each tenant electrical room has a 200 amp 277/480V panel, a 45 kV A step down transformer, and a 100 amp 120/208V panel. If Tenants' electrical allowance (above) permits, they can add taps to the 480V bus duct to access more power. The electrical room on each floor has been sized to allow for the siting of transformer(s) tenants will likely employ.
• Landlord-provided 1.5 MW 60Hz 480V diesel standby emergency generator at grade at building exterior. Generator is sized for 2400A. Two Automatic Transfer Switches
(A TS) divide life safety loads from tenant discretionary loads. 800A is allocated for life safety purposes and 1600 A for tenant discretionary loads. Off this riser each floor has a 200A emergency panel (rated 277/480V, 3-phase, 4 wire) to which tenants have their pro-rata access. There is an 800A emergency panel on the roof. 400A was used to support certain AHU and EF HVAC equipment, and the 400A balance is available for future loads. The opportunity to serve greater tenant loads would be through separate standby power equipment on ground floor.

PLUMBING:

- Building storm and overflow drainage system, including bio-retention system to biologically treat/filter all site-generated storm water.
- Backflow prevention device at main water entry point
- Cold and hot water provided to all restrooms in core and shell.
- Two 2" Cold water stub outs on every floor.
- 4" Waste and 3" vent stub on every floor, located at risers in each quadrant.
- Tenant domestic hot water to be via electric hot water heaters as part of Tenant Improvements.
- Natural gas riser to serve core and shell domestic hot water needs and building penthouse HVAC heat boilers. Tenant natural gas available at each floor with 1-1/4" stub-out at 2psi. Tenant to provide pressure reducing valves and sub-meters.
- No provisions for acid waste. Neutralization, if and as required, to be performed by tenants in tenant spaces.

FIRE /LIFE SAFTEY:

• Existing 2-hour separation between floors.
• Base building sprinkler system with shell configuration heads on every floor as part of base building.
• Fire pump with 60,000 gallon emergency fire water tank at ground floor.
• Main fire alarm closet with main fire alarm panel at ground level (Notifier by Honeywell).
• Code fire alarm devices for core areas at every floor.
• 2-hour fire rating at north fa;ade met with addition of tenant-supplied interior drywall.

SECURITY/ TELECOM:

• Main MPOE room at grade, with central risers up commercial tower connecting tenant IDF rooms on every floor.
• Card access at all exterior points of entry and at parking garage.
• Manned security station in main lobby with 24/7 manned campus security.

EXHIBIT C-1

LABORATORY RULES AND REGULATIONS

1. Any laboratory equipment (glass and cage washers, sterilizers, centrifuges, etc.) being used during Standard Operating Hours must be properly insulated for noise to prevent interruption of other tenants' business. Landlord reserves the right to request all equipment be insulated prior to occupancy. Should other tenants complain of noise, the laboratory tenant will be responsible for abating any noise issues, at the laboratory tenant's sole cost.

2. Any damages to property due to leaks from laboratory equipment will be the sole responsibility of the laboratory tenant. Should damage occur in other tenant spaces, any and all damages and clean-up will be the responsibility of the laboratory tenant.

3. Animal activities are a recognized and necessary process in the biotech industry. Such activities may only be conducted by laboratory tenants pursuant to all the requirements of their respective lease (including any "Use" clause) and require specific, written approval by Landlord in advance. Any animal activities shall be conducted pursuant to all regulations, standards and best industry practices relating to them.

4. The Project is a mixed-use facility, and laboratory tenants share space with office tenants. To reduce the potential interaction with office tenants and their employees and visitors with any biotech animal operations, any animal testing performed, any deliveries of animals and any equipment, foods, cleaners, etc. associated with animal activities, must be coordinated through the loading dock after hours and with the cooperation of the building management and security personnel. The laboratory tenant should make every effort to handle any deliveries relating to animal activities outside of Standard Operating Hours. The freight elevator must be used at all times, and delivery trucks should not be visible to the other tenants in the campus area. No cartons, containers or cardboard boxes bearing the nature of contents may be stored or left in common area spaces, including any garage/freight areas. Feed bags, animal carriers, and any and all other related containers must be disposed of properly and with discretion.

5. All exterior signage relating to laboratory operations (i.e., visible to common areas, including corridors) must be kept to the minimum required by Laws. All signs must have Landlord's approval prior to installation.

EXHIBIT C-2

RULES AND REGULATIONS

1. No sidewalks, entrance, passages, courts, elevators, vestibules, stairways, corridors or halls shall be obstructed or encumbered by Tenant or used for any purpose other than ingress and egress to and from the Premises and if the Premises are situated on the ground floor of the Project, Tenant shall further, at Tenant's own expense, keep the sidewalks and curb directly in front of the Premises clean and free from rubbish.

2. No awning or other projection shall be attached to the outside walls or windows of the Project without the prior written consent of Landlord. No curtains, blinds, shades, drapes or screens shall be attached to or hung in, or used in connection with any window or door of the Premises, without the prior written consent of Landlord. Such awnings, projections, curtains, blinds, shades, drapes, screens and other fixtures must be of a quality, type, design, color, material and general appearance approved by Landlord, and shall be attached in the manner approved by Landlord. All lighting fixtures hung in offices or spaces along the perimeter of the Premises must be of a quality, type, design, bulb color, size and general appearance approved by Landlord.

3. No sign, advertisement, notice, lettering, decoration or other thing shall be exhibited, inscribed, painted or affixed by Tenant on any part of the outside or inside of the Premises or of the Project, without the prior written consent of Landlord. In the event of the violation of the foregoing by Tenant, Landlord may remove same without any liability, and may charge the expense incurred by such removal to Tenant.

4. The sashes, sash doors, skylights, windows and doors that reflect or admit light or air into the halls, passageways or other public places in the Project shall not be covered or obstructed by Tenant, nor shall any bottles, parcels or other articles be placed on the window sills or in the public portions of the Project.

5. No showcases or other articles shall be put in front of or affixed to any part of the exterior of the Project, nor placed in public portions thereof without the prior written consent of Landlord.

6. The water and wash closets and other plumbing fixtures shall not be used for any purposes other than those for which they were constructed, and no sweepings, rubbish, rags or other substances shall be thrown therein. All damages resulting from any misuse of the fixtures shall be borne by Tenant to the extent that Tenant or Tenant's agents, servants, employees, contractors, visitors or licensees shall have caused the same.

7. Tenant shall not mark, paint, drill into or in any way deface any part of the Premises or the Project. No boring, cutting or stringing of wires shall be permitted, except with the prior written consent of Landlord, and as Landlord may direct.

8. No animal or bird of any kind shall be brought into or kept in or about the Premises or the Project, except registered service animals.

9. Tenant shall cooperate with Landlord's efforts to implement the Project's Sustainability Practices and the applicable Green Building Standards, including, but not limited to, complying with Landlord's then-current energy saving efforts and participating in any recycling programs and occupant satisfaction and transportation surveys.

10. Tenant shall not make, or permit to be made, any unseemly or disturbing noises or disturb or interfere with occupants of the Project, or neighboring buildings or premises, or those having business with them. Tenant shall not throw anything out of the doors, windows or skylights or down the passageways.

11. Tenant shall regularly conduct cleaning and janitorial activities, especially in bathrooms, kitchens and janitorial spaces, to remove mildew and prevent moist conditions and shall comply with the Project's Sustainability Practices and the applicable Green Building Standards.

12. No additional locks, bolts or mail slots of any kind shall be placed upon any of the doors or windows by Tenant, nor shall any change be made in existing locks or the mechanism thereof. Tenant must, upon the termination of the tenancy, restore to Landlord all keys of stores, offices and toilet rooms, either furnished to, or otherwise procured by Tenant, and in the event of the loss of any keys so furnished, Tenant shall pay to Landlord the cost thereof.

13. All removals, or the carrying in or out of any safes, freight, furniture, construction material, bulky matter or heavy equipment of any description must take place during the hours which Landlord or its agent may determine from time to time. Landlord reserves the right to prescribe the weight and position of all safes, which must be placed upon two-inch thick plank strips to distribute the weight. The moving of safes, freight, furniture, fixtures, bulky matter or heavy equipment of any kind must be made upon previous notice to the Building Manager and in a manner and at times prescribed by him, and the persons employed by Tenant for such work are subject to Landlord's prior approval. Landlord reserves the right to inspect all safes, freight or other bulky articles to be brought into the Project and to exclude from the Project all safes, freight or other bulky articles which violate any of these Rules and Regulations or the Lease of which these Rules and Regulations are a part.

14. Tenant shall not purchase spring water, towels, janitorial or maintenance or other like service from any company or persons not approved by Landlord. Landlord shall approve a sufficient number of sources of such services to provide Tenant with a reasonable selection, but only in such instances and to such extent as Landlord in its judgment shall consider consistent with security and proper operation of the Project.

15. Landlord shall have the right to prohibit any advertising or business conducted by Tenant referring to the Project which, in Landlord's opinion, tends to impair the reputation of the Project or its desirability as a first class building for offices and/or commercial services and upon notice from Landlord, Tenant shall refrain from or discontinue such advertising.

16. Landlord reserves the right to exclude from the Project between the hours of 6:00 p.m. and 8:00 a.m. Monday through Friday, after 1:00 p.m. on Saturdays and at all hours Sundays and legal holidays, all persons who do not present a pass to the Project issued by Landlord. Landlord may furnish passes to Tenant so that Tenant may validate and issue same. Tenant shall safeguard said passes and shall be responsible for all acts of persons in or about the Project who possess a pass issued to Tenant.

17. Tenant's vendors and contractors shall, while in the Premises or elsewhere in the Project, be subject to and under the control and direction of the Building Manager (but not as agent or servant of said Building Manager or of Landlord) and shall be required to maintain such insurance coverage as reasonably approved by Landlord with liability policies naming Landlord and the Indemnitees as additional insureds.

18. If the Premises is or becomes infested with vermin as a result of the use or any misuse or neglect of the Premises by Tenant, its agents, servants, employees, contractors, visitors or licensees, Tenant shall forthwith at Tenant's expense cause the same to be exterminated from time to time to the satisfaction of Landlord and shall employ such licensed exterminators as shall be approved in writing in advance by Landlord.

19. The requirements of Tenant will be attended to only upon application at the office of the Project. Project personnel shall not perform any work or do anything outside of their regular duties unless under special instructions from the office of the Landlord.

20. Canvassing, soliciting and peddling in the Project are prohibited and Tenant shall cooperate to prevent the same.

21. No water cooler, air conditioning unit or system or other apparatus shall be installed or used by Tenant without the written consent of Landlord.

22. There shall not be used in any premises, or in the public halls, plaza areas, lobbies, or elsewhere in the Project, either by Tenant or by jobbers or others, in the delivery or receipt of merchandise, any hand trucks or dollies, except those equipped with rubber tires and sideguards.

23. Tenant, Tenant's agents, servants, employees, contractors, licensees, or visitors shall not park any vehicles in any driveways, service entrances, or areas posted "No Parking" and shall comply with any other parking restrictions imposed by Landlord from time to time.

24. Tenant shall install and maintain, at Tenant's sole cost and expense, an adequate visibly marked (at all times properly operational) fire extinguisher next to any duplicating or photocopying machine or similar heat producing equipment, which may or may not contain combustible material, in the Premises.

25. Tenant shall keep its window coverings closed during any period of the day when the sun is shining directly on the windows of the Premises.

26. Tenant shall not use the name of the Project for any purpose other than as the address of the business to be conducted by Tenant in the Premises, nor shall Tenant use any picture of the Project in its advertising, stationery or in any other manner without the prior written permission of Landlord. Landlord expressly reserves the right at any time to change said name without in any manner being liable to Tenant therefor.

27. Tenant shall not conduct any restaurant, catering operations, or similar activities at the Premises; provided, however, Tenant may cook and/or prepare food and beverage solely for in-Premises consumption by its employees provided that no odors of cooking or other processes emanate from the Premises. Tenant shall not install or permit the installation or use of any vending machine or permit the delivery of any food or beverage to the Premises except by such persons and in such manner as are approved in advance in writing by Landlord.

28. The Premises shall not be used as an employment agency, a public stenographer or typist, a labor union office, a physician's or dentist's office, a dance or music studio, a school, a beauty salon, or barber shop, the business of photographic, multilith or multigraph reproductions or offset printing (not precluding using any part of the Premises for photographic, multilith or multigraph reproductions solely in connection with Tenant's own business and/or activities), a restaurant or bar, an establishment for the sale of confectionery, soda, beverages, sandwiches, ice cream or baked goods, an establishment for preparing, dispensing or consumption of food or beverages of any kind in any manner whatsoever, or news or cigar stand, or a radio, television or recording studio, theatre or exhibition hall, or manufacturing, or the storage or sale of merchandise, goods, services or property of any kind at wholesale, retail or auction, or for lodging, sleeping or for any immoral purposes.

29. Business machines and mechanical equipment shall be placed and maintained by Tenant at Tenant's expense in settings sufficient in Landlord's judgment to absorb and prevent vibration, noise and annoyance. Tenant shall not install any machine or equipment which causes noise, heat, cold or vibration to be transmitted to the structure of the building in which the Premises are located without Landlord's prior written consent, which consent may be conditioned on such terms as Landlord may require. Tenant shall not place a load upon any floor of the Premises exceeding the floor load per square foot that such floor was designed to carry and which is allowed by Law.

30. Tenant shall not store any vehicle within the parking area. Tenant's parking rights are limited to the use of parking spaces for short-term parking, of up to twenty-four (24) hours, of vehicles utilized in the normal and regular daily travel to and from the Project. Tenants who wish to park a vehicle for longer than a 24-hour period shall notify the Building Manager for the Project and consent to such long-term parking may be granted for periods up to two (2) weeks. Any motor vehicles parked without the prior written consent of the Building Manager for the Project for longer than a 24-hour period shall be deemed stored in violation of this rule and regulation and shall be towed away and stored at the owner's expense or disposed of as provided by Law.

31. Smoking is prohibited in the Premises, the Building and all enclosed Common Areas of the Project, including all lobbies, all hallways, all elevators and all lavatories.

RIDER 1

COMMENCEMENT DATE AGREEMENT

Emery Station West, LLC, a California limited liability company ("**Landlord**"), and Zogenix, a Delaware corporation ("**Tenant**"), have entered into a certain Lease dated as of October 1, 2018 (the "**Lease**"). Unless otherwise defined herein, all capitalized terms shall have the same meaning ascribed to them in the Lease.

WHEREAS, Landlord and Tenant wish to confirm and memorialize the Commencement Date and Expiration Date of the Lease as provided for in Section 2.2(b) of the Lease.

NOW, THEREFORE, in consideration of the foregoing and the mutual covenants contained herein and in the Lease, Landlord and Tenant agree as follows:

1. The Commencement Date is acknowledged to be October 1, 2018.

2. Tenant hereby confirms that it has accepted possession of the Premises pursuant to the terms of the Lease and that the Lease is in full force and effect.

3. Except as expressly modified hereby, all terms and provisions of the Lease are hereby ratified and confirmed and shall remain in full force and effect and binding on the parties hereto.

4. The Lease and this Commencement Date Agreement contain all of the terms, covenants, conditions and agreements between the Landlord and the Tenant relating to the subject matter herein. No prior other agreements or understandings pertaining to such matters are valid or of any force and effect.

TENANT:

Zogenix, Inc.,
a Delaware corporation

By: /s/ Stephen Farr
Print Name: Stephen Farr
Its: CEO & President

By: _____
Print Name: _____
Its: _____

LANDLORD:

Emery Station West, LLC,
a California limited liability company

By: ES West Associates, LLC
a California limited liability company,
its Managing Member

By: Wareham-NZL, LLC
a California limited liability company,
its Manager

By: /s/ Richard K. Robbins
Richard K. Robbins
Manager

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statements on Form S-8 (No. 333-170875, No. 333-181543, No. 333-197998, No. 333-224797) pertaining to the 2006 Equity Incentive Plan of Zogenix, Inc., the 2010 Equity Incentive Award Plan and 2010 Employee Stock Purchase Plan of Zogenix, Inc., the 2010 Equity Incentive Award Plan, as amended of Zogenix Inc., the Employment Inducement Equity Incentive Award Plan of the Zogenix, Inc., and the Registration Statement on Form S-3 (No. 333-220759) of Zogenix, Inc. and in the related Prospectuses, as applicable, of our reports dated February 28, 2019, with respect to the consolidated financial statements of Zogenix, Inc., and the effectiveness of internal control over financial reporting of Zogenix, Inc., and to the reference to our firm under the captions "Risk Factors" included in this Annual Report (Form 10-K) for the year ended December 31, 2018.

/s/ Ernst & Young LLP

Redwood City, California
February 28, 2019

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Stephen J. Farr, certify that:

1. I have reviewed this Annual Report on Form 10-K of Zogenix, Inc. for the fiscal year ended December 31, 2018;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Stephen J. Farr

Stephen J. Farr

President and Chief Executive Officer

Date: February 28, 2019

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael P. Smith, certify that:

1. I have reviewed this Annual Report on Form 10-K of Zogenix, Inc. for the fiscal year ended December 31, 2018;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Michael P. Smith

Michael P. Smith

Chief Financial Officer

Date: February 28, 2019

Exhibit 32.1

CERTIFICATION
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

In connection with the Annual Report on Form 10-K of Zogenix, Inc. (the "Company") for the period ended December 31, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Stephen J. Farr, as Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my 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.

Date: February 28, 2019

/s/ Stephen J. Farr
Stephen J. Farr
Chief Executive Officer

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

CERTIFICATION
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

In connection with the Annual Report on Form 10-K of Zogenix, Inc. (the "Company") for the period ended December 31, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael P. Smith, as Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my 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.

Date: February 28, 2019

/s/ Michael P. Smith
Michael P. Smith
Chief Financial Officer

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.