UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2020

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	**20-5300780**
(State of Incorporation)	**(I.R.S. Employer Identification No.)**
5959 Horton Street, Suite 500 Emeryville, California	**94608**
(Address of principal executive offices)	**(Zip Code)**

(510) 550-8300
(Registrant's telephone number, including area code)

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

Title of each class	Trading symbol	Name of exchange registered
Common Stock, $0.001 par value per share	ZGNX	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 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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 USC. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

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, 2020, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's common stock held by non-affiliates was approximately $1.5 billion.

As of February 19, 2021, there were 55,735,558 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 2021 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, 2020.

ZOGENIX INC.

FORM 10-K

For the Year Ended December 31, 2020

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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:

- our ability to commercialize Fintepla;
- the progress and timing of clinical trials of Fintepla and MT1621;
- the safety and efficacy of our product candidates;
- the impact of the COVID-19 pandemic;
- the timing of submissions to, and decisions made by the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA) 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® and Zogenix™ 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.

SUMMARY OF RISK FACTORS

Investing in our common stock is subject to numerous risks and uncertainties, including those described in Part I, Item 1A, "Risk Factors" of this Annual Report on Form 10-K. The principal risks and uncertainties affecting our business include the following:

- We may not be successful in executing our sales and marketing strategy for the commercialization of Fintepla.
- If Fintepla or MT1621, if approved, does not achieve broad market acceptance or coverage by third-party payors, the revenues that we generate will be limited.
- 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 may 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 success depends substantially on Fintepla as a commercial product and as a product candidate in other indications as well as our product candidate MT1621. We cannot be certain that Fintepla will receive additional regulatory approvals, or be successfully commercialized, or whether MT1621 or any future product candidates will receive regulatory approval or be successfully commercialized.
- We depend on a sole specialty distributor, our customer, for distribution of Fintepla in the United States, and the failure of this specialty distributor to distribute Fintepla effectively would adversely affect sales of Fintepla.
- Our business is subject to risks arising from epidemic diseases, such as the COVID-19 pandemic.
- Fintepla, MT1621 and any of our future product candidates are subject to extensive regulation.
- We may not be able to maintain orphan drug designation or obtain or maintain orphan drug exclusivity for Fintepla or MT1621.
- Our clinical trials may fail to demonstrate acceptable levels of safety and efficacy for our product candidates, which could prevent or significantly delay their regulatory approval.
- 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.
- 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 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.
- 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.
- 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.

ITEM 1. BUSINESS

Overview

Zogenix Inc. is a global biopharmaceutical company committed to developing and commercializing therapies with the potential to transform the lives of patients and their families living with rare diseases. We are primarily focused on developing and commercializing two therapeutic product opportunities: Fintepla, a low-dose fenfluramine, for rare, devastating, difficult-to-treat pediatric epilepsy disorders and MT1621 for a rare, life-threatening mitochondrial depletion disease, thymidine kinase 2 deficiency (TK2d).

Fintepla is approved for marketing in the U.S., the European Union (EU) and in the United Kingdom and is under late-stage development in Japan for the treatment of seizures associated with Dravet syndrome, a rare and devastating pediatric epilepsy disorder.

We own and control worldwide development and commercialization rights to Fintepla. We currently market and commercialize Fintepla in the U.S. through our own highly specialized and focused commercial team. In February 2021, we launched Fintepla in our first market in Europe, Germany, through a similarly specialized commercial team and plan to utilize this self-commercialization strategy throughout major markets in Europe. In March 2019, we entered into an exclusive distribution agreement with Nippon Shinyaku Co., Ltd. to support the sales and distribution of Fintepla in Japan, if approved for marketing in that country. We plan to seek regulatory approvals and make Fintepla available to patients in other select international markets through our commercial team or work with partners in other parts of the world. Fintepla is also under late-stage development for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS), another rare and devastating form of childhood-onset epilepsy. Additionally, we plan to initiate studies for Fintepla in other rare epileptic syndromes and diseases, including CDKL5 Deficiency Disorder (CDD), which we plan to initiate a Phase 3 trial in the second half of 2021, and in multiple other epilepsy disorders through on-going and new Investigator Initiated Studies.

In September 2019, we acquired all the outstanding equity interests of Modis Therapeutics, Inc. (Modis), a privately-held biopharmaceutical company. Through our Modis acquisition, we hold exclusive worldwide license from Columbia University in New York City (Columbia) to certain intellectual property rights owned or controlled by Columbia to develop and commercialize MT1621. MT1621 is an investigational deoxynucleoside-combination substrate enhancement therapy in development for the treatment of TK2d, an inherited mitochondrial DNA depletion disease that predominantly affects children and is often fatal. MT1621 is currently in late-stage development and we are in active discussions with regulatory authorities in the U.S. and in Europe regarding the potential submission of new drug applications (NDAs) for MT1621 as a treatment for patients with TK2d.

Our Strategy

Our mission is to develop and commercialize therapies with the potential to transform the lives of patients and their families living with rare diseases. The critical components of our business strategy include the following:

- ***Successfully launch and commercialize Fintepla for the treatment of patients with Dravet syndrome in the U.S. and Europe, and obtain regulatory approval and commence commercialization in Japan and multiple select geographies throughout the world.*** In June 2020, we announced FDA approval for Fintepla for the treatment of seizures associated with Dravet syndrome in the U.S. Shortly thereafter, in July 2021 we launched Fintepla and made the therapy available to patients in the U.S. through our specialized commercial team, including our care coordination team at Zogenix Central. In December, 2020, we received marketing approval for Fintepla for the treatment of seizures in Dravet syndrome from the European Commission and we launched Fintepla in our first market in Europe, Germany, in February 2021 through a highly focused commercial team. We plan to launch and commercialize Fintepla in other major European markets with similarly focused country-based commercial teams once we are able to secure appropriate reimbursement approvals. In Japan, we are pursuing regulatory approval for Fintepla with our commercial partner, Nippon Shinyaku, and will seek to make Fintepla available to patients in other select international markets through our own commercial teams or partnerships. We have entered into manufacturing and supply agreements for Fintepla and are continuing to build our internal commercial capabilities for potential commercialization in other select international markets.
- ***Seek regulatory approval of Fintepla for the treatment of LGS.*** In February 2020, we reported positive top-line results from our global Phase 3 clinical trial (Study 1601) of Fintepla for the treatment of LGS. The trial met its primary objective of demonstrating that Fintepla at a dose of 0.7 mg/kg/day was statistically

superior to placebo in reducing the frequency of drop seizures and demonstrated statistically significant improvements versus placebo in key secondary efficacy measures, including the proportion of patients with a greater than 50% in drop seizure frequency. We plan to submit a supplemental new drug application (sNDA) for LGS with the FDA in the second half of 2021 and subsequently submit an application for a Type II Variation Marketing Authorization Application (MAA) for an additional LGS indication in Europe. Subject to obtaining approvals, we plan to commercialize Fintepla as a potential treatment for patients with LGS in the U.S. and Europe with a similar self-commercialization approach that we are taking in Dravet syndrome.

- ***Advance the development of MT1621 for the treatment of TK2d.*** In October 2019, we announced positive top-line results from our global, retrospective Phase 2 study (the RETRO study) at the World Muscle Society congress in Copenhagen. 94.7% of treated patients had either improved (68%) or stabilized (26%) overall responses in major functional domains. A survival analysis using a time-dependent Cox regression model showed that the difference in probability of survival between treated patients and untreated natural history control patients was statistically significant ($p<0.0006$). Among clinical responders, a subset demonstrated profound responses, in some cases re-acquiring previously lost motor milestones such as ambulation, respiratory function and feeding. Safety data from RETRO indicated that MT1621 was generally well-tolerated. We held several meetings with the FDA and EMA in 2020 to discuss regulatory requirements and the scope of information needed for NDA and MAA submissions, respectively. Based on the feedback received from the FDA, we expect availability of all required data by the end of 2021 to support an NDA submission, which we are targeting for mid-2022. We anticipate submitting an MAA to obtain marketing authorization in Europe shortly thereafter.
- ***Pursue development of Fintepla for additional indications***. In addition to Dravet syndrome and LGS, we believe that the unique mechanism of action of Fintepla has the potential to treat other serious epileptic encephalopathies where there is a significant unmet medical need. In January 2021 we announced plans to initiate a Phase 3 trial of Fintepla for the treatment of CDD, an infant-onset genetic seizure disorder in 2021. We also plan to continue to explore Fintepla as a potential treatment for additional severe, treatment-resistant rare epilepsies through the initiation of other company-sponsored clinical studies in addition to ongoing Investigator Initiated Studies being conducted in Sunflower Syndrome, CDD and Doose syndrome.

Commercial Product

Fintepla for Patients with Dravet Syndrome

Fintepla is a low-dose, oral solution formulation of fenfluramine, a small molecule with unique serotonergic and positive sigma-1 receptor modulation activity, approved in the U.S. for the treatment of seizures associated with Dravet syndrome in patients 2 years of age and older. To ensure safe use, Fintepla was approved to be available in the U.S. only through a restricted program called the Fintepla REMS. Under the Fintepla REMS program, echocardiogram assessments of patients are required before, during, and after treatment with Fintepla. Fintepla is approved in Europe for the treatment of seizures associated with Dravet syndrome as an add-on therapy to other anti-epileptic medicines for patients two years of age and older and is available via a controlled access program.

In support of the approvals, Fintepla demonstrated positive safety and efficacy results from two randomized, international, multi-center, placebo-controlled Phase 3 trials (Study 1 and Study 2), as well as data from a long-term, open-label extension study in 330 Dravet syndrome patients treated up to 3 years. The Study 1 trial met its primary objective of demonstrating that Fintepla, at a dose of 0.7 mg/kg/day (26 mg/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 ($p<0.001$). The Study 2 trial successfully met the primary objective of demonstrating that Fintepla, at a dose of 0.4 mg/kg/day, when co-administered with the stiripentol regimen, 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 ($p<0.001$). Across both Study 1 and Study 2, Fintepla was generally well-tolerated and no case of valvular heart disease or pulmonary arterial hypertension was observed in any patients.

Dravet syndrome is a rare, lifelong form of pediatric-onset epilepsy, marked with severe, debilitating seizures with life threatening consequences for patients and for which current treatment options are limited. The exact number of people with Dravet syndrome is unknown but has been estimated to be between 1 in 15,700 to 1 in 40,000 people.

Our Clinical Product Candidates

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.

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). The study included a total of 263 patients between the ages of 2 and 35 years whose seizures were currently uncontrolled while on one or more anti-epileptic drugs (AEDs) randomized into three treatment groups: Fintepla 0.7 mg/kg/day (26 mg maximum daily dose; n=87), Fintepla 0.2 mg/kg/day (n=89), and placebo (n=87). The median age of patients was 13 years, with 29% being 18 years or older. Patients entering the study were taking between one and four AEDs and previously had tried and discontinued an average of seven other AEDs. The median baseline drop seizure frequency across the study groups was 77 seizures per month. After establishing baseline seizure frequency for 4 weeks, randomized patients were titrated to their dose over a 2-week titration period, followed by a 12-week fixed dose maintenance period. Patients who completed Part 1 were eligible to enter Part 2 of the clinical trial, an ongoing 12-month open label extension (OLE) study to evaluate the long-term safety, tolerability and effectiveness of Fintepla.

Study 1601 met its primary endpoint of showing a highly statistically significant reduction from baseline compared to placebo in the median percent change in monthly drop seizure frequency. Patients taking Fintepla 0.7 mg/kg/day achieved a median reduction of 26.5% compared to a median reduction of 7.8% in patients taking placebo (p=0.0012). Using a parametric analysis, patients taking Fintepla 0.7 mg/kg/day demonstrated a 26.5% greater reduction in mean monthly drop seizure frequency compared to placebo (p=0.0034). The median percent reduction in monthly drop seizures between baseline and the treatment period for the lower study dose of Fintepla (0.2 mg/kg/day), a secondary endpoint, was 13.2% and did not reach statistical significance compared to placebo (p=0.0915). Additional secondary endpoints of the study were also positive as the proportion of study patients treated with Fintepla 0.7 mg/kg/day who achieved a (≥50%) reduction in monthly drop seizures was superior to placebo (p=0.0165). Also, with regard to Clinical Global Impression of Improvement ratings (CGI-I, a measure of improvement of worsening relative to baseline) as assessed by the investigator, patients who received the Fintepla 0.7 mg/kg/day dose demonstrated a superiority to placebo in terms of the proportion of patients who much improved or very much improved (p=0.0007).

In Study 1601 Fintepla was generally well-tolerated, with the adverse events consistent with those observed in our two prior Phase 3 trials in Dravet syndrome. incidence of patients who experienced at least one treatment emergent adverse event was 89.7% of patients in the Fintepla 0.7 mg/kg/day group, 76.4% in the Fintepla 0.2 mg/kg/day group and 79.3% in the placebo group. The most common adverse events (≥10%) in the Fintepla-treated groups were decreased appetite, somnolence, fatigue, vomiting, diarrhea, and pyrexia. The incidence of serious treatment emergent adverse events was 11.5% (n=10) in the 0.7 mg/kg/day group, 4.5% (n=4) in the 0.2 mg/kg/day group, and 4.6% (n=4) in the placebo group. Six patients in the 0.7 mg/kg/day group had an adverse event leading to study discontinuation compared to four subjects in the 0.2 mg/kg/day group and one patient in the placebo group; the majority of these were considered treatment-related. There was one death during the trial (0.7 mg/kg/day group) caused by SUDEP, which was assessed by the investigator to be unrelated to the study drug. No cases of valvular heart disease or pulmonary hypertension have been observed in Study 1601. A total of 247 (93.9%) patients entered the OLE phase.

We plan to submit a sNDA for LGS with the FDA in the second half of 2021 and subsequently submit an application for a Type II Variation MAA for an additional LGS indication in Europe.

Fintepla for Other Potential Indications

In addition to Dravet syndrome and LGS, we plan to investigate the treatment potential of Fintepla in other serious, treatment-resistant epileptic syndromes. In January 2021, we announced plans to initiate a Phase 3 trial in CDKL5 deficiency disorder (CDD), a genetic neurological disorder that presents clinically with persistent seizures starting at infancy, followed by severe motor impairment in neurological development. In December, 2020 at the annual American Epilepsy Society Meeting, clinical investigators from the New York University Lagone Medical Center reported interim results from the first six patients of an open-label, investigator-initiated study of Fintepla in CDD patients between ages 2 and 35 that patients taking Fintepla at a dose of up to 0.7/mg/kg day experienced a clinically meaningful reduction in both generalized clonic-tonic seizures (90%) and tonic seizures (55%). We expect to enroll the first patient in our Phase 3 trial to evaluate whether Fintepla is safe and effective versus placebo in CDD patients in the second half of 2021.

In addition to this planned study in CDD patients, we also plan to continue to explore Fintepla as a potential treatment for additional severe, treatment-resistant rare epilepsies through the initiation of other company-sponsored clinical studies in addition to ongoing Investigator Initiated Studies being conducted in Sunflower Syndrome and Doose syndrome.

MT1621 for Patients with TK2d

TK2d is a rare, debilitating, and often fatal genetic disorder that primarily affects infants and children and for which there are currently no approved therapies. As of September 6, 2019, the date we acquired Modis, Modis had completed the RETRO study of MT1621 in patients with TK2d and commenced a Phase 2 prospective, OLE study of patients with TK2d, Study MT1621-101. MT1621 has received Breakthrough Therapy designation from the FDA and access to the PRIME scheme by the EMA and we intend to seek accelerated regulatory review pathways in both the United States and Europe.

RETRO was a global retrospective study of MT1621, a fixed combination treatment of two pyrimidine nucleosides deoxycytidine and deoxythymidine (dC/dT), in 38 pediatric and adult patients with TK2d (median age of disease onset, 2.5 years) treated at eight clinical sites in the United States, Spain and Israel.

Subjects received MT1621 for a median of 71 weeks (range 92 days – 7 years). Each subject was scored across motor, respiratory, and feeding domains according to pre-defined response criteria and was compared to pre-treatment status to assess whether responses improved, remained stable, or worsened. Parallel to RETRO, we compiled a comprehensive, global TK2d Natural History dataset from published studies and individual case reports to document untreated patients' disease course. From this natural history dataset, 68 patients reflecting the range of disease severity, age, and age of disease onset, were selected as a control group for treated patients in the RETRO study.

In October 2019 we announced positive top-line results from the pivotal Phase 2 RETRO study at the World Muscle Society congress in Copenhagen. 94.7% of treated patients had either improved (68%) or stabilized (26%) overall responses in major functional domains. A survival analysis using a time-dependent Cox regression model showed that the difference in probability of survival between treated patients and untreated natural history control patients was statistically significant ($p<0.0006$). Among clinical responders, a subset demonstrated profound responses, in some cases re-acquiring previously lost motor milestones such as ambulation, respiratory function and feeding. Safety data from RETRO indicated that MT1621 was generally well-tolerated. Most reported adverse events were considered not related to study drug (199 of 292), with mild or moderate diarrhea being the most common treatment-related adverse event (AE), occurring in 63% of patients. Serious AEs (SAEs) were reported in 14 subjects (37%). The majority of SAEs were deemed related to TK2d; two patients experienced three events related to study drug alone (kidney stone, kidney stone removal, diarrhea). Two adult-onset patients stopped treatment due to asymptomatic increases in aminotransferase liver enzymes (no increase in bilirubin levels), which resolved upon discontinuation of treatment.

In April 2020, we held an End-of-Phase 2 meeting with the FDA and in June 2020, we met with the FDA to discuss chemistry, manufacturing, and controls (CMC) for MT1621. In the meetings, the FDA outlined the additional clinical and non-clinical information needed for an NDA submission. Based on the feedback, we expect availability of all required data by end of 2021 to support an NDA submission, which we are targeting for mid-2022. Also, in the meeting, the FDA requested we include additional information on treated patients who did not participate in the Modis-sponsored portion of the RETRO study in order to have a complete survival analysis for the NDA. This additional information will be collected in a non-interventional medical chart-review study. In addition, we plan to conduct a Phase 1 pharmacokinetic (PK) study in renal impairment which was recommended by the FDA to provide dosing recommendations in the setting of impaired renal function and include the results in the NDA submission. The FDA also concurred with our proposed CMC plan for the prospective NDA submission. We have also had discussions with European regulators in 2020. Based on those interactions, we anticipate submitting an MAA to obtain marketing authorization in Europe after submitting an NDA in the U.S.

Preclinical Pipeline

Tevard Gene Therapy Collaboration for Genetic Epilepsies

In December 2020, we entered into a collaboration with Tevard Biosciences, Inc. for the research, development and commercialization of gene therapies for the treatment of Dravet syndrome and other epilepsy disorders. The collaboration is at the research and discovery stage and will leverage Tevard' s pioneering and novel

t-RNA-based technology to treat genetic disorders not amenable to traditional types of gene therapies, such as Dravet Syndrome.

Please see “Strategic and License Agreements” section for a more detailed description of the terms of our Tevard collaboration.

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 and 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 products, 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. GW’s CBD was subsequently approved for the treatment of Dravet syndrome and LGS by the European Commission (as Epidyolex®) in September of 2019. Epidyolex must be prescribed with clobazam in Europe. 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 clobazam.

Fintepla has a novel biological mechanism of action (selective serotonin and sigma-1 receptor activity) that, is different from the other antiepileptic drugs currently available and in clinical development in the United States and Europe 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.

Multiple companies are developing clinical-stage product candidates for the potential treatment of Dravet syndrome. 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. Additional clinical stage candidates for the treatment of Dravet syndrome include Ataluren from PTC Therapeutics (exploratory Phase 2), clemizole (Phase 2) being evaluated by Epygenix Therapeutics, Inc., Huperzine-A from Supernus Pharmaceuticals (Phase 1/2), STK-001 from Stoke Therapeutics (Phase 1), and NBI-921352 from Neurocrine Biosciences (Phase 1).

Several other companies, including Encoded Therapeutics, Inc., Neucyte, Inc., NeuroCycle Therapeutics and Sarepta Therapeutics, Inc., have disclosed that they are evaluating preclinical drug candidates, including gene therapies and small molecules, for the potential treatment of Dravet syndrome.

MT1621

Currently, we are not aware of any pharmaceutical products that have been approved for the treatment of a primary mitochondrial disease. Similarly, we are not aware of any pharmaceutical companies who are developing a pharmaceutical product candidate for the treatment of TK2d.

Beyond TK2d, a number of pharmaceutical companies are developing clinical-staged product candidates for the potential treatment of other mitochondrial diseases, including Metro International Biotech LLC, PTC Therapeutics, Inc., Reata Pharmaceuticals, Inc., Reneo Pharmaceuticals, Inc., Stealth BioTherapeutics, Inc., and Wellstat Therapeutics Corp.

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, MT1621 or any future product candidates.

Fintepla

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 fenfluramine hydrochloride, the active pharmaceutical ingredient (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. In July 2019, we entered into a supply agreement (PCI Pharma Agreement) with Penn Pharmaceutical Services Limited, trading as PCI Pharma Services (PCI Pharma), pursuant to which PCI Pharma will procure the raw materials (other than the active pharmaceutical ingredient) for, formulate, fill, test and release an oral solution of Fintepla. Pursuant to the PCI Pharma Agreement, at a specified time prior to the anticipated receipt of the first marketing authorization by a regulatory agency to market Fintepla, and then each month following such receipt, we are required to deliver a rolling forecast of our expected commercial orders, a portion of which will be considered a binding, firm order.

The term of the PCI Pharma Agreement is five years, which term shall be automatically extended for successive two-year periods thereafter, unless terminated earlier. After the second anniversary of the Effective Date, either party may terminate the PCI Pharma Agreement at any time without cause following a specified notice period applicable to the respective party. In addition, either party may terminate the agreement (1) upon written notice if the other party has failed to remedy a material breach of any of its representations, warranties or other obligations under the PCI Pharma Agreement within a specified period following receipt of written notice of such breach, (2) immediately in the event of a material breach of the other party's representations, warranties or other obligations under the PCI Pharma Agreement and in the event that such breach is not capable of remedy and (3) in the event that the other party files for bankruptcy, reorganization, liquidation, administration or receivership proceedings, or a substantial portion of the assets of such party is assigned for the benefit of such party's creditors. We may also terminate the PCI Pharma Agreement immediately in the event PCI Pharma is unable to supply Fintepla at specified quantities and within certain times. PCI Pharma may also terminate the Agreement upon notice if it determines its performance of services would violate applicable law. PCI Pharma's manufacturing services under the PCI Pharma Agreement will also terminate automatically if Fintepla is withdrawn as a result of regulatory review or we decide to cease development activities of Fintepla.

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. Third-party manufacturers are and will be used to formulate, fill, label, package, test, release, 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 of our products.

MT1621

As a part of our acquisition of Modis in September 2019, we assumed a manufacturing supply agreement with ST Pharm Co. LTD (ST Pharm), pursuant to which ST Pharm will be our clinical materials manufacturer and supplier of both 2'-deoxycytidine and 2'-deoxythymidine APIs used in MT1621. The term of the supply agreement is five (5) years from the date of agreement (October 2017), which term can be extended for successive two-year periods thereafter, unless terminated earlier. ST Pharm has been providing the API for the clinical trial material supply needs and registration batches since the beginning of MT1621 clinical trials. In addition, we also assumed a supply agreement with Catalent Pharma Solutions (Catalent), pursuant to which Catalent will procure all materials other than the API, fill into drug product packs, and package, test, and release the MT1621 powder for oral solution finished product.

Strategic and License Agreements

Fintepla

In October 2014, we acquired Brabant Pharma Limited (Brabant) in a business acquisition and obtained worldwide development and commercialization rights to Fintepla, one of our lead product candidates. Under the terms of the acquisition, 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 milestones and $45.0 million in sales-based milestones. As of December 31, 2020, all regulatory milestones have been earned.

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 low-dose 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 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 we (a) do 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 we become insolvent or makes 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.

MT1621

As a result of our acquisition of Modis, we became party to the Exclusive License Agreement, by and between Modis and Columbia, dated as of September 26, 2016 (the Columbia Agreement), related to MT1621. We are required to use commercially reasonable efforts to develop and commercialize licensed products worldwide, including to meet certain development and commercialization milestones within specified periods of time. Upon the achievement of certain regulatory and commercial milestones, we are required to pay Columbia up to $2.9 million and $25.0 million, respectively, as well as tiered royalties on sales for each licensed product, at percentages ranging from the mid-single digits to the high single-digits. The royalty obligations and Columbia Agreement will expire on a country-by-country and product-by-product basis upon the later of (i) 15 years after the first bona fide commercial sale of a licensed product, (ii) the expiration of the last to expire valid patent claim covering a licensed product in a country or (iii) expiration of any regulatory exclusivity covering such licensed product. The Columbia Agreement may be terminated either by Columbia or by us in the event of an uncured material breach by the other party, or by Columbia in the event we are subject to specified bankruptcy, insolvency or similar circumstances. We can terminate the Columbia Agreement either in its entirety or on a product-by-product and country-by-country basis, upon specified prior written notice to Columbia, provided we are not exploiting licensed products in such countries.

We also became party to a license agreement between two other research institutions related to MT1621 where we may be required to pay up to $3.0 million for research, development and regulatory milestone events and up to $10.0 million for certain sales milestone events. We are also required to pay tiered royalties ranging from low to mid-single digits on net sales of licensed product.

Tevard Collaboration, Option and License Agreement

In October 2019, we entered into an option agreement with Tevard Biosciences (Tevard), a privately-held company focused on tRNA-based gene therapies. Under the agreement, Tevard granted us an option to license exclusive rights related to a preclinical development program to identify and develop novel tRNA-based gene therapies for Dravet syndrome. During 2020, we extended the option period to exercise our license rights prior to entering into a collaboration, option and license agreement with Tevard. Payments made under the option agreement were nonrefundable, but may be credited against the upfront payment due if we exercise our option on the preclinical development program.

In December 2020, we exercised the option on the Dravet syndrome program and entered into a collaboration, option and license agreement with Tevard (the Tevard Agreement). The financial terms of the Tevard Agreement included an upfront payment of $5.2 million. In connection with the transaction, we also purchased a convertible

promissory note issued by Tevard in the amount of $5.0 million. The note matures in December 2022 and carries interest at 3.5% per year. The note will automatically convert into equity securities issued by Tevard in their next equity financing transaction at a conversion price equal to the price paid per share by other investors of the financing transaction.

In addition to the upfront payments, we have agreed to fund Tevard's early discovery activities under the licensed Dravet syndrome program in accordance with the development plan as determined by the parties to the agreement. Once Tevard completes the early discovery activities for a program, we will be responsible for any potential future development and commercialization activities. Tevard is also eligible to receive additional development, regulatory and commercial-related milestone payments of up to $100.0 million for the Dravet program, as well as tiered royalties on future net sales in the single digits that result from the collaboration. On a country-by-country and product-by-product basis, royalty payments would commence on our first commercial sale of a product and terminate on the later of: (a) the expiration of patent based exclusivity of such product in such country; (b) the expiration of regulatory based exclusivity of such product in such country; and (c) 10 years from the first commercial sale of the product in such country. Tevard has the option with respect to the Dravet syndrome program to elect to reimburse us for certain of our development costs for the Dravet syndrome program in exchange for receiving tiered royalties on future net sales ranging from low double digits to not more than 20% for products from the Dravet syndrome program.

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.

Fintepla

As of December 31, 2020, we have rights to six issued U.S. patents and six 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," have claims covering 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 are assignees of two Orange Book listed patents covering a controlled distribution system for Fintepla and increasing patient exposure to Fintepla when co-administered with cannabidiol that are expected to provide protection in the U.S. 2035 and 2037 respectively. We have received notices of allowance for two additional US patent applications and paid issue fees, one claiming a high purity fenfluramine API used in our product, and the other claiming a method of treating a patient under the controlled distribution system that are expected to provide additional protection until 2036 and 2035 respectively.

MT1621

We have certain patent rights that we obtained through our acquisition of Modis. In September 2016, Modis entered into a license agreement with Columbia University under which Modis was granted an exclusive worldwide license and sublicense to certain intellectual property rights owned or controlled by Columbia to develop and commercialize MT1621 and certain backup compounds for any application or purpose. These licensed patent rights include patents owned by Columbia and patents jointly owned by Columbia and Vall d'Hebron Research Institute (VHIR). VHIR delegated to Columbia the rights to enter into the Columbia Agreement on VHIR's behalf. The patent family jointly owned by Columbia and VHIR is directed to the use of MT1621 to treat TK2d and includes an issued U.S. patent, and two granted patents each in the European, Japanese and Australian patent offices with all six expiring in 2036. In addition, there are pending patent applications in Australia, Brazil, Canada, China, Hong Kong, Israel, India, Japan, Korea, Mexico and Russia, as well as continuing applications in the United States and Europe. There are no patents covering the composition of matter in MT1621.

We have pending, in appropriate jurisdictions, foreign patent applications corresponding to our U.S. patents and US and Patent Cooperation Treaty patent applications for both Fintepla and MT1621. We cannot assure you that any of our patent applications will result in the issuance of patents, that any issued patent will include claims of the breadth we are seeking, or that competitors or other third-parties will not successfully challenge or circumvent our patents if they are issued.

Our ability to maintain and solidify our proprietary and intellectual property position for our products and product candidates will depend on our success in obtaining effective patent claims and enforcing those claims if

granted. However, pending patent applications we have filed or licensed from third parties may not result in the issuance of patents.

We believe our patents are valid and do not infringe the patents or other proprietary rights of others. Accordingly, we believe we are not obligated to pay royalties relating to the use of intellectual property to any third parties except Catholic University of Leuven, University Hospital Antwerp, Columbia University and VHIR from which we have licensed certain 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 good laboratory practice (GLP) regulations and other applicable 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;
- approval by an independent institutional review board (IRB) or ethics committee at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practice (GCP) regulations, to establish the safety and efficacy of the proposed drug product for each intended use;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA advisory committee review, if applicable;
- 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 to ensure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quantity and purity, and of selected clinical investigation sites to assess compliance with GCPs; and
- FDA review and approval of the NDA to permit commercial marketing of the product for particular indications for use in the U.S.

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. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. 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, 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. Clinical trials are

conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

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: The drug is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

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.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development. Sponsors typically use the meetings at the end of the Phase 2 trial to discuss Phase 2 clinical results and present plans for the pivotal Phase 3 clinical trials that they believe will support approval of the new drug.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, 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.

The submission of an NDA may be 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. Under the PDUFA goals that are currently in effect, the FDA has a standard review goal of ten months from the date of filing of a NDA for a new molecular entity, and ten months from the date of receipt for an NDA for a non-new molecular entity, to review and act on the submission. The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for

filing, to determine whether they are sufficiently complete to permit substantive review The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing.

The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality and purity. 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 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.

For some drugs, the FDA may determine that a Risk Evaluation and Mitigation Strategy (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.

In addition, the Pediatric Research Equity Act (PREA) requires a sponsor to conduct pediatric clinical trials for most drugs for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs and supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin. The FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation.

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. For 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 treats a serious condition, and if approved, would provide 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. Under its current review goals, 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, and within six months of the receipt date for non-new molecular entity NDA.

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. Products receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required post-marketing clinical trials or if such trials fail to verify the predicted clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

A sponsor may also 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.

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

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. The FDA may also 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. In addition, the FDA may also require a REMS for an approved product when new safety information emerges.

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. 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 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 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;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product;
- 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.

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.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan 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 individuals in the United States, there is no reasonable expectation that the cost of developing and making a drug product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan designation must be requested before submitting an NDA. After the FDA grants orphan designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity or inability to manufacture the product in sufficient quantities. The designation of such drug also entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. However, competitors, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Orphan exclusivity also could block the approval of one of our product candidates for seven years if a competitor obtains approval of the same drug as defined by the FDA or if our product candidate is determined to be contained within the competitor’s product for the same indication or disease. In addition, if an orphan designated product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan exclusivity.

In the EU, medicinal products: (a) that are used to treat or prevent life-threatening or chronically debilitating conditions that affect no more than five in ten thousand people in the EU when the application is made; or (b) that are used to treat or prevent life-threatening or chronically debilitating conditions and that, for economic reasons, would be unlikely to be developed without incentives; and (c) where no satisfactory method of diagnosis, prevention or treatment of the condition concerned exists, or, if such a method exists, the medicinal product would be of significant benefit to those affected by the condition, may be granted an orphan designation. The application for orphan designation must be submitted to the EMA and approved before an application is made for marketing authorization for the product. Once authorized, orphan medicinal products are entitled to up to ten years of market exclusivity (which may be extended for an additional two years if pediatric data have been produced in accordance with an agreed pediatric investigational plan). During this ten year period, with a limited number of exceptions, neither the competent authorities of the EU Member States, the EMA, or the EC are permitted to accept applications or grant marketing authorization for other similar medicinal products with the same therapeutic indication. However, marketing authorization may be granted to a similar medicinal product with the same orphan indication during the ten year period with the consent of the marketing authorization holder for the original orphan medicinal product or if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities. Marketing authorization may also be granted to a similar medicinal product with the same orphan indication if this latter product is safer, more efficacious or otherwise clinically superior to the original orphan medicinal product. The period of market exclusivity may, in addition, be reduced to six years if it can be demonstrated on the basis of available evidence that the criteria for orphan designation are no longer met or if the orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity.

Rare Pediatric Disease Priority Review Voucher Program

In 2012, Congress authorized the FDA to award priority review vouchers to sponsors of certain rare pediatric disease product applications. This program is designed to encourage development of new drug and biological products for prevention and treatment of certain rare pediatric diseases. Specifically, under this program, a sponsor who receives an approval for a drug or biologic for a "rare pediatric disease" may qualify for a voucher that can be redeemed to receive a priority review of a subsequent marketing application for a different product. The sponsor of a rare pediatric disease drug product receiving a priority review voucher may transfer (including by sale) the voucher to another sponsor. The voucher may be further transferred any number of times before the voucher is used, as long as the sponsor making the transfer has not yet submitted the application. The FDA may also revoke any priority review voucher if the rare pediatric disease drug for which the voucher was awarded is not marketed in the United States within one year following the date of approval.

For purposes of this program, a "rare pediatric disease" is a (a) serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years, including age groups often called neonates, infants, children, and adolescents; and (b) rare diseases or conditions within the meaning of the Orphan Drug Act. Congress has only authorized the Rare Pediatric Disease Priority Review Voucher program until September 30, 2024. Consequently, sponsors of marketing applications approved after that date will not receive the voucher unless Congress reauthorizes the Rare Pediatric Disease Priority Review Voucher program. However, even if the program is not reauthorized, if a drug candidate receives Rare Pediatric Disease Designation before October 1, 2024, the sponsor of the marketing application for such drug will be eligible to receive a voucher if the application for the designated drug is approved by the FDA before October 1, 2026.

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.

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 Schedule IV 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.

Foreign Regulation of Drug Development and Approval

In addition to regulations in the U.S., we are subject to a variety of foreign regulatory requirements including those governing drug development, pre-clinical trials, human clinical trials, marketing approval, manufacturing, pharmacovigilance and post-marketing regulation for drugs. The foreign regulatory approval process includes all of the risks associated with FDA approval set forth above, as well as additional country-specific regulations. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. Approval by one regulatory authority does not ensure approval by regulatory authorities in other jurisdictions. The approval process varies from country to country, can involve additional testing beyond that required by FDA, and may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing, promotion, and reimbursement vary greatly from country to country.

Under the EU regulatory system, we may submit applications for marketing authorizations in more than one EU Member State either under a centralized, decentralized, or mutual recognition marketing authorization procedure. The centralized procedure provides for the grant of a single marketing authorization for a medicinal product by the EC on the basis of a positive opinion by the EMA Committee for Medicinal Products for Human Use (ChMP) and is mandatory for certain categories of medicinal products, including orphan medicinal products. A centralized marketing authorization is valid for all EU Member States and the European Economic Area states. The decentralized procedure and the mutual recognition procedure apply between EU Member States. The decentralized marketing authorization procedure involves the submission of an application for marketing authorization to the competent authority of all EU member states in which the product is to be marketed. One national competent authority, selected by the applicant, assesses the application for marketing authorization. The competent authorities of the other EU Member States are subsequently required to grant marketing authorization for their territory on the basis of this assessment, except where grounds of potential serious risk to public health require this authorization to be refused. The mutual recognition procedure provides for mutual recognition of marketing authorizations delivered by the national competent authorities of EU Member States by the competent authorities of other EU Member States. The holder of a national marketing authorization may submit an application to the competent authority of an EU Member State member state requesting that this authority recognize the marketing authorization delivered by the competent authority of another EU Member State member state for the same medicinal product. The EC may agree upon recommendation of the EMA to grant for medicines including those designated as orphan medicines a (i) conditional marketing authorization in the interest of public health under certain conditions; namely that unmet medical needs will be fulfilled, the benefit-risk balance of the product is positive, the benefit to public health of the medicinal product's immediate availability on the market outweighs the risks due to need for further data and it is likely that the applicant will be able to provide comprehensive data; or (ii) marketing authorization under "exceptional circumstances" when the applicant can show that it is unable to provide comprehensive data on the efficacy and safety under normal conditions of use and subject to specific procedures being introduced. This may arise in particular when the intended indications are very rare, in the present state of scientific knowledge, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles.

In 2016, the EMA launched its Priority Medicines, or PRIME, scheme. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicines that target unmet medical needs. It is based on increased interaction and early dialogue with companies developing promising medicines, to optimize their product development plans and speed up their evaluation to help them reach patients earlier. The scheme focuses on medicines that may offer a major therapeutic advantage over existing treatments, or benefit patients without treatment options. These medicines are considered priority medicines by the EMA. To be accepted for PRIME, a medicine has to show its potential to benefit patients with unmet medical needs based on early clinical data. The benefits of a PRIME designation include the appointment of a CHMP rapporteur before submission of the marketing authorization application, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review earlier in the application process.

Similar to the U.S., both marketing authorization holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA and the competent authorities of the individual EU Member States both before and after grant of the manufacturing and marketing authorizations. This includes control of compliance by the companies within the EU legal framework (i.e., GCP, GLP, cGMP and pharmacovigilance rules, which govern quality control of the manufacturing process and require documentation policies and procedures). We and our third party manufacturers are required under regulations to ensure that all of our processes, methods, and equipment are compliant with GCP, GLP, cGMP and pharmacovigilance rules. The EMA and national competent authorities have in the past, and expect that they will continue to, may arrange inspections to ensure that we adhere to these principles and regulations. Any adverse findings from such inspections, depending on their severity, may result in significant delays in obtaining a marketing authorization, may impose penalties or may result in other action by regulatory authorities.

Failure by us or by any of our third party partners, including suppliers, manufacturers, marketers and distributors to comply with EU laws and the related national laws of individual EU Member States governing the conduct of clinical trials, manufacturing approval, marketing authorization of medicinal products, pre-approval promotion of products, reporting of adverse health events, both before and after grant of marketing authorization, and marketing/promotion of such products following grant of authorization may result in administrative, civil, or criminal penalties. These penalties could include delays in or refusal to authorize the conduct of clinical trials or to grant marketing authorization, product withdrawals and recalls, product seizures, suspension, or variation of the marketing authorization, total or partial suspension of production, distribution, manufacturing, or clinical trials, operating restrictions, injunctions, suspension of licenses, fines, and criminal penalties.

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.

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. 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. 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 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, (collectively, the ACA) also imposed new reporting and disclosure requirements on drug manufacturers for any "transfer of value" made or distributed to teaching hospitals and physicians (as defined by statute), and any ownership or investment interested held by such physicians and their immediate family members during the preceding calendar year. Beginning in 2022, such reporting obligations will extend to any payments and other transfer of value made during the prior calendar year to certain other health care professionals, including physician assistants and nurse practitioners. Failure to submit required information may result in civil monetary penalties for any payments, transfers of value or ownership or investment interests not reported in an annual submission, and additional penalties for "knowing failures". 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.

Violations of any of these laws or other governmental regulations may result in civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, individual imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements or oversight if the drug manufacturer becomes subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment or restructuring of its operations.

Data Privacy and Security Laws

We and our collaborators and third-party providers may be subject to federal, state and foreign data privacy and security laws and regulations. In the United States, numerous federal and state laws and regulations, including

health information privacy laws, data breach notification laws, and consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), 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 and third-party service providers. For example, we may be subject to, or our marketing activities may be limited by, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and regulations implemented thereunder, which establishes a set of national privacy and security standards for the protection of protected health information by "covered entities" (health plans, health care clearinghouses and certain health care providers) and the "business associates" with whom such covered entities contract for services that involve creating, receiving, maintaining or transmitting protected health information.

In addition, certain state and non-U.S. laws, such as the California Consumer Privacy Act of 2018 (CCPA), the California Privacy Rights Act (CPRA) and the EU General Data Protection Regulation (GDPR), govern the privacy and security of personal information, including health-related information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. In addition, the GDPR increases the scrutiny of transfers of personal data from clinical trial sites located in the EEA to the United States and other jurisdictions that the European Commission does not recognize as having "adequate" data protection laws; in July 2020, the Court of Justice of the European Union limited how organizations could lawfully transfer personal data from the EEA to the United States by invalidating the EU-US Privacy Shield and imposing further restrictions on use of the standard contractual clauses, which could increase our costs and our ability to efficiently process personal data from the EEA. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

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 ACA 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 now provide 70% 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.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA. By way of example, the Tax Cuts and Jobs Acts, or Tax Act, was enacted, which, among other things, removes penalties for not complying with the individual mandate to carry health insurance. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the entire ACA is invalid based primarily on the fact that the Tax Act repealed the tax-based shared responsibility payment imposed by the ACA, on certain individuals who fail to maintain qualifying health coverage for all or part of a year, which is commonly referred to as the "individual mandate". On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the district court's decision that the individual mandate was unconstitutional but remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court is currently reviewing the case, although it is unclear how the Supreme Court will rule. It is unclear how other efforts, if any, to challenge, repeal or replace the ACA will impact the law.

Other legislative changes have also been proposed and adopted in the United States since the ACA 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 2030, with the exception of a

temporary suspension from May 1, 2020 through March 31, 2021, 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, and/or continue to put pressure on pharmaceutical pricing, as well as increase our regulatory burdens and operating costs, any of 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.

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.

Human Capital

As of December 31, 2020, we had 218 full-time employees, consisting of 168 employed in the United States, 47 employed in the United Kingdom and other European countries and three in Japan. Of these employees, 100 were engaged primarily in product development, quality assurance and clinical development and regulatory activities, 58 were engaged primarily in sales and commercialization activities, seven were engaged primarily in manufacturing, and the remaining 53 were engaged primarily in management and general and administrative activities.

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.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, and incentivizing our management team and our clinical, scientific and other employees and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and motivate personnel through the granting of stock-based and cash-based compensation awards, in order to align our interests and the interests of our stockholders with those of our employees and consultants.

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 5959 Horton Street, Suite 500, 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 free of charge 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 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 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 Fintepla as commercial product and as a product candidate in other indications as well as our product candidate MT1621. We cannot be certain that Fintepla will receive additional regulatory approvals we may pursue, or be successfully commercialized, or whether MT1621 or any future product candidates will receive regulatory approval or be successfully commercialized.

Our business depends substantially on the successful commercialization of Fintepla, and the development and commercialization of Fintepla for additional indications or other changes and of MT1621. Although Fintepla has been approved in the United States and Europe for the treatment of seizures associated with Dravet syndrome in patients two years of age and older, we may not be able to obtain supplemental approvals for Fintepla or obtain initial approvals for MT1621 in the future. Accordingly, Fintepla, MT1621 and any future 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 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 an NDA or NDA supplement 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.

For example, MT1621 has been evaluated in a Phase 2 retrospective treatment clinical study called RETRO, which demonstrated increased survival probability and improved functional abilities for patients treated with MT1621 compared with untreated natural history control patients. However, the FDA or EMA may disagree with the design of the RETRO and the reliance on a natural history dataset as the comparator, and we may be required to conduct additional trials prior to seeking regulatory approval.

Obtaining regulatory approval for a product candidate is a lengthy, expensive and uncertain process, and may not be successful. Any failure to obtain regulatory approvals for MT1621 or any future product candidate, and any supplemental approvals for Fintepla, 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 MT1621 and would have a material and adverse impact on our business.

Even if we successfully obtain additional regulatory approvals to market Fintepla, or initial approvals to market MT1621, 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.

We may not be successful in executing our sales and marketing strategy for the commercialization of Fintepla.

We have built a highly specialized and focused commercial sales and marketing organization, including sales, marketing and customer support functions, to commercialize Fintepla in the United States and Germany, our first market in Europe. We will need to build a commercial sales and marketing organization to launch and commercialize Fintepla in other markets if we are able to secure appropriate marketing and reimbursement approvals. Prior to commercial launch of Fintepla, we had no prior experience in the marketing and sale of a rare disease product, and there are significant risks involved in managing a sales organization, including our ability to retain and incentivize qualified individuals, provide adequate training to sales and marketing personnel, generate

sufficient sales leads, effectively manage a sales and marketing team, and handle any unforeseen costs and expenses. In addition, even if our self-commercialization strategy works in one market, such strategy may not be successful in other markets. If we are unable to successfully maintain our sales and marketing organization, implement our commercialization plans and facilitate adoption by patients and physicians of Fintepla, then we will not be able to generate significant revenue which will have a material adverse effect on our business, results of operations, financial condition and prospects.

We depend on a sole specialty distributor, our customer, for distribution of Fintepla in the United States, and the failure of this specialty distributor to distribute Fintepla effectively would adversely affect sales of Fintepla.

We rely on our only customer, a specialty distributor for the distribution of Fintepla in the United States. Our customer subsequently resells our product through its related specialty pharmacy provider to patients and health care providers. A specialty pharmacy is a pharmacy that specializes in the dispensing, and a specialty distributor is a distributor that specializes in the distribution, of medications for complex or chronic conditions, which often require a high level of patient education, physician administration and ongoing management. The use of a specialty distributor who distributes Fintepla through its related specialty pharmacy provider to patients and health care providers involves certain risks, including, but not limited to, risks that our customer will:

- not provide us accurate or timely information regarding their inventories, the number of patients who are using our product or complaints about our product;
- reduce or discontinue their efforts to sell or support or otherwise not effectively sell or support our product;
- not devote the resources necessary to sell our products in the volumes and within the time frames that we expect;
- engage in unlawful or inappropriate business practices that result in legal or regulatory enforcement activity which could result in liability to us or damage the goodwill within the Dravet syndrome community associated with Fintepla; and
- be unable to satisfy financial obligations to us or others.

In the event that our customer does not fulfill its contractual obligations to us or refuses to or fails to adequately perform distribution of Fintepla to patients and healthcare providers, or the agreements with us are terminated without adequate notice, shipments of Fintepla, and associated revenues, would be adversely affected.

Further, if our customer becomes subject to bankruptcy, is unable to pay us for our products or is acquired by a company that wants to terminate the relationship with us, or if we otherwise lose our relationship with our customer, our revenue, results of operations and cash flows would be adversely affected. If our customer cannot perform as agreed or the relationship is otherwise terminated, we may be unable to replace them on a timely basis or at all. Even if we are able to replace our customer with a different specialty distributor/customer, such transition could result adversely affect our results of operations and cash flows.

Our business is subject to risks arising from epidemic diseases, such as the COVID-19 pandemic.

The current COVID-19 worldwide pandemic has presented substantial public health and economic challenges and is affecting our employees, patients, communities and business operations, as well as the U.S. and global economy and financial markets. International and U.S. governmental authorities in impacted regions are taking actions to slow the spread of COVID-19, including issuing varying forms of “stay-at-home” orders, and restricting business functions outside of one’s home. In response, we closed our offices for all but the most essential activities and have implemented a policy allowing all employees to work from across all locations, following the guidelines or directives issued by federal, state and local government agencies in the U.S. as well as the U.K. government. As a result of these restrictions, our sales force has not been able to conduct in-person interactions with physicians and healthcare providers and have been restricted to primarily conducting educational and promotional activities for Fintepla virtually, which may impact our ability to market Fintepla. To date, we have been able to continue to supply Fintepla commercially to our patients in the U.S. and Germany and both Fintepla and MT1621 to our patients currently enrolled in our clinical trials and we do not currently anticipate any interruptions in clinical or commercial supply. In addition, while we are continuing the clinical trials we have underway in sites across the globe, we expect that COVID-19 precautions may directly or indirectly impact the timeline for some of our clinical trials. As the COVID-19 pandemic continues to spread around the globe, we may experience disruptions that could severely impact our business, clinical trials and manufacturing and supply chains, including:

- an inability to effectively market Fintepla or interruptions in patient site access as part of our REMS program;
- further delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures, which may impact the integrity of subject data and clinical study endpoints;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems, including interruption of commercial supply;
- delays or inability of us or our independent registered public accounting firm to count and/or observe the counts of our physical inventories;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials and interruption in global shipping that may affect the transport of clinical trial materials;
- limitations on employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- delays in receiving feedback or approvals from the FDA, EMA or other regulatory authorities with respect to future clinical trials or regulatory submissions, including for MT1621;
- changes in local regulations as part of a response to COVID-19 which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue such clinical trials altogether;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;
- refusal of the FDA or EMA to accept data from clinical trials in certain geographies; and
- difficulties launching or commercializing products, including due to reduced access to doctors as a result of social distancing protocols.

In addition, the spread of COVID-19 has had and may continue to severely impact the trading price of shares of our common stock and could further severely impact our ability to raise additional capital on a timely basis or at all.

The COVID-19 pandemic continues to rapidly evolve. The extent to which the COVID-19 may impact our business, including our commercial sales, clinical trials, manufacturing and supply chains and financial condition will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the geographic spread of certain variants of the disease that may be less susceptible to available vaccines, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

To the extent the COVID-19 pandemic adversely affects our business and financial results, many of the other risks described in this “Risk Factors” section may be heightened.

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

Our product candidates are prone to the risks of failure inherent in drug development. Before obtaining U.S. regulatory approval for a product candidate 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 our product candidates are 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 our product candidates may not necessarily be predictive of the results of future clinical trials or preclinical studies. The results of prior clinical trials of our product candidates may not be replicated in any future clinical trials of these product candidates. 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 our product candidates, the development timeline and regulatory approval and commercialization prospects for our product candidates and our business and financial prospects, would be adversely affected.

Further, Fintepla may not be approved for LGS even though recent, positive topline results from our ongoing Phase 3 trial of Fintepla for LGS showed that Fintepla met its primary and certain key secondary endpoints. Similarly, MT1621 may not be approved even though the RETRO data demonstrated improved survival probability of patients treated with MT1621 compared with a natural history patient control group. 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, including with the design of the Phase 2 retrospective study comparing the outcomes from the MT1621 active treatment group against outcomes from a natural history dataset. 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.

Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or topline data from our clinical studies, which are based on preliminary analyses of then-available data. Such preliminary results and related findings and conclusions are subject to change following more comprehensive reviews 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 topline 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. Topline 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, topline data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our clinical studies. Interim data from this clinical trial and future clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues, following more comprehensive reviews of the data, and as more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses of data from preclinical studies or clinical trials of its product candidates, or may interpret or weigh the importance of data differently, which could impact the value of the particular product candidate, the approvability or prospects for commercialization of the product candidate, or our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and stockholders and others may not agree with what we determine is the

material or otherwise appropriate information to include in our disclosure. Information that we decide not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product, product candidate or our business. If the interim, topline or preliminary data that we disclose differ from actual results, or if others, including regulatory authorities, disagree with the conclusions we reach based on our analyses of such data, 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 MT1621 or pre-clinical or clinical testing for any future product candidates could result in increased costs to us and delay or limit our ability to pursue regulatory approvals 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 MT1621 or pre-clinical or clinical testing for any future product candidates could significantly affect our product development costs and business plan.

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 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 or MT1621 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, 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, MT1621 and any future product candidates may be harmed, which may 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 any of our product candidates' indications 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 marketing products and obtaining regulatory approvals for product candidates and other resources than we do.

For example, Fintepla competes against other products and product candidates approved and in development for the treatment of Dravet syndrome. 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. GW's CBD was subsequently approved for the treatment of Dravet syndrome and LGS by the European Commission (as Epidyolex®) in September of 2019. 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. Multiple companies are developing clinical-staged product candidates for the potential treatment of Dravet syndrome. 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. Additional clinical stage candidates for the treatment of Dravet syndrome include Ataluren from PTC Therapeutics (exploratory Phase 2), Huperzine-A from Supernus Pharmaceuticals (Phase 1/2), and clemizole (Phase 1) being evaluated by Epygenix Therapeutics, Inc.

We expect Fintepla 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. While we currently are not aware of any pharmaceutical companies who are developing a pharmaceutical product candidate for the treatment of TK2d that would compete against MT1621, 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 or MT1621, if approved, 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 in Dravet syndrome or, if approved, in other indications, or of MT1621, 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 are critical for commercial success. The degree of market acceptance of Fintepla or 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.

Breakthrough therapy designation and access to the PRIME scheme for MT1621 may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that MT1621 or any of our product candidates will receive marketing approval.

In February 2019, the FDA granted breakthrough therapy designation for MT1621 in the United States for the treatment of TK2d. 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. 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 though MT1621 qualifies as a breakthrough therapy, the FDA may later decide that MT1621, or any of our other product candidates that may qualify as a breakthrough therapy, 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 rescinded breakthrough therapy designation for Fintepla for Dravet syndrome due to the existence of two recently approved therapies for Dravet syndrome and, therefore, the administrative criteria for designation were no longer met.

The EMA has established the PRIME scheme to expedite the development and review of product candidates that show a potential to address to a significant extent an unmet medical need, based on early clinical data. In November 2018, the EMA admitted MT1621 to the PRIME scheme for the treatment of patients with TK2d was admitted to the PRIME scheme of the EMA. Even though we have access to PRIME for MT1621, this may not result in a materially faster development process, review or approval compared to conventional EMA procedures. Further, obtaining access to PRIME does not assure or increase the likelihood of EMA's grant of a marketing authorization (MA).

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 have sought and may seek FDA approval in the future 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 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 $1.3 billion as of December 31, 2020. During the year ended December 31, 2020, net cash used in operating activities was $167.5 million. 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 and MT1621. Additionally, in the event that MT1621 is approved in the United States or the EU, we will owe milestone payments related to our 2019 acquisition of development and commercialization rights to MT1621. Our ability to generate revenues from Fintepla or MT1621, if approved, will depend on a number of factors including our ability to successfully complete clinical trials, obtain necessary regulatory approvals in target countries 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 or MT1621, if approved, or any future 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 and planned Phase 3 programs for Fintepla and our clinical development program of MT1621. 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 GCP requirements for clinical studies of our product candidates, and 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 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 September 2019, we completed the acquisition of Modis, which owns worldwide development and commercialization rights to MT1621. 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 do not own or operate manufacturing facilities and have no plans to build our own clinical or commercial scale manufacturing capabilities. We outsource all manufacturing and packaging of the clinical trial materials for Fintepla and MT1621 to third parties and will rely on third parties for commercial manufacturing and packaging of Fintepla, and for MT1621, if approved. In February 2019, we entered into a master supply agreement with Aptuit, pursuant to which Aptuit became our commercial manufacturer and supplier of the fenfluramine API. In addition, in July 2019 we entered into the PCI Pharma Agreement, pursuant to which PCI Pharma became our commercial manufacturer and supplier for Fintepla. We may never be able to establish additional sources of supply for Fintepla.

The facilities used by third-party manufacturers to manufacture our product candidates must be approved by the FDA or other regulatory agencies pursuant to inspections that will be conducted after we submit a an NDA to the FDA or their equivalent to other regulatory agencies. We do not control the manufacturing process of, and are completely dependent on, third-party manufacturers for compliance with cGMP requirements for manufacture of our drug products. If these third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, including requirements related to the manufacturing of high potency and pure compounds or other products, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates, or if regulatory authorities withdraw any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market Fintepla or our other product candidates, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. Our or a third-party's failure to execute on our manufacturing requirements, to do so on commercially reasonable terms, or to comply with cGMP could adversely affect our business in a number of ways, including an inability to initiate or continue clinical trials of any future product candidates under development, delays in submitting regulatory applications, or receiving marketing approvals, for our product candidates, requirements to cease development or to recall batches of our product candidates, and an inability to meet commercial demands for Fintepla or our other products, if approved. In addition, 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, 2020, we had 218 full-time employees, consisting of 168 employed in the United States, 47 employed in the United Kingdom and other European countries and three in Japan. Of these employees, 100 were engaged primarily in product development, quality assurance and clinical development and regulatory activities, 58 were engaged primarily in sales and commercialization activities, seven were engaged primarily in manufacturing, and the remaining 53 were engaged primarily in management and general and administrative activities. 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 have our headquarters. 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 (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 continued development and commercialization of Fintepla and our other 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.

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 Fintepla or 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 Fintepla and 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 (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 be unable to obtain regulatory approvals for or commercialize MT1621 or any future product candidates outside of the United States.

We intend to market Fintepla and if approved, MT1621 outside of the United States. 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" and those disclosed in Part I, Item 1A of our 2018 Annual Report on Form 10-K regarding FDA approval in the United States, as well as other risks.

For example, in the European Economic Area (EEA), which is comprised of 28 EU member states plus Iceland, Liechtenstein, and Norway, medicinal products can only be commercialized after obtaining a 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 an MAA 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.

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

Following a national referendum and enactment of legislation by the government of the UK, the UK formally withdrew from the EU on January 31, 2020 and entered into a transition period during which it will continue its ongoing and complex negotiations with the EU relating to the future trading relationship between the parties. Significant political and economic uncertainty remains about whether the terms of the relationship will differ materially from the terms before withdrawal, as well as about the possibility that a so-called "no deal" separation will occur if negotiations are not completed by the end of the transition period.

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 may significantly reduce global market liquidity, restrict the ability of key market participants to operate in certain financial markets or restrict our access to capital. In addition, 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. Any of these factors could have a material adverse effect on our business, financial condition and results of operations and reduce the price of our common stock.

Risks Related to Our Financial Position and Capital Requirements

We have incurred significant operating losses and negative cash flows from operations since inception and are dependent upon external sources of financing to fund our business and development.

We currently have limited collaboration revenue under an arrangement with Nippon Shinyaku Co., Ltd. We commenced the commercial launch of Fintepla in the United States in July 2020 and in Germany in February 2021,

which have produced limited revenue to date. We have financed our operations primarily through the proceeds from the issuance of equity securities and debt, and have incurred negative cash flow from operations in each year since our inception. For the years ended December 31, 2020, 2019 and 2018, we incurred net losses of $209.4 million, $419.5 million and $123.9 million, respectively, and our cash used in operating activities was $167.5 million, $111.5 million and $111.7 million, respectively. As of December 31, 2020, we had an accumulated deficit of $1.3 billion. The net 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 may 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 Fintepla and any other 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.

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 indebtedness and liabilities could limit the cash flow available for our operations, expose us to risks that could adversely affect our business, financial condition and results of operations and impair our ability to satisfy our obligations under the Convertible Senior Notes.

In September 2020, we issued $200.0 million aggregate principal amount of our Convertible Senior Notes in a private offering exempt from registration under the Securities Act of 1933. In connection with the offering, we granted the initial purchasers an option to purchase up to an additional $30.0 million in principal amount of Convertible Senior Notes, which was exercised in full in October 2020. We may also incur additional indebtedness to meet future financing needs. Our indebtedness could have significant negative consequences for our security holders and our business, results of operations and financial condition by, among other things:

- increasing our vulnerability to adverse economic and industry conditions;
- limiting our ability to obtain additional financing;
- requiring the dedication of a substantial portion of our cash flow from operations to service our indebtedness, which reduces the amount of cash available for other purposes;
- limiting our flexibility to plan for, or react to, changes in our business;
- diluting the interests of our existing stockholders as a result of issuing shares of our common stock upon conversion of the Convertible Senior Notes; and
- placing us at a possible competitive disadvantage with competitors that are less leveraged than us or have better access to capital.

Our business may not generate sufficient funds, and we may otherwise be unable to maintain sufficient cash reserves, to pay amounts due under our indebtedness, including the Convertible Senior Notes, and our cash needs may increase in the future. In addition, any future indebtedness that we may incur may contain financial and other restrictive covenants that limit our ability to operate our business, raise capital or make payments under our other indebtedness. If we fail to comply with these covenants or to make payments under our indebtedness when due, then we would be in default under that indebtedness, which could, in turn, result in that and our other indebtedness becoming immediately payable in full.

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. Concerns over inflation, energy costs, geopolitical issues, public health emergencies, the availability and cost of credit, and the U.S. financial markets have in the past contributed to, and may continue in the future to contribute to, increased volatility and diminished expectations for the economy and the markets. For example, the COVID-19 pandemic has impacted the global economy, including limiting global travel, impacting our operations and the operations of the third-parties we work with. The extent to which the COVID-19 pandemic will impact our results of operations will depend on future developments, which are highly uncertain and cannot be predicted, including the progress on the distribution of vaccinations in the locations where we operate, new information which may emerge concerning the severity of any variants of COVID-19 and the actions to contain COVID-19 or treat its impact, among others. In addition, 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, in May 2016, we entered into an at-the-market sales agreement (the ATM Sales Agreement), with Cantor Fitzgerald & Co. (Cantor), pursuant to which Cantor agreed to act as a sales agent in connection with sale of our common stock from time to time pursuant to an effective registration statement. In June 2020, we filed a prospectus supplement (the 2020 ATM Prospectus), to our automatic "shelf" registration statement on Form S-3 registering the offering, issuance and sale of up to $200.0 million in gross aggregate proceeds of common stock pursuant to the 2016 Sales Agreement. As of December 31, 2020, there was $194.9 million remaining for future sales under the 2020 ATM Prospectus. 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 U.K. tax legislation.

As a company that carries out extensive research and development activities, we benefit from the U.K.'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 U.K. 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 U.K. 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 U.K.'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 U.K.'s SME R&D tax relief scheme in the future as we increase our personnel and expand our business because we may no longer qualify as an SME. In order to qualify as an SME for R&D tax credits, we must continue to be a company with fewer than 500 employees and also have either an annual turnover not exceeding €100 million or a balance sheet not exceeding €86 million. We may also benefit in the future from U.K.'s R&D Expenditure Credit scheme, or the RDEC scheme, available to larger companies. However, the RDEC scheme has a significantly lower credit than the SME scheme. In addition, changes in U.K. tax legislation may reduce or limit any future claims. For example, a policy paper was published on October 29, 2018 setting out HMRC's intention from April 2020 to cap the amount of cash rebate that a qualifying loss-making business can receive in any one year under the research and development tax credit regime for SMEs at three times the company's total liability for National Insurance contributions and income tax under the Pay As You Earn system.

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 (the Code), 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 disallowed business interest deductions) (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 rolling 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. Although we have experienced several ownership changes in the past, we do not anticipate that the limitations arising from prior ownership changes will significantly impact our ability to utilize our net operating losses and tax credit carryforwards. We may also experience ownership changes in the future, however, which could limit the use of our tax attributes and have an adverse effect on our consolidated results of operations. In addition, pursuant to the Tax Cuts and Jobs Act of 2017 (Tax Act), as modified by the Coronavirus Aid, Relief and Economic Security Act, we may not use net operating loss carryforwards arising in taxable years beginning after December 31, 2017 to reduce our taxable income by more than 80% in any taxable year beginning after December 31, 2020. These limitations may require us to pay federal income taxes in future years despite generating a loss for federal income tax purposes in prior years.

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

As of December 31, 2020, our cash, cash equivalents and marketable securities totaled $251.2 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, MT1621 and any of our future product candidates are subject to extensive regulation.

Fintepla is approved in the United States for the treatment of seizures associated with Dravet syndrome in patients two years and older, and we currently are developing Fintepla for the treatment of seizures associated with LGS and CDKL5 Deficiency Disorder (CDD), and are developing MT1621 for the treatment of TK2d. 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.

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 for its proposed indication;
- 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.

Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA approval. We cannot guarantee that the FDA will interpret trial results as we do, and more trials could be required before we are able to submit applications seeking approval of our product candidates. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Of the large number of drugs in development, only a small percentage successfully complete the regulatory approval processes and are commercialized. This lengthy approval process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain additional regulatory approvals to market Fintepla, or our failure to obtain initial regulatory approvals to market MT1621 or any other product candidate, which would significantly harm our business, results of operations and prospects.

In addition, the FDA may approve a product candidate for a more limited indication or patient population than we originally requested, and the FDA may approve a product candidate with a REMS or a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. For example, the FDA approved Fintepla for the treatment of seizures associated with Dravet syndrome subject to the Fintepla REMS program, which requires echocardiogram assessments of patients before, during, and after treatment with Fintepla. The FDA may also grant approval contingent on the performance of costly post-marketing clinical trials. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

We may not be able to maintain orphan drug designation or obtain or maintain orphan drug exclusivity for Fintepla or MT1621.

We have obtained orphan drug designation for Fintepla in the United States and Europe for both the treatment of Dravet syndrome and LGS. We have also received orphan drug designation for MT1621 for the treatment of TK2d. 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 or MT1621 has incremental benefit over any other approved product for that orphan disorder. 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.

Use of our product candidates could be associated with side effects, adverse events or other properties or safety risks, which could delay or preclude approval, cause us to suspend or discontinue clinical trials, abandon a product candidate, limit the commercial profile of the label for an approved product candidate, or result in other significant negative consequences that could severely harm our business, prospects, operating results and financial condition.

Results of our clinical trials could reveal a high and unacceptable severity and prevalence, or unexpected characteristics of side effects. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials, result in a more restrictive label for the product candidate, or delay or cause the denial of regulatory approval of the product candidate by the FDA or comparable foreign regulatory authorities. The drug-related side effects could also affect patient recruitment for our clinical trials, or the ability of enrolled patients to complete the trials, or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Moreover, if our product candidates are associated with undesirable side effects in clinical trials or have characteristics that are unexpected, we may elect to abandon their development or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the commercial prospects for the product candidate if approved. We may also be required to modify our plans for future studies based on findings in our ongoing clinical trials. Many compounds that initially showed promise in early-stage testing have later been found to cause side effects that prevented further development of the compound. In addition, regulatory authorities may draw different conclusions or require additional testing to confirm these determinations.

Additionally, if we or others identify undesirable side effects, or other previously unknown problems, caused by Fintepla, or by MT1621 or any of our future product candidates, if approved, a number of potentially significant negative consequences could result, including:

- regulatory authorities may not approve, or may withdraw their approval of 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 implement a REMS or 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.

Even though we have obtained regulatory approval for Fintepla, and even if we obtain approval for MT1621 or any other product candidate, we will remain subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions on marketing or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates, when and if any of them are approved.

Following potential approval of any of our product candidates, the FDA may impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly and time-consuming post-approval studies, post-market surveillance or clinical trials to monitor the safety and efficacy of the product. The FDA may also require a REMS as a condition of approval of our product candidates, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. For example, the FDA approved Fintepla for the treatment of seizures associated with Dravet syndrome subject to the Fintepla REMS program, which among other things, requires echocardiogram assessments of patients before, during, and after treatment with Fintepla. In addition, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our products will be subject to extensive and ongoing regulatory requirements following approval. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCP requirements for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with our products, including adverse events of unanticipated type, severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- restrictions on product distribution or use, or requirements to conduct post-marketing studies or clinical trials;
- fines, restitutions, disgorgement of profits or revenues, warning letters, untitled letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications we filed or suspension or revocation of approvals;

- product seizure or detention, or refusal to permit the import or export of our products; and
- injunctions or the imposition of civil or criminal penalties.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

In addition, the product labeling, advertising and promotion for Fintepla, and for any of our product candidates that may receive approval, will be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about drug products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. For example, the FDA-approved label for Fintepla is limited to the treatment of seizures associated with Dravet syndrome in patients two years of age and older. Physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. 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 sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

The FDA and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. For example, the results of the 2020 U.S. Presidential Election may impact our business and industry. Namely, the Trump administration took several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict whether or how these orders will be implemented, or whether they will be rescinded and replaced under the Biden administration. The policies and priorities of the new administration are unknown and could materially impact the regulations governing our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, 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, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the FDA 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 or modifications to approved 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.

Separately, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most foreign inspections of manufacturing facilities, and subsequently, on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020 the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Regulatory authorities outside the United States may adopt

similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

The successful commercialization of Fintepla and our product candidates will depend in part on the extent to which third-party payors, including governmental authorities and private health insurers, provide funding, establish favorable coverage and pricing policies, and set adequate reimbursement levels. Failure to obtain or maintain coverage and adequate reimbursement for Fintepla or any of our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

Our ability to commercialize Fintepla and any of our product candidates successfully, particularly in orphan or rare disease indications, will depend in part on the availability of favorable coverage and the adequacy of reimbursement for the product and alternative treatments from third-party payors (e.g., governmental authorities, private health insurers and other organizations). Obtaining coverage and adequate reimbursement is contingent on our ability to:

- obtain clinical data that supports payor value/benefit assessments;
- execute formal payor value/benefit assessment processes;
- obtain coverage that enables use in populations reflected in any product candidate's approved product label; and
- effectively negotiate favorable pricing and reimbursement terms.

While in some markets, there is a single payor, in other markets there are multiple payors that can have different ways of assessing prescription drugs. To commercialize our product candidates successfully, we will be required to have sufficient expertise and resources to execute on the respective product candidate's coverage and reimbursement strategy, which we cannot be certain we will be able to do.

Governmental authorities, private health insurers and other third-party payors have attempted to control costs by delaying the time to reimbursement, and by restricting the breadth of patient-coverage and limiting the amount of reimbursement for particular products in terms of lower pricing and increasing the proportion of the cost for which the patient is responsible. There may be significant delays in obtaining reimbursement for newly approved products or product indications, coverage may be more limited than the purposes for which the product is approved by the FDA or similar regulatory authorities outside the United States, and reimbursement rates may vary according to the use of the product and the clinical setting in which it is used. Coverage and reimbursement barriers by payors may materially impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available, or available only at limited levels, or if such coverage will require patient out-of-pocket costs that are unacceptably high, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval. Moreover, any coverage or reimbursement that may be obtained may be decreased or eliminated in the future.

Third-party payors continue to introduce new tactics to contain costs, including more rigorous value/benefit assessment processes and criteria. It is possible that third-party payors will change the clinical comparators that serve as benchmarks for determining relative value. The result of such a change would be a more challenging value/benefit assessment caused by a more challenging basis for comparison and the potential for a worse relative outcome. Third-party payors may determine that we have failed to generate sufficient evidence to support a value/benefit assessment and refuse to provide coverage and reimbursement, thereby impacting or preventing the progression to a price negotiation. The potential of third-party payors to introduce more rigorous value/benefit assessment processes and criteria could have a negative impact on our ability to commercialize our product candidates successfully.

Third-party payors are also introducing more challenging price negotiation tactics, including in re-visiting established coverage and reimbursement in cases when new competitors, including brands, generics and biosimilars enter the market. It is possible that a third-party payor may consider our product candidates as substitutable and only offer to cover the cost of the alternative product. Even if we show improved efficacy or improved convenience of administration with Fintepla or any our product candidates, if approved, pricing of competitive products may limit the amount we will be able to charge for our product candidates. Third-party payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed

products at levels that are too low to enable us to realize an appropriate return on our investment in our products. In some cases, when new competitor generic and biosimilar products enter the market, there are mandatory price reductions for the innovator compound, in other cases, payors employ “therapeutic category” price referencing and seek to lower the reimbursement levels for all treatment in the respective therapeutic category. In other cases, new competitor brand drugs can trigger therapeutic category reviews in the interest of modifying coverage and or reimbursement levels. The potential of third-party payors to introduce more challenging price negotiation tactics could have a negative impact on our ability to commercialize our product candidates successfully.

Evolving health policy and associated legislative changes related to coverage and reimbursement aimed at lowering healthcare expenditure could impact the commercialization of Fintepla and our product candidates. Pharmaceutical pricing has been, and likely will continue to be, a central component of these efforts.

The regulations that govern regulatory approvals, pricing and reimbursement for new pharmaceutical products vary widely from country to country. In markets of some countries we may pursue outside of the United States for any of our product candidates, the products may be subject to extensive governmental price control or other price regulations. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country, but then be subject to price negotiations that delay our commercial launch of the product candidate, possibly for lengthy time periods, which may negatively impact the revenues we are able to generate from the sale of the product candidate in that country. Adverse pricing and reimbursement limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval.

Net prices for products may be reduced by mandatory discounts or legislated rebates that must be paid in order to participate in government healthcare programs or paid to other third-party payors. Mandatory discounts can be legislated at any time in any market. Similarly, some markets currently have pricing legislation that sets the price of a pharmaceutical product in their market by referencing the price of that product in other markets, known as international reference pricing. International reference pricing has the potential to impact price cuts in individual countries and the countries that reference the pricing of certain other individual countries. Expansion of mandatory discounts and international reference pricing, including into the United States, presents a material risk to our ability to achieve favorable pricing and adequate reimbursement.

Drug importation and cross-border trade, both sanctioned and unsanctioned, occurs when a pharmaceutical product from a market where the official price is set lower is shipped and made commercially available in a market where the official price is set higher. Any future relaxation of laws that presently restrict or limit drug importation or cross-border trade, including in the United States, could have a material negative impact on our ability to commercialize our product candidates, if approved.

We expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and biologics and surgical procedures and other treatments, has become intense. As a result, we may not be able to achieve or sustain favorable pricing for our product candidates and adequate reimbursement.

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 Fintepla or 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 ACA, was signed into law, which included measures to significantly change the way health care is financed by both governmental and private insurers. Among the provisions of the ACA 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 now agree to offer point-of-sale discounts of 70% 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;
- 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.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA. By way of example, the Tax Act was enacted, which, among other things, removes penalties for not complying with the ACA's individual mandate to carry health insurance. 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 ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court's decision that the individual mandate was unconstitutional but remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court is currently reviewing the case, although it is unclear how the Supreme Court will rule. It is also unclear how other efforts, if any, to challenge, repeal or replace the ACA will impact the law or our business.

Other legislative changes have also been proposed and adopted in the United States since the ACA 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 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2021, 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.

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 EU, 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 EU or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, 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 EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU 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 EU, 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 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 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;
- federal civil and criminal false claims laws, including the False Claims Act, 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. 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 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;
- 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;
- federal "sunshine" requirements that require drug manufacturers to report and disclose any "transfer of value" made or distributed to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other health care professionals beginning in 2022, 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
- similar healthcare laws and regulations in the EU and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers.

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.

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

Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could adversely affect our business, results of operations, and financial condition.

The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal and foreign laws, requirements and regulations governing the collection, use, disclosure, retention, and security of personal data. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business,

affect our ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulation, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our operations, financial performance and business.

As our operations and business grow, we may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities. In the U.S., HIPAA imposes, among other things, certain standards relating to the privacy, security, transmission and breach reporting of individually identifiable health information. Certain states have also adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. In addition, the California Consumer Privacy Act of 2018 (CCPA) went into effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability, and many similar laws have been proposed at the federal level and in other states. Further, the California Privacy Rights Act (CPRA) recently passed in California. The CPRA will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

In Europe, the GDPR went into effect in May 2018 and imposes strict requirements for processing the personal data of individuals within the EEA. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. In addition, the GDPR increases the scrutiny of transfers of personal data from clinical trial sites located in the EEA to the United States and other jurisdictions that the European Commission does not recognize as having “adequate” data protection laws; in July 2020, the Court of Justice of the European Union limited how organizations could lawfully transfer personal data from the EEA to the United States by invalidating the EU-US Privacy Shield and imposing further restrictions on use of the standard contractual clauses, which could increase our costs and our ability to efficiently process personal data from the EEA. Further, from January 1, 2021, we are subject to the GDPR and also the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, e.g. fines up to the greater of €20 million (£17.5 million) or 4% of global turnover. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear, and it is unclear how UK data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the United Kingdom will be regulated in the long term. Currently there is a four to six-month grace period agreed in the EU and UK Trade and Cooperation Agreement, ending June 30, 2021 at the latest, whilst the parties discuss an adequacy decision. However, it is not clear whether (and when) an adequacy decision may be granted by the European Commission enabling data transfers from EU member states to the United Kingdom long term without additional measures. These changes will lead to additional costs and increase our overall risk exposure.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, collaborators, or other third parties to comply with such requirements or adequately address privacy and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation, and adversely affect our business and results of operations.

Risks Related to Our 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 (the Universities).

Prior to receiving rights to four 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 composition of matter patents covering the API in Fintepla have expired and therefore it is not subject to patent protection. With respect to our MT1621 product candidate, we have certain patent rights that we obtained through our acquisition of Modis. In September 2016, Modis entered into a license agreement (the Columbia Agreement), with Columbia, under which Modis was granted an exclusive worldwide license and sublicense to certain intellectual property rights owned or controlled by Columbia to develop and commercialize MT1621 and certain backup compounds for any application or purpose. These licensed patent rights include patents owned by Columbia and patents jointly owned by Columbia and Vall d'Hebron Research Institute (VHIR). VHIR delegated to Columbia the rights to enter into the Columbia Agreement on VHIR's behalf. The patent family jointly owned by Columbia and VHIR is directed to the use of MT1621 to treat TK2d and includes a granted U.S. patent and a granted European patent application, pending applications in Australia, Brazil, Canada, China, Hong Kong, Israel, India, Japan, Korea, Mexico and Russia, as well as continuing applications in the United States and Europe. There are no patents covering the API in MT1621.

The initial applications covering MT1621 or the 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 Fintepla and MT1621 matters 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 these matters may not have been completely familiar with U.S. patent law or the patent law in various countries, possibly resulting in inadequate disclosure, improperly claiming inventions 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 and MT1621 did not and may still not have sufficient knowledge relating to preferred procedures and the legal requirements related to the protection of intellectual property. They published papers which adversely affected our licensed rights, particularly in jurisdictions without a grace period for inventors' own disclosures. 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. Even if additional patents issue, such issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts.

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 (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 may soon become, commercially available in generic drug products, and no patent protection will be available without regard to formulation or method of use;
- the APIs in MT1621 are well-known and available commercially from many sources, and no patent protection claiming the APIs as a composition of matter will be available;
- 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 and MT1621 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 and Columbia 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 and MT1621. 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 (i) patent applications filed only in the United States may be maintained in secrecy until the patents are issued, (ii) other United States patent applications and patent applications filed in many foreign jurisdictions are typically not published until eighteen months after their filing date, (iii) 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 filed a U.S. patent application prior to March 16, 2013 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. We are currently defending an opposition to one of our patents in the European Patent Office, and in the future 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. In any such proceedings, a court or other administrative body may decide that a patent of ours is invalid, in whole or in part or construe our patent's claims narrowly resulting in a loss of our patent position. 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.

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, 2020, the price per share for our common stock on The Nasdaq Global Market has ranged from a low sale price of $16.65 to a high sale price of $57.22. 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 MT1621;
- the development status of Fintepla or MT1621, including the results from our clinical trials;
- variations in the level of expenses related to Fintepla or MT1621 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, public health crises, pandemics such as COVID-19 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 the risk factors described in this section of this Annual Report on Form 10-K, 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 and MT1621 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:

- timing and level of commercial sales of Fintepla;
- variations in the level of development and/or regulatory expenses related to Fintepla and MT1621 development programs;
- results of clinical trials for Fintepla or MT1621;
- any intellectual property infringement lawsuit in which we may become involved;
- 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.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict.

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. We commenced the commercial launch of Fintepla in the United States in July 2020 and in Germany in February 2021. Additionally, from time to time, in addition to the existing Shinyaku Agreement, we may enter into collaborative arrangements with other companies that include development funding and significant upfront and milestone payments and/or royalties, which may become an important source of our revenue. Accordingly, our revenue may depend on development funding and the achievement of development and clinical milestones under current and any potential future collaborative arrangements and sales of Fintepla and our other products, if approved. Furthermore, revenues may consist of the recognition of deferred revenue from upfront, nonrefundable payments that we received from Shinyaku or payments we may receive under future collaboration agreements and the timing of recognizing deferred revenue is subject to significant management judgments, including estimating total costs at completion. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next. As a result, any period-to-period comparisons of our operating results may not be meaningful. Accordingly, the results of any one period should not be relied upon as an indication of future performance.

We have been involved in securities class action litigation and may become involved in future 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 have in the past and may in the future become involved in securities class action litigation. 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, 2020, we had research coverage by only nine 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, 2020, we had approximately 57.3 million 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.

General Risk Factors

As a result of operating as a public company, we incur significant legal and accounting compliance costs and we are subject to the Sarbanes-Oxley Act, and we can provide no assurance that we will, at all times, in the future be able to report that our internal controls over financial reporting are effective.

As a public company, we incur significant legal, accounting and other expenses. 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. 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. In addition, we currently do not have an internal audit function, and we may in the future need to hire additional accounting and financial staff to establish such a function. Moreover, effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent fraud. If we

cannot conclude that we have effective internal controls over our financial reporting, or our independent registered public accounting firm is unable to provide an unqualified opinion regarding the effectiveness of our internal control over financial reporting, investors could lose confidence in the reliability of our financial statements. In addition, 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.

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.

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. Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. As a result of the COVID-19 pandemic, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. For example, we have been the target of cyber-attacks seeking to misappropriate our funds and have also experienced failures in our information systems and computer servers. We cannot be sure that similar cyber-attacks or 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. We have in the past experienced cyber-attacks, and 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 cyber-attack 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

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

As of December 31, 2020, our corporate headquarters, which includes executive offices and research and development and business operations, consist of approximately 37,307 square feet of leased office and laboratory space in Emeryville, California. In Maidenhead, United Kingdom, we lease approximately 7,331 square feet of office space. We also maintain limited office space for our recently formed subsidiaries in Ireland, Germany, Italy and Japan

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

See Item 8. Financial Statements—Notes to Consolidated Financial Statements—Note 12, *Commitments and Contingencies*.

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

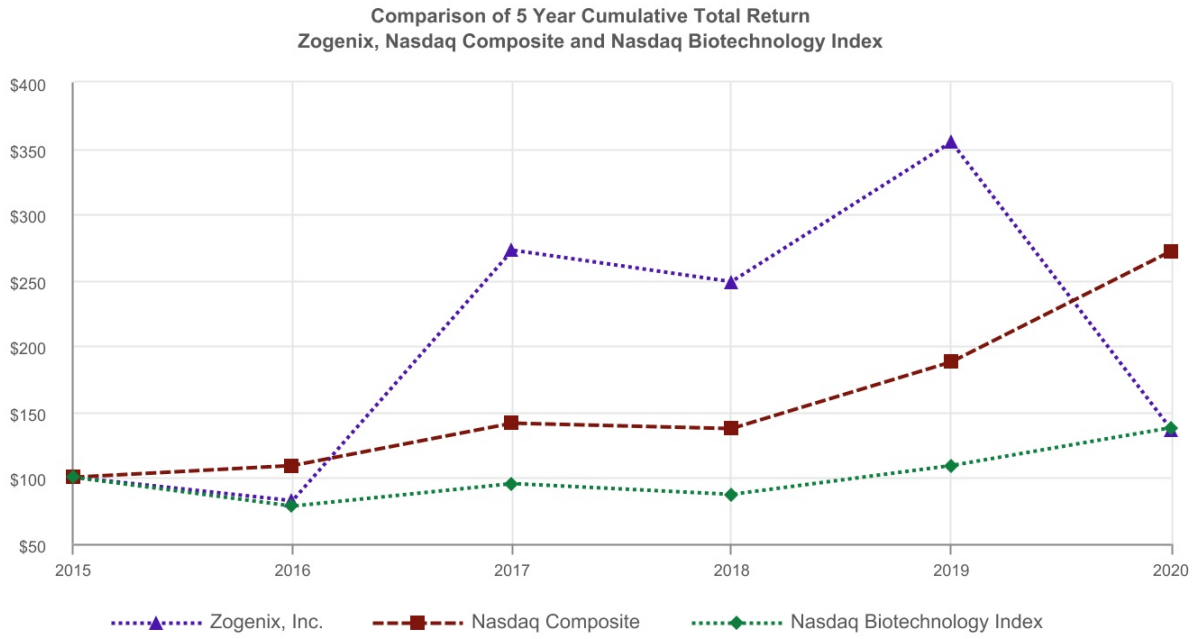
Zogenix common stock is listed on The Nasdaq Global Market under the symbol ZGNX.

Holders of Common Stock

According to the records of our transfer agent, there were nine holders of record of our common stock on February 19, 2021. 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, 2020 to the Nasdaq Composite Index and the Nasdaq Biotechnology Index. The graph assumes an initial investment of $100 on December 31, 2015, 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. RESERVED

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATION

Please read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes included under Part II, Item 8 of 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. Unless otherwise noted or the context otherwise requires, references in this Annual Report on Form 10-K to "we," "us" or "our" refer to Zogenix Inc. and its subsidiaries.

This discussion and analysis generally addresses 2020 and 2019 items and year-over-year comparisons between 2020 and 2019. Discussions of 2018 items and year-over-year comparisons between 2019 and 2018 that are not included in this Annual Report on Form 10-K can be found in Part II, Item 7 of our 2019 Annual Report on Form 10-K filed with the SEC on March 2, 2020.

Overview

We are a global biopharmaceutical company committed to developing and commercializing therapies with the potential to transform the lives of patients and their families living with rare diseases. Our first rare disease therapy, Fintepla (fenfluramine) oral solution has been approved by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for the treatment of seizures associated with Dravet syndrome, a rare, severe lifelong epilepsy. We have two additional late-stage development programs underway: Fintepla for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS), another rare epilepsy and MT1621, an investigational therapy for the treatment of TK2 deficiency (TK2d), a rare genetic disease.

We own and control worldwide development and commercialization rights to Fintepla, which was originally obtained in 2014 pursuant to an acquisition of Brabant Pharma, a privately-held U.K.-based pharmaceutical company. In March 2019, we entered into an exclusive distribution agreement with Nippon Shinyaku Co., Ltd. to distribute Fintepla in Japan, if approved for marketing in that country.

Fintepla for Patients with Rare Epilepsy Disorders

Dravet Syndrome

On June 25, 2020, the FDA granted approval of Fintepla for the treatment of seizures associated with Dravet syndrome in patients 2 years of age and older. During the third quarter of 2020, we commercially launched Fintepla through a restricted distribution program, called the Fintepla Risk Evaluation and Mitigation Strategy (REMS) Program. On December 18, 2020, the European Commission (EC) granted marketing authorization for Fintepla for the treatment of seizures associated with Dravet syndrome as an add-on therapy to other anti-epileptic medicines for patients two years of age and older. Fintepla will be available in Europe under a controlled access program requested by the EMA to prevent off-label use for weight management and to confirm that prescribing physicians have been informed of the need for periodic cardiac monitoring in patients taking Fintepla. We initially launched Fintepla for sale in Germany in February 2021 and expect to expand into other European markets thereafter. The approval for marketing of Fintepla in the U.S. and Europe was based on positive safety and efficacy results from two randomized, international, multi-center, placebo-controlled Phase 3 trials (Study 1 and Study 2), as well as data from an interim analysis of a long-term, open-label extension study in 330 Dravet syndrome patients treated up to three years.

In September 2020, we reported positive top-line results from our third Phase 3 trial (Study 3) of Fintepla for the treatment of seizures associated with Dravet syndrome. Study 3 corroborates the substantial impact of Fintepla on convulsive seizure reduction in patients with Dravet syndrome as previously demonstrated in Studies 1 and 2. Study 3 expands the countries where Fintepla has been evaluated to include Japan. We expect to include Study 3 as the pivotal study in our planned submission of a Japanese New Drug Application (J-NDA) in the second half of 2021.

Lennox-Gastaut Syndrome

In February 2020, we reported positive top-line results from our Phase 3 multicenter, global LGS trial (Study 1601), a double-blind, placebo-controlled study to assess the safety, tolerability and efficacy of Fintepla when added

to a patient's current anti-epileptic regimen. Study 1601 included a total of 263 patients between the ages of 2 and 35 years whose seizures were uncontrolled while on one or more anti-epileptic drugs. The trial met its primary objective of demonstrating that Fintepla at a dose of 0.7 mg/kg/day was superior to placebo in reducing the frequency of drop seizures and demonstrated statistically significant improvements versus placebo in key secondary efficacy measures, including proportion of patients with a clinically meaningful reduction in drop seizure frequency. We are working to gather the additional data required to support a supplemental New Drug Application (sNDA), including two-year carcinogenicity data from our non-clinical study in rats and additional safety data from our ongoing open label extension study. Based on our clinical development plan and written feedback received from the FDA in September 2020, we expect to submit the sNDA in the second quarter of 2021.

Fintepla for Other Potential Indications

In addition to Dravet syndrome and LGS, we are evaluating the treatment potential of Fintepla in other serious, treatment-resistant epileptic syndromes.

MT1621 for Patients with TK2 Deficiency

As a result of our acquisition of Modis in September 2019, we became a party to the Exclusive License Agreement, by and between Modis and Columbia, dated as of September 26, 2016 (the Columbia Agreement), related to MT1621. MT1621 is an investigational deoxynucleoside-combination substrate enhancement therapy in development for the treatment of TK2d, a rare, debilitating, and often fatal genetic mitochondrial DNA depletion disease that primarily affects infants and children and for which there are currently no approved therapies.

In April 2020, we held an End-of-Phase 2 meeting with the FDA and in June 2020, we met with the FDA to discuss chemistry, manufacturing, and controls (CMC) for MT1621. In the meetings, the FDA outlined the additional clinical and non-clinical information needed for an NDA submission. Based on the feedback, we expect availability of all required data by end of 2021 to support an NDA submission, which we are targeting for mid-2022. In addition, we plan to conduct a Phase 1 pharmacokinetic (PK) study in renal impairment which was recommended by the FDA to provide dosing recommendations in the setting of impaired renal function and include the results in the NDA submission. The FDA also concurred with our proposed CMC plan for the prospective NDA submission.

Collaborative Arrangement with Nippon Shinyaku

In March 2019, we entered into an exclusive distribution agreement (Shinyaku Agreement) with Nippon Shinyaku Co., Ltd. (Shinyaku) for the potential commercialization of Fintepla in Japan. We retained responsibility for clinical development programs for Fintepla, including completion of an additional Phase 3 trial (Study 3) to expand the countries to include Japan, amongst others, where Fintepla for the treatment of Dravet syndrome has been evaluated. Upon signing of the agreement, Shinyaku agreed to make upfront payments of $20.0 million over two years to support our research and development efforts. As of December 31, 2020, we have received $17.0 million, with the remaining amounts expected to be received in 2021. We will also be eligible to receive future regulatory and sales-based milestone payments of up to $108.5 million. Once Fintepla is approved for marketing in Japan, if ever, we are obligated to supply product to Shinyaku and will receive a tiered transfer price of up to a high-double digit percentage of the annual net sales of Fintepla in Japan. In September 2020, we reported positive top-line results from Study 3, which corroborates the substantial impact of Fintepla on convulsive seizure reduction in patients with Dravet syndrome as previously demonstrated in Studies 1 and 2. We expect to include Study 3 as the pivotal study in our planned submission of a J-NDA in the second half of 2021.

Tevard Collaboration, Option and License Agreement

In October 2019, we entered into an option agreement with Tevard Biosciences (Tevard), a privately-held company focused on tRNA-based gene therapies. Under the agreement, Tevard granted us an option to license exclusive rights related to a preclinical development program to identify and develop novel tRNA-based gene therapies for Dravet syndrome. During 2020, we extended the option period to exercise our license rights prior to entering into a collaboration, option and license agreement with Tevard. Payments made under the option agreement were nonrefundable, but may be credited against the upfront payment due if we exercise our option on the preclinical development program. Payments made under the option agreement of $2.0 million in 2019 and

$5.5 million in 2020 were included in acquired IPR&D expense and related costs in our consolidated statement of operations.

In December 2020, we exercised the option on the Dravet syndrome program and entered into a collaboration, option and license agreement with Tevard (the Tevard Agreement). The financial terms of the Tevard Agreement included an upfront payment of $5.2 million. In connection with the transaction, we also purchased a convertible promissory note issued by Tevard in the amount of $5.0 million. The note matures in December 2022 and carries interest at 3.5% per year. The note will automatically convert into equity securities issued by Tevard in their next equity financing transaction at a conversion price equal to the price paid per share by other investors of the financing transaction.

In addition to the upfront payments, we have agreed to fund Tevard's early discovery activities under the licensed Dravet syndrome program in accordance with the development plan as determined by the parties to the agreement. Once Tevard completes the early discovery activities for a program, we will be responsible for any potential future development and commercialization activities. Tevard is also eligible to receive additional development, regulatory and commercial-related milestone payments of up to $100.0 million for the Dravet program, as well as tiered royalties on future net sales in the single digits that result from the collaboration. We are also entitled to rights of negotiation and rights of first refusal to potentially obtain licenses to compounds subsequently discovered and developed by Tevard. The agreement, if not terminated sooner, would expire upon the expiration of all applicable royalty terms under the agreement with respect to a licensed program or product; however, we have the unilateral right to terminate the agreement with 180 days advanced notice

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

Business Update Regarding the COVID-19 Pandemic

The current COVID-19 worldwide pandemic has presented substantial public health and economic challenges and is affecting our employees, patients and their families and caregivers, communities and business operations, as well as the U.S. and global economies and financial markets. International and U.S. governmental authorities in impacted regions are taking actions in an effort to slow the spread of COVID-19, including issuing varying forms of "stay-at-home" orders, and restricting business functions outside of one's home. In response, we closed our offices for all but the most essential activities and have implemented a policy allowing all employees to work from across all locations, following the guidelines or directives issued by federal, state and local government agencies in the U.S. as well as the U.K. government.

We commenced the commercial launch of Fintepla in the United States in July 2020 and in Germany in February 2021. Our commercialization efforts will need to navigate through the operational restrictions imposed on our sales force from quarantines, travel restrictions and bans and other governmental and healthcare restrictions related to COVID-19. As a result of these restrictions, our sales force has not been able to conduct in-person interactions with physicians and healthcare providers and have been restricted to primarily conducting educational and promotional activities for Fintepla virtually, which may impact our ability to market Fintepla. In addition, Fintepla is being launched through our Fintepla REMS program in the U.S. and a controlled access program in Europe, with each program requiring patients to obtain echocardiograms during this pandemic.

To date, we have been able to continue to supply Fintepla and MT1621 to our patients currently enrolled in our clinical trials and do not currently anticipate any interruptions in supply. Any delays in the completion of our clinical trials and any disruption in our supply chain could have a material adverse effect on our business, results of operations and financial condition. The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain it or treat COVID-19, as well as the economic impact on local, regional, national and international markets.

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 management to make judgments, assumptions, and estimates that affect the amounts reported in our consolidated financial statements and accompanying notes. 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.

The significant accounting policies followed, and methods used, in the preparation of our financial statements are detailed in Note 2 to the consolidated financial statements included in this Form 10-K. We believe that the application of the policies discussed below are significantly affected by critical accounting estimates. Such accounting policies require significant judgments, assumptions, and estimates used in the preparation of the consolidated financial statements and actual results could differ from these estimates under different assumptions or conditions. Adjustments to these estimates would impact our financial position and future results of operations.

Revenue Recognition

Our revenues consist of product sales of Fintepla and revenues derived from our collaboration arrangement with Nippon Shinyaku Co., Ltd. (Shinyaku).

Net Product Sales

We recognize revenue when control of the promised good or service is transferred to the customer, in an amount that reflects the consideration we expect to be entitled to in exchange for those goods or services. We determine revenue recognition through the following steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy a performance obligation. We only apply the five-step model to contracts when collectability of the consideration to which we are entitled in exchange for the goods or services we transfer to the customer is determined to be probable.

We distribute Fintepla in the U.S. through an arrangement with a specialty distributor who is our customer. The specialty distributor subsequently resells our product through its related specialty pharmacy to patients and health care providers. Separately, we have or may enter into payment arrangements with various third-party payers including pharmacy benefit managers, private healthcare insurers and government healthcare programs who provide coverage and reimbursement for our products that have been proscribed to a patient. For the year ended December 31, 2020, our revenue from net product sales were only generated in the U.S. following the FDA's approval for marketing of Fintepla for the treatment associated with seizures in Dravet syndrome in June 2020. In Europe, we launched Fintepla for Dravet syndrome in February 2021 following the EMA's approval for marketing in December 2020.

Revenue from product sales is recorded at the net sales price (transaction price), which includes estimates of consideration payable to our customer and third-party payers for which reserves are established and that result from government rebates, chargebacks, co-pay assistance, prompt-payment discounts and other allowances that are offered under arrangements between us, our customer, and third-party payers related to the sales of Fintepla. These reserves are classified as either reductions of accounts receivable (if the amounts are payable to our customer) or as refund liabilities within current liabilities (if the amounts are payable to a party other than our customer). Amounts billed or invoiced are included in accounts receivable, net on our consolidated balance sheet. We did not have any contract assets (unbilled receivables) at December 31, 2020, as we generally invoice our customer before or at the time of revenue recognition. We also did not have any contract liabilities at December 31, 2020, as we did not receive payments in advance of fulfilling our performance obligations to customer.

Estimates of our allowance for credit losses consider a number of factors including existing contractual payment terms, individual customer circumstances, historical payment patterns of our customers, a review of the local economic environment and its potential impact on expected future customer payment patterns. We have standard payment terms that generally require payment within approximately 30 days. At December 31, 2020, an allowance for credit losses was not considered necessary as the accounts receivable due from our exclusive arrangement with a single specialty distributor in the U.S. was deemed collectible.

We recognize product revenues when a customer obtains control of our product, which occurs at a point in time and is typically upon delivery to the customer or, in the case of products that are subject to consignment agreements, when the customer takes title of the product from our consigned inventory location for shipment directly to a patient or healthcare provider. In the event the variable consideration is constrained, we include an amount to the extent it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur in a future reporting period. Depending on the type of variable consideration, we use either the most likely method or expected value method to estimate variable consideration related to Fintepla product sales. We do not have any

material constraints on our variable consideration included within the transaction price for Fintepla product sales. The actual amount of consideration ultimately received may differ from our estimates. If actual results in the future vary from estimates, the estimates will be adjusted, which will affect our revenue from net product sales in the period that such variances become known.

Each unit of Fintepla that is ordered by our customers represent a separate performance obligation that is completed when the customer obtains control of our product. We record product revenues, net of variable consideration, any applicable constraint, and consideration payable to parties other the customer at that point in time. We record shipping and handling costs within cost of product sales on our consolidated statements of operations. We classify payments to customers or its affiliates for certain services, to the extent that the services provided are distinct from the sale of our product and we can reasonably estimate its fair value, as selling, general and administrative expenses on our consolidated statements of operations. We have elected to exclude taxes collected from our customers and remitted to governmental authorities from the measurement of the transaction price.

We sell Fintepla to our customer at wholesale acquisition cost, and calculate product revenue from Fintepla sales, net of variable consideration and consideration payable to parties other than our customer. Variable consideration and consideration payable to parties other than the customer consists of estimates related to the following categories:

Trade Discounts and Allowances: We provide customers with discounts for prompt payment and we also pay fees to customers for distribution services rendered that are not distinct from product sales. We expect customers to earn these discounts and fees, and accordingly we deduct these discounts and fees in full from our gross product revenue and accounts receivable at the time we recognize the related revenue.

Government Rebates: Fintepla is eligible for purchase by, or qualifies for reimbursement from, Medicaid and other government programs that are eligible for rebates on the price they pay for Fintepla. To determine the appropriate amount to reserve for these rebates, we identify the government-funded health insurer of patients who receive Fintepla as sold by our customer, apply the applicable government discount to these sales, and estimate the portion of total rebates that we anticipate will be claimed.

Other Rebates and Chargebacks: We may contract with various third-party payers for coverage and reimbursement of Fintepla. We estimate the rebates and chargebacks that we expect to be obligated to provide to such third-party payers based upon the terms of the applicable arrangement or negotiations with such third-party payers and our visibility regarding the payer mix.

Patient Assistance Program: We provide financial assistance to eligible patients whose insurance policies have high deductibles or co-payments and deduct our estimate of the amount of such assistance from gross product revenue.

Product Returns: We do not provide contractual return rights to our customer, except in instances where the product is damaged or defective, which we expect to be rare.

Collaboration Revenue

We earn revenue in connection with a collaborative arrangement with Shinyaku entered into in March 2019 (Shinyaku Agreement). See Note 3 for a more detailed discussion on revenue recognition under the agreement.

We analyze our collaboration arrangements to assess whether such arrangements, or transactions between arrangement participants, involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities or are more akin to a vendor-customer relationship. In making this evaluation, we consider whether the activities of the collaboration are considered to be distinct and deemed to be within the scope of the collaborative arrangement guidance and those that are more reflective of a vendor-customer relationship and, therefore, within the scope of the revenue with contracts with customers guidance. This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement.

For elements of collaboration arrangements that are not accounted for pursuant to the revenue from contracts with customers guidance, an appropriate recognition method is determined and applied consistently, generally by analogy to the revenue from contracts with customers guidance. Amounts related to transactions with a counterparty in a collaborative arrangement that is not a customer are presented as collaboration revenue and on a

separate line item from revenue recognized from contracts with customers, if any, in our consolidated statements of operations.

Amounts received prior to satisfying the revenue recognition criteria are recorded as deferred revenue in the consolidated balance sheets. If the related efforts underlying the deferred revenue is expected to be satisfied within the next twelve months this will be classified in current liabilities. Unconditional rights to receive consideration in advance of performance are recorded as receivables and deferred revenue in the consolidated balance sheets when we have a contractual right to bill and receive the payment, performance is expected to commence shortly and there is less than a year between billing and performance. Amounts recognized for satisfied performance obligations prior to the right to payment becoming unconditional are recorded as contract assets in the consolidated balance sheets. If we expect to have an unconditional right to receive consideration in the next twelve months, this will be classified in current assets. A net contract asset or liability is presented for each contract with a customer.

For arrangements or transactions between arrangement participants determined to be within the scope of the contracts with customers guidance, we perform the following steps to determine the appropriate amount of revenue to be recognized as we fulfill our obligations: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations based on estimated selling prices; and (v) recognition of revenue when (or as) we satisfy each performance obligation.

At contract inception, we assess the goods or services promised in a contract with a customer and identify those distinct goods and services that represent a performance obligation. A promised good or service may not be identified as a performance obligation if it is immaterial in the context of the contract with the customer, if it is not separately identifiable from other promises in the contract (either because it is not capable of being separated or because it is not separable in the context of the contract), or if the performance obligation does not provide the customer with a material right.

We consider the terms of the contract and our customary business practices to determine the transaction price. The transaction price is the amount of consideration to which we expect to be entitled in exchange for transferring promised goods or services to a customer. The consideration promised in a contract with a customer may include fixed amounts, variable amounts, or both. Variable consideration will only be included in the transaction price when it is not considered constrained, which is when it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur.

If it is determined that multiple performance obligations exist, the transaction price is allocated at the inception of the agreement to all identified performance obligations based on the relative stand-alone selling prices unless the transaction price is variable and meets the criteria to be allocated entirely to one or more, but not all, performance obligations in the contract. The relative selling price for each performance obligation is based on observable prices if it is available. If observable prices are not available, we estimate stand-alone selling price for the performance obligation utilizing the estimated cost of the performance obligation with an estimated assumed margin. Once the transaction price has been allocated to a performance obligation using the applicable methodology, it is not subject to reassessment for subsequent changes in stand-alone selling prices.

Revenue is recognized when, or as, we satisfy a performance obligation by transferring a promised good or service to a customer. An asset is transferred when, or as, the customer obtains control of that asset. For performance obligations that are satisfied over time, we recognize revenue using an input or output measure of progress that best depicts our satisfaction of the relevant performance obligation. Revenues from performance obligations associated with a purchase order of Fintepla will be recognized when the customer obtains control of our product, which will occur at a point in time which may be upon shipment or delivery to the customer.

After contract inception, the transaction price is reassessed at every period end and updated for changes such as resolution of uncertain events. Any change in the overall transaction price is allocated to the performance obligations on the same methodology as at contract inception.

Management may be required to exercise judgment in estimating revenue to be recognized. Judgment is required in identifying performance obligations, estimating the transaction price, estimating the stand-alone selling prices of identified performance obligations, which may include forecasted revenue, development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success, and estimating the progress towards satisfaction of performance obligations.

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, contract manufacturing costs for products that have not obtained regulatory approval, 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, materials used in clinical trials and research and development and costs incurred related to our agreement with Nippon Shinyaku Co., Ltd. We expense 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 recorded as prepaid assets on our consolidated balance sheets until the goods or services are realized or consumed. We classify such prepaid assets as current or non-current assets based on our estimates of the timing of when the goods or services will be realized or consumed.

Our expense accruals for clinical trials are based on estimates of the services received from clinical trial investigational sites, contract research organizations (CROs) and other third-party vendors that support us in our research and development efforts. Payments under some of our contracts with these service providers depend on factors such as the achievement of clinical milestones such as the successful enrollment of certain numbers of patients, site initiation, or completion of a clinical trial. In accruing for these services at each reporting date, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If available, we obtain information regarding unbilled services directly from these service providers. However, we may be required to estimate our accrual based only on information available to us. Once established, accruals are adjusted from time to time, as appropriate, in light of additional information. Amounts ultimately incurred in relation to amounts accrued for these services at a reporting date may be substantially higher or lower than our estimates.

Convertible Senior Notes

In accounting for the issuance of the Notes, we performed an assessment of all embedded features of the debt instrument to determine if (i) such features should be bifurcated and separately accounted for, and (ii) if bifurcation requirements are met, whether such features should be classified and accounted for as equity or liability instruments. If the embedded feature meets the requirements to be bifurcated and accounted for as a liability, the fair value of the embedded feature is measured initially, included as a liability on the consolidated balance sheets and re-measured to fair value at each reporting period.

We determined the embedded conversion feature in the Notes is not required to be separately accounted for as a derivative liability instrument because it is considered to be indexed to our common stock. However, since the Notes may be settled with a combination of cash and shares, at our election, we are required to separate the Notes into debt and equity components. The value assigned to the debt component is the estimated fair value, as of the issuance date, of a similar debt instrument issued by us without the conversion feature. The difference between the full principal amount of the Notes and this estimated fair value was recorded as a debt discount on the Notes, with a corresponding offset to additional paid-in capital (the equity component). In addition, debt issuance costs associated with the Notes were allocated to the debt and equity components in proportion to the allocation of the full principal amount to those components.

At issuance, the debt component of the Notes was estimated to have a fair value of $152.1 million based on contractual cash flows discounted at our estimated non-convertible debt borrowing rate of 9.7%. Our determination of an appropriate discount rate was based on a yield curve derived from then-recent publicly-traded bond offerings with a similar term for companies with similar credit ratings to us (Level 2 inputs). As a result, the equity component of $77.9 million, which represents the difference between the proceeds from the issuance of the Notes and the fair value of the debt component, was recognized as a debt discount. In addition, debt issuance costs of $7.5 million related to the issuance of the Notes were comprised of $4.9 million attributable to the debt component, and recorded as debt discount, with the remaining $2.5 million attributable to the equity component and netted with the equity component discussed above resulting in $75.3 million recorded to additional paid-in capital within stockholders' equity on the consolidated balance sheet. The debt discount and issuance costs of $82.8 million are being amortized as interest expense over the expected term of the Notes of seven years using the effective interest rate of 9.9%. The equity component is not remeasured as long as it continues to meet the conditions for equity classification. As of December 31, 2020, the outstanding Notes were not subject to conversion under the Indenture. At December 31, 2020, the Notes had a weighted-average remaining term of approximately 6.7 years and the equity component continues to meet the conditions for equity classification.

Intangible Assets

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 indefinite-lived intangibles is determined to exist when the fair value is less than the carrying value of the net assets being tested.

Finite-lived intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets (group) may not be recoverable. Recoverability of assets is determined by comparing the estimated undiscounted net cash flows of the operations related to the assets (asset group) to their carrying amount. If the carrying value of the assets (asset group) exceeds its undiscounted cash flows, we then compare the fair value of the assets (asset group) to their carrying value to determine the impairment loss. The impairment loss will be allocated to the carrying values of the asset group, but not below their individual fair values.

If we determine that events and circumstances warrant a revision to the remaining period of amortization or depreciation for a specific finite-lived asset, its remaining estimated useful life will be revised, and the remaining carrying amount of the finite-lived asset will be depreciated or amortized prospectively over the revised remaining estimated useful life. There were no impairment charges for our finite-lived asset for all periods presented.

Until June of 2020, our indefinite-lived intangible asset consisted of in-process research and development (IPR&D) acquired in a business combination that were used in research and development activities but had not yet reached technological feasibility, regardless of whether they had alternative future use. The primary basis for determining the technological feasibility of these projects at the time of acquisition was obtaining regulatory approval to market the underlying products in an applicable geographic region which was upon the FDA's June 2020 approval of Fintepla. Therefore, we classified in-process research and development acquired in a business combination as an indefinite-lived intangible asset until completion of the associated research and development efforts which occurred in June 2020. Upon completion of the associated research and development efforts, we performed a final test for impairment of this indefinite-lived intangible asset prior to its being recorded as a finite-lived intangible asset subject to amortization. In performing this final impairment test, the accounting guidance allows an entity the option to first assess qualitative factors to determine whether it is necessary to perform a quantitative test. If we believe, as a result of our qualitative assessment, that it is more-likely-than-not that the fair value of our IPR&D asset is less than its carrying amount, a quantitative impairment test must be performed. Otherwise, no further testing is required.

When performing a qualitative test, we considered the results of our 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 including discount rates, the probability of successfully of obtaining regulatory approval, costs to complete research and development efforts, sales price of the approved product, the number of patients who will be diagnosed and treated with our product and tax rates. Using these drivers of fair value, 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 will proceed with quantitatively determining the fair value of the IPR&D asset. For the final impairment test, we performed a qualitative test and concluded that it is more-likely-than-not that the fair value of our IPR&D asset exceeded its carrying value and no further testing was required after considering the positive impact on future cash flows associated with the IPR&D asset attributable with the removal of regulatory approval uncertainty and the final US price of our product.

Finite-lived intangible assets are subject to amortization over its estimated useful life. Finite-lived intangible assets are amortized using the method that best reflects how their economic benefits are utilized or, if a pattern of economic benefits cannot be reliably determined, on a straight-line basis over their estimated useful lives. Due to the inherent subjectivity of forecasting the timing in which the cash flows may be generated from our Fintepla intangible asset over a long-term time horizon, we concluded the pattern of economic benefit could not be reliably determined. We have therefore elected to use the straight-line method of amortization for this intangible asset.

The estimate of the useful life of our Fintepla intangible asset involves management judgment. In determining the estimated useful life, we considered the estimated period over which the asset will contribute directly or indirectly to our future cash flows, the strength of issued patents and related period of intellectual property

protection, the availability of competitor products treating similar indications and the impact of patent expiry on the sustainability of future operating cash flows of the asset.

Results of Operations

Revenues

(In thousands)	Year Ended December 31, 2020	2019	$ Change
Net product sales	$ 9,587	$ —	$ 9,587
Collaboration revenue	4,056	3,648	408
Total revenues	$ 13,643	$ 3,648	$ 9,995

We began to derive product revenue following the approval of Fintepla by the FDA in June 2020 and the commercial launch in the U.S. Prior to the commercial launch of Fintepla, our revenues were generated entirely through a collaboration agreement with Shinyaku entered into in March 2019.

Net Product Sales

For the year ended December 31, 2020, we recognized $9.6 million in net product revenue related to sales of Fintepla in the U.S. following our commercial launch in July 2020. In February 2021, we launched Fintepla for Dravet syndrome in Germany following the EMA's approval for marketing in December 2020. We expect our net product revenue to increase in 2021 compared to 2020.

Collaboration Revenue

Collaboration revenue increased by $0.4 million for 2020 as compared to 2019, as we conducted an additional clinical trial (Study 3) to expand the countries where Fintepla has been evaluated to include Japan in fulfillment of our performance obligations under the collaboration arrangement. We anticipate Study 3 will be the pivotal study included in our planned submission of a J-NDA, expected to occur in the second half of 2021.

As recognition of our collaboration revenue is based on costs incurred to date relative to total estimated costs at completion when measuring progress combined with the uncertainty of when the events underlying various milestones are resolved, we expect our collaboration revenue will fluctuate from period to period.

Cost of Product Sales (Excluding Intangible Asset Amortization)

Cost of product sales (excluding intangible asset amortization) includes the cost of producing and distributing inventories that are related to product revenues during the respective period (including salary-related and stock-based compensation expenses for employees involved with production and distribution, freight and indirect overhead costs) and third-party royalties payable on our net product revenues. Cost of product sales may also include costs related to excess or obsolete inventory adjustment charges, abnormal costs, unabsorbed manufacturing and overhead costs, and manufacturing variances.

For the year ended December 31, 2020, cost of sales primarily consisted of royalties payable on net sales of Fintepla under a license agreement and labeling and packaging costs. Substantially all of the cost of product sold in 2020 were for packaging and labeling as our inventory had a zero-cost basis. Prior to receiving FDA approval for Fintepla, we recorded all manufacturing product costs as research and development expense. We expect our cost of sales for Fintepla to increase as a percentage of net sales in beginning in mid-2021 in the future as we produce and then sell inventory that reflects the full cost of manufacturing.

Research and Development Expense

Research and development (R&D) expense consist of expenses incurred in developing, testing and seeking marketing approval of our product candidates, including: payments made to third-party clinical research organizations (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; commercial quantities of certain product candidates prior to the date we anticipate that such products will receive regulatory

approval, personnel related expenses, such as salaries, benefits, travel and other related expenses, including stock-based compensation; and facility, maintenance, depreciation and other related expenses.

For each of our R&D programs, we incur both external and internal costs. External costs include clinical and non-clinical activities performed by CROs, lab services, purchases of product candidate materials and manufacturing development costs. We track external R&D expenses for each of our key development programs. We have not tracked internal costs on a program-by-program basis because our R&D employees and infrastructure resources are utilized across our product candidate development programs.

The table below sets forth components of our research and development expenses for the periods presented.

	Year Ended December 31,		
(In thousands)	2020	2019	$ Change
External costs:			
Fintepla for Dravet syndrome	$ 32,287	$ 39,679	$ (7,392)
Fintepla for LGS	34,920	30,320	4,600
MT1621[(1)]	13,703	3,243	10,460
Tevard gene-therapy program for Dravet syndrome	739	—	—
Other[(2)]	1,942	1,986	(44)
Total external costs	83,591	75,228	7,624
Internal costs	54,411	40,411	14,000
Total research and development expense	$ 138,002	$ 115,639	$ 21,624

(1) External costs incurred subsequent to our acquisition of Modis in September 2019.
(2) Other external costs include early-phase exploratory research programs.

R&D expenses related to Fintepla for Dravet syndrome decreased by $7.4 million year-over-year primarily due to wind-down of clinical activities related to Study 2, partially offset by costs incurred to conduct a Phase 3 clinical trial (Study 3) to support the planned submission of a J-NDA, expected to occur in 2021. R&D expenses related to Fintepla for LGS increased by $4.6 million year-over-year reflecting the progression and expansion of our clinical trial activities within Study 1601. R&D expenses related to MT1621 increased by $10.5 million year-over-year as we continued to advance the MT1621 development program, including work related to chemistry, manufacturing, and controls process requirements. Internal costs for research and development activities increased by $14.0 million year-over-year primarily driven by personnel-related expenses from increased headcount.

Selling, General and Administrative Expense

	Year Ended December 31,		
(In thousands)	2020	2019	$ Change
Selling, general and administrative	$ 99,574	$ 60,792	$ 38,782

Selling, general and administrative expense consists primarily of salaries and related costs for our personnel, including stock-based compensation, market research expenses for our product and product candidates that are in development and marketing expenses to support our commercial launch efforts, executive, finance, accounting, business development and internal support functions, facility-related costs and consulting fees, in each case not otherwise included in research and development expenses.

Selling, general and administrative expense increased by $38.8 million year-over-year. The increase was primarily attributable to a $16.0 million increase in personnel-related costs, which included a $4.9 million increase for stock-based compensation as we build out our specialized and focused commercial teams in support of our Fintepla product launch in the U.S. and in preparation of our product launch in Europe and headcount additions in general and administrative to support our commercial team. In addition, commercial spend related to market research, strategic and logistic planning for our product launch also contributed $12.9 million to the increase. The remainder of the increase was attributable to higher insurance premium costs and an increase in utilization of professional services, as well as infrastructure and facilities-related costs.

Intangible Asset Amortization

Our intangible asset consist of worldwide development, commercialization and related intellectual property rights including patents and licenses for our product, Fintepla, which at the time of our acquisition in October 2014 and as of December 31, 2019, was classified as an indefinite-lived IPR&D asset. Upon FDA approval of Fintepla in June 2020, this indefinite-lived asset was reclassified to a finite-lived intangible asset subject to amortization.

In July 2020, we commercially launched Fintepla and commenced amortization of this asset on a straight-line basis over its estimated useful life. For the year ended December 31, 2020, intangible asset amortization expense was $3.9 million. In 2019, the intangible asset was considered to be indefinite-lived and not subject to amortization as the IPR&D program was determined to be incomplete.

Acquired In-Process Research and Development and Related Costs

Acquired IPR&D consists of existing research and development projects at the time of the acquisition. Projects that qualify as IPR&D assets represent those that have not yet reached technological feasibility and have no alternative future use.

For the year ended December 31, 2020, acquired IPR&D expense of $10.7 million consisted of non-refundable, option maintenance payments and exercise fees paid to Tevard to acquire license rights under the Dravet syndrome development program.

For the year ended December 31, 2019, our acquisition of Modis in September 2019 included one IPR&D project, MT1621. We determined we did not acquire a business and $249.4 million of the purchase price was attributable to an IPR&D asset based on relative fair value allocation that was determined to have no alternative use and charged to expense at the acquisition date. In addition, acquired IPR&D expense also included $2.0 million paid to Tevard, who granted us an option to license rights under the Dravet syndrome development program. The development program had not yet reached technological feasibility and had no alternative future use which resulted in a write-off of IPR&D to acquired in-process research and development and related costs in our consolidated statement of operations.

Change in Fair Value of Contingent Consideration

	Year Ended December 31,	
(In thousands)	2020	2019
Change in fair value of contingent consideration	$ 8,600	$ 5,600

The contingent consideration liability relates to milestone payments under an existing agreement in connection with our prior acquisition of Fintepla. At each reporting period, the estimated fair value of the liability is determined by applying the income approach which utilizes variable inputs, such as the probability of success for achieving regulatory/commercial milestones, anticipated future cash flows, risk-free adjusted discount rates, and nonperformance risk. Any change in the fair value of contingent consideration is recorded within operating expenses.

For the year ended December 31, 2020, the estimated fair value of our contingent consideration liabilities increased by $8.6 million in 2020 as we adjusted the probability of regulatory approval for Fintepla in the U.S. and in Europe to 100%. For the year ended December 31, 2019, the estimated fair value of our contingent consideration liabilities increased by $5.6 million primarily due to the inclusion of sales in Japan in our forecast associated with the execution of the Shinyaku Agreement, which accelerated the estimated timing of when certain sales milestones will be reached, a higher estimated probability of success of Fintepla for the treatment of Dravet syndrome and a market driven decrease in the discount rate.

Other Income (Expense), Net

(In thousands)	Year Ended December 31, 2020	2019	$ Change
Interest income	$ 2,891	$ 9,804	$ (6,913)
Interest expense	(3,759)	(2)	3,757
Other income	21,777	516	21,261
Total other income, net	$ 20,909	$ 10,318	$ 18,105

Interest income decreased year-over-year by $6.9 million, as cash balances were used in 2019 to fund our operations and the acquisition of Modis. Interest expense increased year-over-year by $3.8 million and was attributable to our outstanding $230.0 million Convertible Senior Notes issued between September and October 2020. Other income increased year-over-year by $21.3 million primarily due to a $19.7 million gain related to our election to surrender net operating losses for our 2017 and 2018 tax years in exchange for cash payments under U.K's R&D Tax Relief Scheme. For our 2020 and 2019 U.K. tax year, we have not yet decided whether to seek tax relief by surrendering some of our losses for refundable cash credits or electing to receive enhanced U.K. tax deductions on our eligible R&D activities. Under U.K's tax legislation, there is a two-year window after the end of a tax year to seek relief under this scheme. See Notes 2 and 18 to our consolidated financial statements in this Form 10-K for additional information.

Liquidity and Capital Resources

Excluding gains from two discrete business divestitures, we have incurred significant net losses and negative cash flows from operating activities since inception.. As of December 31, 2020, we had an accumulated deficit of $1.3 billion. We recently launched Fintepla in the U.S. and Europe and generate revenue from product sales. We also generate collaboration revenue from our collaborative arrangement with Nippon Shinyaku Co., Ltd. We expect to continue to incur significant operating losses and negative cash flows from operations as we begin to commercialize Fintepla and advance our product candidates through development in the short-term. The following is a discussion of our recent financing transactions.

At-the-Market Offerings

We have an at-the-market sales agreement (the ATM Sales Agreement) with Cantor Fitzgerald & Co. (Cantor) pursuant to which Cantor agreed to act as a sales agent in connection with sales of our common stock from time to time pursuant to an effective registration statement.

In December 2017, we filed a prospectus supplement to our automatic "shelf" registration statement on Form S-3 registering the offering, issuance and sale of up to $75.0 million in gross aggregate proceeds of common stock under the ATM Sales Agreement. During 2019 and 2018, we sold approximately 904,000 and 740,000 shares of common stock, respectively, resulting in net proceeds of approximately $42.6 million and $30.3 million, respectively, after deducting commissions and other offering costs.

In June 2020, we filed a prospectus supplement to our automatic "shelf" registration statement on Form S-3 registering the offering, issuance and sale of up to $200.0 million in gross aggregate proceeds of our common stock under the ATM Sales Agreement. During 2020, we sold 203,000 shares of common stock and realized net proceeds of approximately $4.9 million, after deducting commissions and other offering costs.

Underwritten Public Offerings

In August 2018, we completed an underwritten public offering of 6,000,000 shares of our common stock at an offering price of $52.00 per share. Net proceeds realized from the offering amounted to approximately $292.9 million, after deducting commissions and other offering expenses.

In March 2020, we completed an underwritten public offering of 9,798,000 shares of our common stock at an offering price of $23.50 per share, including 1,278,000 shares sold pursuant to the underwriters' full exercise of their option to purchase additional shares. Net proceeds realized from the offering amounted to approximately $221.7 million, after deducting commissions and other offering costs.

2.75% Convertible Senior Notes Due 2027

Between September 2020 and October 2020, we issued $230.0 million principal amount of 2.75% convertible senior notes due 2027 in a private offering (collectively, the Convertible Senior Notes or Notes). Total proceeds realized from the sale of the Notes, net of issuance costs of $7.5 million, were $222.5 million. The Notes are governed by an indenture (Indenture), dated as of September 28, 2020, between Zogenix and U.S. Bank National Association, as trustee. Under the Indenture, the Notes are senior, unsecured obligations of Zogenix, are equal in right of payment with its future senior, unsecured indebtedness of Zogenix, and structurally subordinated to all indebtedness and liabilities of its subsidiaries. The principal amount of the Notes was issued at par value and the Notes accrue interest at a rate of 2.75% per year, payable semi-annually in arrears on April 1 and October 1 of each year, beginning on April 1, 2021. The Notes mature on October 1, 2027, unless earlier converted by the holders or redeemed or repurchased by us in accordance with their terms prior to such date. The Indenture contains customary terms and covenants, including certain events of default upon which the Notes may be due and payable immediately, but does not contain any financial covenants.

The Notes are convertible, subject to certain conditions described below, into shares of our common stock at an initial conversion rate of 41.1794 shares per $1,000 principal amount of the Notes, which represents an initial conversion price of approximately $24.28 per share, subject to adjustments upon the occurrence of certain events. Certain corporate events described in the Indenture may increase the conversion rate for holders who elect to convert their Notes in connection with such corporate event should they occur. We also may choose to repurchase outstanding Notes through open-market transactions, including through Rule 10b5-1 trading plan to facilitate open-market repurchases, or otherwise, from time to time.

Holders may convert the Notes in multiples of $1,000 principal amount at any time prior to October 1, 2027, but only in the following circumstances:

- during any calendar quarter ending after December 31, 2020, if our closing stock price exceeds 130% of the conversion price on each of at least 20 trading days of the last 30 consecutive trading days of the immediately preceding calendar quarter;
- during the five consecutive business day period after any 10 consecutive trading day period in which the Notes' trading price is less than 98% of the product of our closing stock price times the conversion rate; or
- the occurrence of certain corporate events, such as a change of control, merger, default or liquidation.

In addition, holders may also convert their Notes at their option at any time beginning on July 1, 2027 until the close of business on the second scheduled trading day immediately before the maturity date for the Notes, without regard to the foregoing circumstances.

Upon conversion, we will pay or deliver, as the case may be, cash, shares of our common stock or a combination thereof at our election.

We may not redeem the Notes prior to October 7, 2024. On or after October 7, 2024, the Notes are redeemable for cash, in whole or in part (subject to minimum redemption amounts), at our option at any time, and from time to time, before the 40th scheduled trading day immediately before October 1, 2027, at a cash redemption price equal to 100% of the principal amount of the Notes to be redeemed, plus accrued and unpaid interest, if any, but only if our closing stock price exceeds 130% of the conversion price on (1) each of at least 20 trading days, whether or not consecutive, during the 30 consecutive trading days ending on, and including, the trading day immediately before the date we send the related redemption notice; and (2) the trading day immediately before the date we send such notice. In addition, calling any note for redemption will constitute a make-whole fundamental change with respect to that Note, in which case the conversion rate applicable to the conversion of that Note will be increased in certain circumstances if it is converted after it is called for redemption.

The Indenture contains representations and warranties by us, indemnification provisions in favor of the lenders and customary affirmative and negative covenants related to timing filings and reporting, and events of default. As of December 31, 2020, we were in compliance with all covenants under the Indenture.

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:

- our ability to successfully market and sell, and the level of demand for, Fintepla;

- delays and cost increases as a result of the COVID-19 pandemic;
- the costs incurred to manage our commercial infrastructure, including our sales and marketing personnel, and costs incurred under our agreements with third parties for warehousing, distribution, cash collection and related commercial activities;
- 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 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, terms and timing of manufacturing for Fintepla and our product candidates;
- 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.

The following table summarizes our cash, cash equivalents and marketable securities as of December 31, 2020 and 2019:

	December 31,		
(In thousands)	**2020**	**2019**	**$ Change**
Cash and cash equivalents	$ 166,916	$ 62,070	$ 104,846
Marketable securities	338,193	189,085	149,108
Total	$ 505,109	$ 251,155	$ 253,954

As of December 31, 2020, we had $505.1 million in cash, cash equivalents and marketable securities. We believe our existing cash and investment balances will be sufficient to fund our operations in the normal course of business and allow us to meet our liquidity needs for at least the next twelve months from the date hereof.

During 2019, the increase of $254.0 million in our cash, cash equivalents and marketable securities balances from $251.2 million as of December 31, 2019 to $505.1 million as of December 31, 2020 was primarily attributable to our proceeds from equity offerings and the issuance of convertible notes offset by cash used to fund our operations.

Sources and Uses of Cash

The following table summarizes our cash flow activities:

(In thousands)	Year Ended December 31, 2020	2019
Net cash used in operating activities	$ (167,531)	$ (111,519)
Net cash (used in) provided by investing activities	(165,100)	73,121
Net cash provided by financing activities	437,477	32,014

Operating Activities

Net cash used in operating activities of $167.5 million in 2020 was primarily attributable to our net loss as we continue to invest in research and development related to our various late-stage development programs and expansion of our infrastructure as we transition to a commercial-staged company.

Net cash used in operating activities of $111.5 million in 2019 was primarily attributable to our net loss and research and development spend related to clinical trials and manufacturing process development for Fintepla and general and administrative costs to support our research and development activities, offset by upfront payments received of $17.0 million in connection with the Shinyaku Agreement entered into in March 2019, cash received of $7.1 million from a claim submitted under U.K.'s R&D Tax Relief Scheme for qualifying R&D expenditures incurred in our 2016 U.K. tax year and the receipt of $3.1 million in tenant improvement allowance related to our new headquarters.

Investing Activities

Net cash used in investing activities in 2020 of $165.1 million included cash outflows of $509.3 million as we invested the proceeds from our capital raises and debt financing transaction in available-for-sale marketable securities. Cash outflows were partially offset by cash inflows of $347.6 million from maturities of available-for-sale securities.

Net cash provided by investing activities in 2019 of $73.1 million included net sales/maturities of our available-for-sale marketable securities of $262.2 million, of which approximately $179.6 million was used to fund the cash portion of the upfront payment for the asset acquisition of Modis. In addition, we incurred capital expenditures of $9.5 million primarily related to the build-out of our new headquarters, which we began to occupy in early March 2019.

Financing Activities

Net cash provided by financing activities of $437.5 million in 2020 consisted of net proceeds of $226.6 million pursuant to our equity offerings, $223.1 million from the issuance of convertible notes and $5.5 million from issuance of common stock under equity incentive plans, offset by $15.0 million in contingent consideration payments and $2.2 million for payment of employee withholding taxes related to net share settlement of equity awards.

Net cash provided by financing activities of $32.0 million in 2019 consisted of net proceeds of $42.6 million from the sale of common stock pursuant to the 2017 Sales Agreement and $10.2 million from issuance of common stock under equity incentive plans, offset by $20.0 million in contingent consideration payments and $0.7 million for payment of employee withholding taxes related to net share settlement of equity awards.

Contractual Obligations

The following table describes our contractual cash obligations and commitments as of December 31, 2020:

(In thousands)	Payments due by period: Total	2021	2022	2023	2024	2025	Thereafter
Principal on Convertible Senior Notes due 2027[(1)]	$ 230,000	$ —	$ —	$ —	$ —	$ —	$ 230,000
Coupon interest on Convertible Senior Notes[(1)]	44,294	6,344	6,325	6,325	6,325	6,325	12,650
Operating lease obligations	14,344	2,327	2,265	2,321	2,330	2,070	3,031
Total	$ 288,638	$ 8,671	$ 8,590	$ 8,646	$ 8,655	$ 8,395	$ 245,681

(1) Assumes the notes are not converted or redeemed prior to the maturity date.

We have supply agreements for the manufacture of active pharmaceutical ingredient (API) used in Fintepla and procurement of raw materials (other than the API) used to formulate, fill, test and release an oral solution of Fintepla. As of December 31, 2020, annual minimum purchase commitments under these supply agreements were not material.

In addition, we enter into contracts in the normal course of business with CROs for preclinical studies and clinical trials and contract manufacturing organizations for the manufacture of drug materials. The contracts are cancellable, with varying provisions regarding termination. If a contract with a specific vendor were to be cancelled, we would only be obligated for costs of products or services that have been incurred by the vendor prior the effective date of cancellation, plus applicable cancellation fees.

In connection with our acquisition of Brabant, Modis and under our Tevard Agreement, we may be required to make certain development, regulatory or sales-based milestone payments, as applicable. 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 4 and 5 to our consolidated financial statements in this Form 10-K for additional details.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of SEC Regulation S-K, such as relationships with unconsolidated entities or financial partnerships, which are often referred to as structured finance or special purpose entities, established for the purpose of facilitating financing transactions that are not required to be reflected on our consolidated balance sheets.

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 8, Notes to Consolidated Financial Statements, which is incorporated herein by reference.

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, 2020, we had cash, cash equivalents and marketable securities of $505.1 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 also have an outstanding balance of $230.0 million aggregate principal amount of Convertible Senior Notes that mature in 2027, which has a fixed interest rate of 2.75% per year. We carry these instruments at face value, less unamortized discounts and issuance costs, on our accompanying consolidated balance sheets. Since these instruments bear interest at fixed rates, we have no financial statement risk associated with changes in interest rates. However, the fair value of these instruments fluctuates as interest rate changes and, in the case of our convertible senior notes, when the market price of our common stock fluctuates.

Foreign Exchange Risk

As a result of our U.K. and European 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 December 31, 2020, 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

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All financial statement schedules have been omitted, since the required information is not applicable or is not present in amounts sufficient to require submission of the schedule, or because the information required is included in the consolidated financial statements and accompanying notes.

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, 2020 and 2019, 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, 2020, and the related notes (collectively referred to as the “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, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, 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, 2020, 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 March 1, 2021 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.

Critical Audit Matters

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

Accrued clinical trial expenses

Description of the Matter

As of December 31, 2020, the Company recorded $16.5 million for accrued clinical trial expenses. As described in Note 2 to the financial statements, the Company's expense accruals for clinical trials are based on estimates of contracted services provided but not yet billed by third-party vendors. When billing terms under such contracts do not coincide with the timing of when the work is performed, management is required to make estimates of outstanding obligations to those third parties at the end of each reporting period. Accrual estimates are based on a number of factors, including management's knowledge of the research and development program activities, invoicing to date, and the provisions in the contract. If possible, the Company obtains information regarding unbilled services directly from these service providers and performs procedures to challenge these estimates based on their internal understanding of the services provided to date.

Auditing accrued clinical trial expenses was complex because of the judgments applied by management to determine the commencement and completion date of vendor tasks, and the cost and extent of work performed during the reporting period for services not yet billed by contracted third-party vendors. Testing the Company's accrued clinical trial expense models also involved increased effort due to the high volume of data used to determine the estimated accrual.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of internal controls over the Company's process for estimating the accrued clinical trial expenses, including controls over management's assessment and measurement of clinical trial progress and related estimates of accrued clinical trial costs, and the completeness and accuracy of underlying data used in the analysis.

We evaluated the estimate of accrued clinical trial expenses. We performed audit procedures that included, among others, direct confirmation of contract terms and conditions with a sample of the Company's third-party vendors. We confirmed progress of contracted clinical activities with third-party vendors and compared such data to the Company's estimates of progress as reflected in their accrual models. We tested the accuracy of the calculations and data utilized, and evaluated the reasonableness of the assumptions used in management's accrual models by vouching actual invoices paid to date, agreeing inputs back to contractual terms and holding discussions with clinical or administrative staff outside of the finance function to corroborate progress and estimated level of expended effort incurred by the Company's third-party vendors.

Convertible senior notes

Description of the Matter

Between September 2020 to October 2020, the Company issued $230.0 million of 2.75% convertible senior notes due October 1, 2027. As discussed in Note 10 of the financial statements, the Company determined the separate liability and equity components of the convertible senior notes based on the estimated fair value of a similar liability without an associated conversion feature. The resulting liability was recorded at its estimated fair value on the date of issuance. The carrying amount of the liability component of the convertible senior notes as of December 31, 2020 was $149.4 million.

Auditing the valuation of the equity component of the convertible senior notes was complex and involved a high degree of subjectivity as the Company used complex valuation methodologies that incorporated significant assumptions, including the expected volatility of the Company's common stock, its assumed credit rating, and its credit spread.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of internal controls over the Company's valuation of the conversion option, including controls over management's review of the valuation model and the significant assumptions used in the calculation.

We evaluated the estimated fair value of the equity component of the convertible senior notes. We performed audit procedures that included, among others, involving valuation specialists to assist in evaluating the methodologies and significant assumptions used in the valuation model. We compared the discount rate that was adjusted for the Company's credit risk to the interest rates on comparable debt instruments, and the forward looking implied volatility to our independent estimate of equity volatility specific to the convertible senior notes.

United Kingdom research and development tax relief scheme

Description of the Matter

As of December 31, 2020, the Company recorded $19.7 million of other income for amounts received under the United Kingdom's ("UK's") small and medium-sized enterprises ("SME") research and development ("R&D") tax relief scheme. As described in Note 18 to the consolidated financial statements, the Company carries out extensive research and development activities that benefit from UK's SME R&D tax relief scheme, whereby an entity can make an election 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. The Company records these amounts as a component of other income, net after an election for tax relief in the form of cash payments has been made for a discrete tax year by submitting the claim, and collectability is deemed probable and reasonably assured.

Auditing the amounts recorded related to the UK's SME R&D tax relief scheme was complex due to the judgment involved in the application of foreign tax regulations that allow the Company to claim a cash refundable benefit.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of internal controls over the Company's process for calculating the UK's SME R&D tax relief scheme.

We evaluated other income recorded for the UK's SME R&D tax relief scheme. We performed audit procedures that included, among others, utilizing professionals with specialized skill and knowledge to assist in evaluating the Company's eligibility to participate in the scheme, inspecting the reasonableness of types of qualified the expenses and programs used to determine the claim, and evaluating the reasonableness of the Company's application of relevant foreign tax regulations associated with the UK's SME R&D tax relief scheme. We tested the completeness, accuracy, and relevance of information used in the calculation of the claim. We evaluated the status, results of communications and audits by the UK tax authorities associated with past and current claims made by the Company under the UK's SME R&D tax relief scheme.

/s/ Ernst & Young LLP

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

Redwood City, California

March 1, 2021

ZOGENIX INC.
CONSOLIDATED BALANCE SHEETS

(In thousands, except par value)	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 166,916	$ 62,070
Marketable securities	338,193	189,085
Accounts receivable, net	3,824	—
Inventory	1,026	—
Prepaid expenses	7,279	8,593
Acquisition holdback placed in escrow	—	25,000
Other current assets	4,936	2,491
Total current assets	522,174	287,239
Property and equipment, net	8,724	9,424
Operating lease right-of-use assets	7,748	7,774
Intangible asset, net	98,558	102,500
Goodwill	6,234	6,234
Other non-current assets	7,692	1,079
Total assets	$ 651,130	$ 414,250
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 11,945	$ 7,979
Accrued and other current liabilities	54,964	30,117
Acquisition holdback liability	—	24,444
Deferred revenue, current	5,318	5,927
Current portion of operating lease liabilities	1,688	1,322
Current portion of contingent consideration	8,800	25,600
Total current liabilities	82,715	95,389
Deferred revenue, non-current	5,479	7,425
Operating lease liabilities, net of current portion	10,314	10,752
Contingent consideration, net of current portion	33,600	38,200
Deferred tax liability	—	17,425
Convertible Senior Notes	149,353	—
Total liabilities	281,461	169,191
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000 shares authorized, none issued and outstanding	—	—
Common stock, $0.001 par value; 100,000 and 50,000 shares authorized and 55,736 and 45,272 shares issued and outstanding at December 31, 2020 and 2019, respectively	56	45
Additional paid-in capital	1,694,524	1,360,092
Accumulated other comprehensive (loss) income	(71)	379
Accumulated deficit	(1,324,840)	(1,115,457)
Total stockholders' equity	369,669	245,059
Total liabilities and stockholders' equity	$ 651,130	$ 414,250

See accompanying notes to the consolidated financial statements.

ZOGENIX INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)	Year Ended December 31, 2020	2019	2018
Revenues:			
Net product sales	$ 9,587	$ —	$ —
Collaboration revenue	4,056	3,648	—
Total revenues	13,643	3,648	—
Operating costs and expenses:			
Cost of product sales (excluding intangible asset amortization)	542	—	—
Research and development	138,002	115,639	100,925
Selling, general and administrative	99,574	60,792	38,950
Intangible asset amortization	3,942	—	—
Acquired in-process research and development and related costs	10,700	251,438	—
Change in fair value of contingent consideration	8,600	5,600	1,300
Total operating expenses	261,360	433,469	141,175
Loss from operations	(247,717)	(429,821)	(141,175)
Other income (expense):			
Interest income	2,891	9,804	7,170
Interest expense	(3,759)	(2)	(6)
Other income, net	21,777	516	10,295
Loss from continuing operations before income taxes	(226,808)	(419,503)	(123,716)
Income tax benefit	(17,425)	—	—
Loss from continuing operations	(209,383)	(419,503)	(123,716)
Loss from discontinued operations	—	—	(198)
Net loss	$ (209,383)	$ (419,503)	$ (123,914)
Net loss per share, basic and diluted[(1)]	$ (3.90)	$ (9.74)	$ (3.27)
Weighted average common shares outstanding, basic and diluted	53,706	43,078	37,884

(1) Net loss per share for both continuing operations and discontinued operations, basic and diluted, was the same for all periods presented.

See accompanying notes to the consolidated financial statements.

ZOGENIX INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)	Year Ended December 31, 2020	2019	2018
Net loss	$ (209,383)	$ (419,503)	$ (123,914)
Other comprehensive income (loss):			
Net unrealized (loss) gains on marketable securities	(183)	702	3
Reclassification adjustments for realization of gain on sale of marketable securities included in net loss	(7)	(326)	—
Foreign currency translation loss	(260)	—	—
Total other comprehensive (loss) income	(450)	376	3
Comprehensive loss	$ (209,833)	$ (419,127)	$ (123,911)

See accompanying notes to the consolidated financial statements.

ZOGENIX INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(In thousands)	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2017	34,808	$ 35	$ 873,526	$ —	$ (572,040)	$ 301,521
Net loss	—	—	—	—	(123,914)	(123,914)
Other comprehensive income	—	—	—	3	—	3
Issuance of common stock, net of issuance costs	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
Net loss	—	—	—	—	(419,503)	(419,503)
Other comprehensive income	—	—	—	376	—	376
Issuance of common stock, net of issuance costs	904	1	42,575	—	—	42,576
Issuance of common stock under employee equity plans	712	—	10,182	—	—	10,182
Shares repurchased for tax withholdings related to net share settlement of employee equity awards	(17)	—	(744)	—	—	(744)
Issuance of common stock in connection with asset acquisition	1,595	2	68,122			68,124
Stock-based compensation	—	—	21,247	—	—	21,247
Balance at December 31, 2019	45,272	$ 45	$ 1,360,092	$ 379	$ (1,115,457)	$ 245,059
Net loss	—	—	—	—	(209,383)	(209,383)
Other comprehensive loss	—	—	—	(450)	—	(450)
Issuance of common stock, net of issuance costs	10,000	10	226,566	—	—	226,576
Equity component of Convertible Senior Notes	—	—	75,333	—	—	75,333
Issuance of common stock under employee equity plans	546	1	5,514	—	—	5,515
Shares repurchased for tax withholdings related to net share settlement of employee equity awards	(82)	—	(2,157)	—	—	(2,157)
Stock-based compensation	—	—	29,176	—	—	29,176
Balance at December 31, 2020	55,736	$ 56	$ 1,694,524	$ (71)	$ (1,324,840)	$ 369,669

See accompanying notes to the consolidated financial statements.

ZOGENIX INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)	Year Ended December 31, 2020	2019	2018
Cash flows from operating activities:			
Net loss	$ (209,383)	$ (419,503)	$ (123,914)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	29,176	21,247	15,492
Depreciation and amortization	5,465	1,268	155
Deferred income taxes	(17,425)	—	—
Noncash lease expense	1,137	1,221	—
Amortization of debt discount and issuance costs	2,143	—	—
Net accretion and amortization of investments in marketable securities	(570)	(4,887)	(1,998)
Acquired in-process research and development (IPR&D)	10,700	251,437	—
Change in fair value of contingent consideration	8,600	5,600	1,300
Other	(205)	(471)	(169)
Changes in operating assets and liabilities:			
Accounts receivable	(3,824)	—	—
Inventory	(1,026)	—	—
Prepaid expenses and other current assets	(575)	7,573	(9,335)
Other assets	(1,613)	(5,723)	266
Accounts payable, accrued and other current liabilities	13,711	5,647	6,545
Operating lease liability	(1,287)	11,720	—
Deferred revenue	(2,555)	13,352	—
Net cash used in operating activities	(167,531)	(111,519)	(111,658)
Cash flows from investing activities:			
Cash paid for IPR&D assets	(10,700)	(179,624)	—
Purchase of note receivable	(5,000)	—	—
Purchases of marketable securities	(509,335)	(329,641)	(569,515)
Proceeds from maturities of marketable securities	12,987	415,020	125,783
Proceeds from sale of marketable securities	347,627	176,858	—
Purchases of property and equipment	(679)	(9,492)	(1,018)
Net cash (used in) provided by investing activities	(165,100)	73,121	(444,750)
Cash flows from financing activities:			
Payments of contingent consideration amounts previously established in purchase accounting	(15,000)	(20,000)	—
Proceeds from issuance of common stock under equity incentive plans	5,515	10,182	9,654
Taxes paid related to net share settlement of equity awards	(2,157)	(744)	(1,430)
Net proceeds from issuance of Convertible Senior Notes	223,100	—	—
Payment of debt issuance costs	(557)	—	—
Proceeds from issuance of common stock, net	226,576	42,576	323,135
Net cash provided by financing activities	$ 437,477	$ 32,014	$ 331,359
Net increase (decrease) in cash and cash equivalents	$ 104,846	$ (6,384)	$ (225,049)
Cash and cash equivalents at beginning of period	$ 62,070	$ 68,454	$ 293,503
Cash and cash equivalents at end of period	$ 166,916	$ 62,070	$ 68,454
Noncash investing and financing activities:			
Common stock issued as consideration for asset acquisition	$ —	$ 68,124	$ —
Net liabilities assumed in connection with asset acquisition	$ —	$ 3,688	$ —
Purchases of property and equipment in accounts payable	$ —	$ —	$ 1,762

See accompanying notes to the consolidated financial statements.

ZOGENIX INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1 — Organization and Description of Business

Zogenix Inc., and subsidiaries (also referred to as Zogenix, we, our or us) is a global biopharmaceutical company committed to developing and commercializing therapies with the potential to transform the lives of patients and their families living with rare diseases. Our first rare disease therapy, Fintepla (fenfluramine) oral solution, has been approved by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency for the treatment of seizures associated with Dravet syndrome, a rare, devastating, severe lifelong epilepsy. Fintepla is also currently under development in Japan. We also have two additional late-stage development programs underway: one for Fintepla for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS), and one for MT1621, an investigational therapy for the treatment of thymidine kinase 2 deficiency (TK2d), a rare genetic disease.

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. We operate as a single operating segment engaged in the research, development and commercialization of pharmaceutical products, and our headquarters are located in Emeryville, California.

Liquidity

As of December 31, 2020, our cash, cash equivalents and marketable securities totaled $505.1 million. Excluding gains from two discrete business divestitures, we have incurred significant net losses and negative cash flows from operating activities since inception resulting in an accumulated deficit of $1.3 billion as of December 31, 2020. We expect to continue to incur significant operating losses and negative cash flows from operations to support the marketing and commercialization of Fintepla for Dravet syndrome as well as continuing to advance our clinical programs. Additionally, we are obligated to make future milestone payments that are contingent upon the successful achievement of certain development, regulatory and sales-based milestone events related to Fintepla and MT1621 (See Notes 4 and 5). Historically, we have relied primarily on the proceeds from equity and convertible debt offerings to finance our operations. We believe our cash, cash equivalents and marketable securities balances will be sufficient to meet our anticipated operating requirements for at least the next 12 months following the date of issuance of these consolidated financial statements. Until such time, if ever, we can generate a sufficient amount of revenue to finance our cash requirements, we may need to continue to rely on additional financing to achieve our business objectives. However, there is no assurance that such financings could be consummated on acceptable terms or at all. Market volatility resulting from the global novel coronavirus disease (COVID-19) pandemic or other factors could also adversely impact our ability to access capital when and as needed. Failure to raise sufficient capital when needed could require us to significantly delay, scale back or discontinue one or more of our product development programs or commercialization efforts or other aspects of our business plans, and our operating results and financial condition would be adversely affected.

Note 2 — Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The consolidated financial statements and accompanying notes have been prepared in accordance with accounting principles generally accepted in the United States (GAAP). Certain prior year amounts in the consolidated financial statements and notes thereto have been reclassified to conform to the current year's presentation. These reclassifications did not affect our financial position, net loss, comprehensive loss, or cash flows as of and for the periods presented. The consolidated financial statements include the accounts of Zogenix Inc. and its wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Variable Interest Entities

We consolidate a variable interest entity (VIE) if we are the primary beneficiary, defined as the party that has both the power to direct the activities that most significantly impact the VIE’s economic performance and the obligation to absorb losses of or the right to receive benefits from the VIE that could potentially be significant to the VIE. A variable interest is a contractual, ownership or other interest that changes with changes in the fair value of

the VIE's net assets exclusive of variable interests. To determine whether a variable interest we hold could potentially be significant to the VIE, we consider both qualitative and quantitative factors regarding the nature, size and form of our involvement with the VIE. Changes in the economic interests (either by us or third parties) or amendments to the governing documents of the VIE could affect an entity's status as a VIE or the determination of the primary beneficiary. If we are determined to be the primary beneficiary of a VIE, we would include the assets, liabilities, noncontrolling interests and results of activities of the VIE in our consolidated financial statements. The primary beneficiary evaluation is updated continuously.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Revenue Recognition

Our revenues consist of product sales of Fintepla and revenues derived from our collaboration arrangement with Nippon Shinyaku Co., Ltd. (Shinyaku). See Note 3.

Net Product Revenues

We recognize revenue when control of the promised good or service is transferred to the customer, in an amount that reflects the consideration we expect to be entitled to in exchange for those goods or services. We determine revenue recognition through the following steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy a performance obligation. We only apply the five-step model to contracts when collectability of the consideration to which we are entitled in exchange for the goods or services we transfer to the customer is determined to be probable.

We distribute Fintepla in the U.S. through and arrangement with a specialty distributor who is our customer. The specialty distributor subsequently resells our product through its related specialty pharmacy provider to patients and health care providers. Separately, we have or may enter into payment arrangements with various third-party payers including pharmacy benefit managers, private healthcare insurers and government healthcare programs who provide coverage and reimbursement for our products that have been proscribed to a patient. For the year ended December 31, 2020, our revenue from net product sales were only generated in the U.S. following the FDA's approval for marketing of Fintepla for the treatment associated with seizures in Dravet syndrome in June 2020.

Revenue from product sales is recorded at the net sales price (transaction price), which includes estimates of consideration payable to our customer and third-party payers for which reserves are established and that result from government rebates, chargebacks, co-pay assistance, prompt-payment discounts and other allowances that are offered under arrangements between us, our customer, and third-party payers related to the sales of Fintepla. These reserves are classified as either reductions of accounts receivable (if the amounts are payable to our customer) or as refund liabilities within current liabilities (if the amounts are payable to a party other than our customer). Amounts billed or invoiced are included in accounts receivable, net on our consolidated balance sheet. We did not have any contract assets (unbilled receivables) at December 31, 2020, as we generally invoice our customer before or at the time of revenue recognition. We also did not have any contract liabilities at December 31, 2020, as we did not receive payments in advance of fulfilling our performance obligations to customers.

We recognize product revenues when a customer obtains control of our product, which occurs at a point in time and is typically upon delivery to the customer or, in the case of products that are subject to consignment agreements, when the customer takes title of the product from our consigned inventory location for shipment directly to a patient or healthcare provider. In the event the variable consideration is constrained, we include an amount to the extent it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur in a future reporting period. Depending on the type of variable consideration, we use either the most likely method or expected value method to estimate variable consideration related to Fintepla product sales. We do not have any material constraints on our variable consideration included within the transaction price for Fintepla product sales. The actual amount of consideration ultimately received may differ from our estimates. If actual results in the future vary from estimates, the estimates will be adjusted, which will affect our revenue from net product sales in the period that such variances become known.

Each unit of Fintepla that is ordered by our customers represent a separate performance obligation that is completed when the customer obtains control of our product. We record product revenues, net of variable consideration, any applicable constraint, and consideration payable to parties other the customer at that point in time. We record shipping and handling costs within cost of product sales on our consolidated statements of operations. We classify payments to customers or its affiliates for certain services, to the extent that the services provided are distinct from the sale of our product and we can reasonably estimate its fair value, as selling, general and administrative expenses on our consolidated statements of operations. We have elected to exclude taxes collected from our customers and remitted to governmental authorities from the measurement of the transaction price.

We sell Fintepla to our customer at wholesale acquisition cost, and calculate product revenue from Fintepla sales, net of variable consideration and consideration payable to parties other than our customer. Variable consideration and consideration payable to parties other than the customer consists of estimates related to the following categories:

Trade Discounts and Allowances: We provide customers with discounts for prompt payment and we also pay fees to customers for distribution services rendered that are not distinct from product sales. We expect customers to earn these discounts and fees, and accordingly we deduct these discounts and fees in full from our gross product revenue and accounts receivable at the time we recognize the related revenue.

Government Rebates: Fintepla is eligible for purchase by, or qualifies for reimbursement from, Medicaid and other government programs that are eligible for rebates on the price they pay for Fintepla. To determine the appropriate amount to reserve for these rebates, we identify the government-funded health insurer of patients who receive Fintepla as sold by our customer, apply the applicable government discount to these sales, and estimate the portion of total rebates that we anticipate will be claimed.

Other Rebates and Chargebacks: We may contract with various third-party payers for coverage and reimbursement of Fintepla. We estimate the rebates and chargebacks that we expect to be obligated to provide to such third-party payers based upon the terms of the applicable arrangement or negotiations with such third-party payers and our visibility regarding the payer mix.

Patient Assistance Program: We provide financial assistance to eligible patients whose insurance policies have high deductibles or co-payments and deduct our estimate of the amount of such assistance from gross product revenue.

Product Returns: We do not provide contractual return rights to our customer, except in instances where the product is damaged or defective, which we expect to be rare.

Collaboration Revenue

We analyze our collaboration arrangements to assess whether such arrangements, or transactions between arrangement participants, involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities or are more akin to a vendor-customer relationship. In making this evaluation, we consider whether the activities of the collaboration are considered to be distinct and deemed to be within the scope of the collaborative arrangement guidance and those that are more reflective of a vendor-customer relationship and, therefore, within the scope of the revenue with contracts with customers guidance. This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement.

For elements of collaboration arrangements that are not accounted for pursuant to the revenue from contracts with customers guidance, an appropriate recognition method is determined and applied consistently, generally by analogy to the revenue from contracts with customers guidance. Amounts related to transactions with a counterparty in a collaborative arrangement that is not a customer are presented as collaboration revenue and on a separate line item from revenue recognized from contracts with customers, if any, in our consolidated statements of operations.

Amounts received prior to satisfying the revenue recognition criteria are recorded as deferred revenue in the consolidated balance sheets. If the related efforts underlying the deferred revenue is expected to be satisfied within the next twelve months this will be classified in current liabilities. Unconditional rights to receive consideration in advance of performance are recorded as receivables and deferred revenue in the consolidated balance sheets when we have a contractual right to bill and receive the payment, performance is expected to commence shortly

and there is less than a year between billing and performance. Amounts recognized for satisfied performance obligations prior to the right to payment becoming unconditional are recorded as contract assets in the consolidated balance sheets. If we expect to have an unconditional right to receive consideration in the next twelve months, this will be classified in current assets. A net contract asset or liability is presented for each contract with a customer.

For arrangements or transactions between arrangement participants determined to be within the scope of the contracts with customers guidance, we perform the following steps to determine the appropriate amount of revenue to be recognized as we fulfill our obligations: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations based on estimated selling prices; and (v) recognition of revenue when (or as) we satisfy each performance obligation.

At contract inception, we assess the goods or services promised in a contract with a customer and identify those distinct goods and services that represent a performance obligation. A promised good or service may not be identified as a performance obligation if it is immaterial in the context of the contract with the customer, if it is not separately identifiable from other promises in the contract (either because it is not capable of being separated or because it is not separable in the context of the contract), or if the performance obligation does not provide the customer with a material right.

We consider the terms of the contract and our customary business practices to determine the transaction price. The transaction price is the amount of consideration to which we expect to be entitled in exchange for transferring promised goods or services to a customer. The consideration promised in a contract with a customer may include fixed amounts, variable amounts, or both. Variable consideration will only be included in the transaction price when it is not considered constrained, which is when it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur.

If it is determined that multiple performance obligations exist, the transaction price is allocated at the inception of the agreement to all identified performance obligations based on the relative stand-alone selling prices unless the transaction price is variable and meets the criteria to be allocated entirely to one or more, but not all, performance obligations in the contract. The relative selling price for each performance obligation is based on observable prices if it is available. If observable prices are not available, we estimate stand-alone selling price for the performance obligation utilizing the estimated cost of the performance obligation with an estimated assumed margin. Once the transaction price has been allocated to a performance obligation using the applicable methodology, it is not subject to reassessment for subsequent changes in stand-alone selling prices.

Revenue is recognized when, or as, we satisfy a performance obligation by transferring a promised good or service to a customer. An asset is transferred when, or as, the customer obtains control of that asset. For performance obligations that are satisfied over time, we recognize revenue using an input or output measure of progress that best depicts our satisfaction of the relevant performance obligation. Revenues from performance obligations associated with a purchase order of Fintepla will be recognized when the customer obtains control of our product, which will occur at a point in time which may be upon shipment or delivery to the customer.

After contract inception, the transaction price is reassessed at every period end and updated for changes such as resolution of uncertain events. Any change in the overall transaction price is allocated to the performance obligations on the same methodology as at contract inception.

Management may be required to exercise judgment in estimating revenue to be recognized. Judgment is required in identifying performance obligations, estimating the transaction price, estimating the stand-alone selling prices of identified performance obligations, which may include forecasted revenue, development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success, and estimating the progress towards satisfaction of performance obligations.

Cost of Product Sales (Excluding Intangible Asset Amortization)

Cost of product sales (excluding intangible asset amortization) includes the cost of producing and distributing inventories that are related to product revenues during the respective period (including salary-related and stock-based compensation expenses for employees involved with production and distribution, freight and indirect overhead costs) and third-party royalties payable on our net product revenues. Cost of product sales may also

include costs related to excess or obsolete inventory adjustment charges, abnormal costs, unabsorbed manufacturing and overhead costs, and manufacturing variances.

For the year ended December 31, 2020, other than royalties and packaging costs, substantially all of our Fintepla inventory sold had a zero-cost basis as it was manufactured prior to the FDA's approval.

Accounts Receivable, Net

We record accounts receivable, net of certain fees paid to our customer for distribution services rendered to us that are not distinct from sales of product to our customer, prompt payment discounts and chargebacks based on contractual terms. We are also subject to credit risk from our accounts receivable related to our product sales. Accounts receivable are stated net of an allowance that reflects our current estimate of credit losses expected to occur over the life of the receivable. Estimates of our allowance for credit losses consider a number of factors including existing contractual payment terms, individual customer circumstances, historical payment patterns of our customers, a review of the local economic environment and its potential impact on expected future customer payment patterns. We have standard payment terms that generally require payment within approximately 30 days. At December 31, 2020, an allowance for credit losses was not considered necessary as the accounts receivable due from our exclusive arrangement with a single specialty distributor in the U.S. was deemed collectible.

Accounts receivable, net excludes amounts payable to us for the portion of the upfront payments related to the Shinyaku Agreement that was to be paid to us in installments. As of December 31, 2020, a $1.5 million receivable from Shinyaku was recorded within current assets on our consolidated balance sheets and was subsequently collected in February 2021.

Inventory

Inventory is recorded at the lower of cost or net realizable value, with cost determined on a first-in, first-out basis. Inventory costs include third-party contract manufacturing, third-party packaging services, freight, labor costs for personnel involved in the manufacturing process, and indirect overhead costs. We primarily use actual costs to determine the cost basis for our inventory. We periodically review our inventories to identify obsolete, slow moving, excess or otherwise unsaleable items. If obsolete, slow moving, excess or unsaleable items are observed and there are no alternate uses for the inventory, we record a write-down to net realizable value. The determination of net realizable value requires judgment including consideration of many factors, such as estimates of future product demand, product net selling prices, current and future market conditions and potential product obsolescence, among others.

Prior to regulatory approval, we expense costs associated with the manufacture of our product candidates to research and development expense unless we are reasonably certain such costs have future commercial use and net realizable value. Since we consider attaining regulatory approval of a product candidate to be highly uncertain and difficult to predict, we expect only in rare instances will pre-launch inventory be capitalized, if at all.

Acquisitions

We evaluate acquisitions of assets and other similar transactions to assess whether or not the transaction should be accounted for as a business combination or asset acquisition by first applying a screen test to determine if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. If the screen is met, the transaction is accounted for as an asset acquisition. If the screen is not met, further determination is required as to whether or not we have acquired inputs and processes that have the ability to create outputs which would meet the definition of a business. Significant judgment is required in the application of the screen test to determine whether an acquisition is a business combination or an acquisition of assets.

If the transaction is determined not to be a business combination, it is accounted for as an asset acquisition. For asset acquisitions, a cost accumulation model is used to determine the cost of an asset acquisition. Common stock issued as consideration in an asset acquisition is generally measured based on the acquisition date fair value of the equity interests issued. Direct transaction costs are recognized as part of the cost of an asset acquisition. We also evaluate which elements of a transaction should be accounted for as a part of an asset acquisition and which should be accounted for separately. Consideration deposited into escrow accounts are evaluated to determine whether it should be included as part of the cost of an asset acquisition or accounted for as contingent consideration. Amounts held in escrow where we have legal title to such balances but where such accounts are not

held in our name, are recorded on a gross basis as an asset with a corresponding liability in our consolidated balance sheet.

The cost of an asset acquisition, including transaction costs, are allocated to identifiable assets acquired and liabilities assumed based on a relative fair value basis. Goodwill is not recognized in an asset acquisition. Any difference between the cost of an asset acquisition and the fair value of the net assets acquired is allocated to the non-monetary identifiable assets based on their relative fair values. Assets acquired as part of an asset acquisition that are considered to be in-process research and development (IPR&D) are immediately expensed unless there is an alternative future use in other research and development projects.

In addition to upfront consideration, our asset acquisitions may also include contingent consideration payments to be made for future milestone events or royalties on net sales of future products. We assess whether such contingent consideration meets the definition of a derivative. Contingent consideration payments in an asset acquisition not required to be accounted for as derivatives are recognized when the contingency is resolved, and the consideration is paid or becomes payable. Contingent consideration payments required to be accounted for as derivatives are recorded at fair value on the date of the acquisition and are subsequently remeasured to fair value at each reporting date. Contingent consideration payments made prior to regulatory approval are expensed as incurred. Contingent consideration payments made subsequent to regulatory approval are capitalized as intangible assets and amortized, subject to impairment assessments.

We classify cash payments related to purchased intangibles in an asset acquisition, including IPR&D assets, as a cash outflow from investing activities because we expect to generate future income and cash flows from these assets if they can be developed into commercially successful products.

If the acquisition is determined to be a business combination, all tangible and intangible assets acquired, including any IPR&D asset, and liabilities assumed, including contingent consideration, are recorded at their fair value. Goodwill is recognized for any difference between the price of acquisition and our fair value determination. In addition, direct transaction costs in connection with business combinations are expensed as incurred, rather than capitalized.

Fair Value of Financial Instruments

Our financial instruments, including cash and cash equivalents, other current assets, promissory note receivable, 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 Note 7 for financial instruments measured or disclosed at fair value for marketable securities, contingent consideration liabilities and our Convertible Senior Notes.

Cash Equivalents and Marketable Securities

We consider 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.

We invest our 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. All of our marketable securities have been accounted for as available-for-sale and carried at fair value. We have classified all of our available-for-sale marketable securities, including those with maturity dates beyond one year, as current assets on the consolidated balance sheets as we may sell these securities at any time for use in current operations even if they have not yet reached maturity. 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 on marketable securities are included in other income (expense). Gains and losses on sales are recorded based on the trade date and determined using the specific identification method.

We periodically assess our available-for-sale marketable securities for impairment. For debt securities in an unrealized loss position, this assessment first takes into account our intent to sell, or whether it is more likely than not that we will be required to sell the security before recovery of its amortized cost basis. If either of these criteria are met, the debt security's amortized cost basis is written down to fair value through interest and other, net. For debt securities in an unrealized loss position that do not meet the aforementioned criteria, we assess whether the decline in fair value has resulted from credit losses or other factors. In making this assessment, we consider the extent to which fair value is less than amortized cost, any changes to the rating of the security by a rating agency,

and any adverse conditions specifically related to the security, among other factors. If this assessment indicates that a credit loss may exist, the present value of cash flows expected to be collected from the security are compared to the amortized cost basis of the security. If the present value of cash flows expected to be collected is less than the amortized cost basis, a credit loss exists and an allowance for credit losses will be recorded in other income (expense), net, limited by the amount that the fair value is less than the amortized cost basis. Any additional impairment not recorded through an allowance for credit losses is recognized in other comprehensive loss. Changes in the allowance for credit losses are recorded as provision for (or reversal of) credit loss expense. Losses are charged against the allowance when management believes the uncollectability of an available-for-sale security is confirmed or when either of the criteria regarding intent or requirement to sell is met. These changes are recorded in other income (expense), net.

Concentration of Credit Risk

As is common in the pharmaceutical industry for products treating rare diseases, Fintepla is distributed through an exclusive arrangement with a single specialty distributor in the U.S. As a result, our accounts receivable is exposed to concentration of credit risk as 100% of the accounts receivable is due from this customer.

In addition, our investments in cash equivalents and marketable securities potentially subject us to concentrations of credit risk. As stated in our investment policy, the primary objective of our investment activities is to preserve principal and maintain a desired level of liquidity to meet working capital needs. Accordingly, our investment portfolio consists of investment-grade rated securities with active secondary or resale markets and is subject to established guidelines relative to diversification and maturities to maintain safety and liquidity. Historically, we have not experienced any material credit losses on our investments and we believe our exposure to credit risk related to our investing activities are limited. We maintain amounts on deposit with various financial institutions, which may exceed federally insured limits. However, management periodically evaluates the credit-worthiness of those institutions, and we have not experienced any losses on such deposits.

Concentration of Supplier Risk

Certain materials and key components that we utilize in our operations are obtained through single suppliers. Since the suppliers of key components and materials must be named in a New Drug Application (NDA) or supplemental NDA (sNDA) 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 our suppliers were interrupted for any reason, we may be unable to supply any of our approved products or product candidates for clinical trials.

Impact of COVID-19 Pandemic

The ongoing COVID-19 pandemic continues to cause disruptions and uncertainties. We are following all legislatively-mandated travel directives in the various countries where we operate, and we have also put additional travel restrictions in place for our employees designed to reduce the risk from COVID-19. For example, our offices continue to be closed and our employees continue to work remotely. We commenced the commercial launch of Fintepla in the U.S. in July 2020 and in Germany in February 2021 and our commercialization efforts requires us to navigate through the operational restrictions imposed on our sales force from quarantines, travel restrictions and bans and other governmental and healthcare restrictions related to COVID-19. As a result of these restrictions, our sales force has not been able to conduct in-person interactions with physicians and healthcare providers and have been restricted to primarily conducting educational and promotional activities for Fintepla virtually, which may impact our ability to market Fintepla. As of December 31, 2020, the COVID-19 pandemic has not impacted the carrying values of our inventory, finite-lived intangible asset, goodwill, long-lived assets and right-of-use assets. The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain it or treat COVID-19, as well as the economic impact on local, regional, national and international markets. If the financial markets and/or the overall economy are impacted for an extended period, our business, results of operations and financial condition may be adversely affected.

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

Upon sale or retirement of the assets, the cost and related accumulated depreciation are removed from the consolidated balance sheet and the resulting gain or loss is recognized in the consolidated statement of operations. Expenditures for maintenance and repairs are expensed as incurred.

Goodwill and Purchased Intangible Asset

Goodwill represents the difference between the purchase price and the estimated fair value of the net assets acquired in a business acquisition. The goodwill balance of $6.2 million at December 31, 2020 and 2019 is directly attributable to our acquisition of Brabant Pharma Limited (Brabant) in 2014 to obtain worldwide development and commercialization rights to Fintepla. In connection with the acquisition of Brabant, we also recorded in-process research and development (IPR&D) with an estimated fair value of $102.5 million on the acquisition date, determined using an income approach described further below. IPR&D represents incomplete research projects that we acquire through a business acquisition which, at the time of acquisition, have not reached technological feasibility, regardless of whether they have alternative use.

Goodwill

Goodwill is not amortized, but instead is reviewed for impairment at least annually on our assessment date of October 1, or more frequently if events occur or circumstances change that would indicate the carrying amount may be impaired. Goodwill is assigned to, and impairment testing is performed at, the reporting unit level. We determined we have only one reporting unit, which is the same as our operating segment, as well as our reportable segment. Accordingly, our impairment testing is performed at the entity-wide level.

For the year ended December 31, 2020, we performed a quantitative impairment test by comparing the fair value of our net assets with their carrying amounts. As we have a single reporting unit, an appropriate measure of the fair value of our net assets is our market capitalization on the assessment date. Our market capitalization, excluding any potential adjustment for a control premium, exceeded the carrying amount of our net assets as of October 1, 2020 by a significant amount and we determined our goodwill was not impaired. There were no goodwill impairment charges for all periods presented.

Purchased Intangible Asset

Intangible assets acquired in a business combination related to IPR&D projects are considered to be indefinite-lived until the completion or abandonment of the associated research and development efforts. IPR&D intangible assets are tested at least annually until the project is completed or abandoned. Upon determining an IPR&D project has been completed, a final impairment test is performed and then the IPR&D asset is accounted for as a finite-lived intangible asset subject to amortization over its estimated useful life as well as being assessed for impairment as a long-lived asset. Finite-lived intangible assets are amortized using the method that best reflects how their economic benefits are utilized or, if a pattern of economic benefits cannot be reliably determined, on a straight-line basis over their estimated useful lives (see Note 9).

In performing impairment assessment for IPR&D, the accounting guidance allows an entity the option to first assess qualitative factors to determine whether it is necessary to perform a quantitative test. If we believe, as a result of our qualitative assessment, that it is more-likely-than-not that the fair value of the IPR&D asset is less than its carrying amount, the quantitative impairment test is required. Otherwise, no further testing is required.

When performing a qualitative test, we consider the results of our most recent quantitative impairment test and identify the most relevant drivers 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 of fair value, 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 will proceed with quantitative impairment test.

Under a quantitative test, we use an 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 judgmental 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 product sales, which are based on estimates of the sales price of the product, the number of patients who will be diagnosed and treated and our competitive position in the marketplace, and appropriate discount and tax rates. If the fair value is less than the carrying amount based on this test, any impairment loss is recognized in our consolidated statements of operations by adjusting the carrying value of the IPR&D asset on our consolidated balance sheet to its fair value.

As of December 31, 2019 and in June 2020, the date Fintepla was approved for marketing by the FDA and was also when the associated research and development efforts for our IPR&D asset were considered to be complete, we performed a qualitative test and concluded that it is more-likely-than-not that the fair value of our IPR&D asset exceeded its carrying value and no further testing was deemed necessary. There were no impairment losses recorded for IPR&D in any of the years presented.

In June 2020, we reclassified the intangible asset balance of $102.5 million related to Fintepla rights from IPR&D to a finite-lived intangible asset on our consolidated balance sheets as the IPR&D project was considered complete and commenced amortization.

Impairment Assessments Related to Long-Lived Assets

Long-lived assets, including finite-lived intangible assets and right-of-use operating lease assets, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets (group) may not be recoverable. Recoverability of assets is determined by comparing the estimated undiscounted net cash flows of the operations related to the assets (asset group) to their carrying amount. If the carrying value of the assets (asset group) exceeds its undiscounted cash flows, we then compare the fair value of the assets (asset group) to their carrying value to determine the impairment loss. The impairment loss will be allocated to the carrying values of the long-lived assets (asset group), but not below their individual fair values.

If we determine that events and circumstances warrant a revision to the remaining period of amortization or depreciation for a specific long-lived asset, its remaining estimated useful life will be revised, and the remaining carrying amount of the long-lived asset will be depreciated or amortized prospectively over the revised remaining estimated useful life. There were no impairment charges for long-lived assets (groups) for all periods presented.

Leases

We determine whether the contract is or contains a lease at the inception of the arrangement and if such a lease is classified as a financing lease or operating lease at lease commencement. All of our leases are classified as operating leases. Leases with a term greater than one year are included in operating lease right-of-use assets (ROU asset), current portion of lease liabilities, and lease liabilities, net of current portion in our consolidated balance sheet. If a lease contains an option to renew, the renewal option is included in the calculation of lease liabilities if we are reasonably certain at lease commencement the renewal option will be exercised. Lease liabilities and their corresponding ROU assets are measured at the present value of the remaining lease payments, discounted at an appropriate incremental borrowing rate at lease commencement. Management uses judgment to estimate the appropriate incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. Certain adjustments to the ROU asset may be required for items such as initial direct lease costs, lease incentives, scheduled rent escalations and impairment charges if we determine the ROU asset is impaired. Operating lease expense is recognized on a straight-line basis over the lease term.

We do not separate lease components from non-lease components for all existing lease classes. We also do not record leases on our consolidated balance sheets when a lease has a term of one year or less.

Segment Information

Operating segments are defined as components of an enterprise for which discrete financial information is available that is evaluated on a regular basis by our chief operating decision-maker (CODM) in deciding how to

allocate resources to an individual segment and in assessing performance of the segment. We operate as a single operating segment engaged in the research, development and commercialization of pharmaceutical products. Our CODM, which is our President/Chief Executive Officer, reviews our operating results on a consolidated basis and manages our operations as a single operating segment. Substantially all of our long-lived assets are located in the U.S. For the year ended December 31, 2020, all of our product sales were made to one customer who is located in the U.S.

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 regulatory approval, license fees prior to regulatory approval, professional services, travel costs, dues and subscriptions, depreciation, materials used in clinical trials and research and development and costs incurred related to our agreement with Nippon Shinyaku Co., Ltd. We expense costs relating to the purchase and production of pre-approval inventories as research and development expense in the period incurred until regulatory approval is received. Payments made prior to the receipt of goods or services to be used in research and development are recorded as prepaid assets on our consolidated balance sheets until the goods or services are realized or consumed. We classify such prepaid assets as current or non-current assets based on our estimates of the timing of when the goods or services will be realized or consumed.

Our expense accruals for clinical trials are based on estimates of the services received from clinical trial investigational sites, contract research organizations (CROs) and other third-party vendors that support us in our research and development efforts. Payments under some of our contracts with these service providers depend on factors such as the achievement of clinical milestones such as the successful enrollment of certain numbers of patients, site initiation, or completion of a clinical trial. In accruing for these services at each reporting date, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If available, we obtain information regarding unbilled services directly from these service providers. However, we may be required to estimate our accrual based only on information available to us. Once established, accruals are adjusted from time to time, as appropriate, in light of additional information. Amounts ultimately incurred in relation to amounts accrued for these services at a reporting date may be substantially higher or lower than our estimates.

Advertising Costs

Advertising costs, which include promotional expenses are expensed as incurred and recorded within selling, general and administrative expenses. For the year ended December 31, 2020, advertising costs to launch Fintepla after receiving FDA's approval for marketing in June 2020 was $1.6 million. We did not incur any advertising costs prior to having a commercial product for sale.

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. We provide 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. We recognize 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 tax position.

On March 18, 2020, the Families First Coronavirus Response Act (FFCR Act) and on March 27, 2020, The Coronavirus Aid, Relief and Economic Security Act (CARES Act) were signed into law in response to the COVID-19 pandemic. The FFCR Act and CARES Act, includes provisions related to refundable payroll tax credits, deferment of employer side social security payments, retroactively and temporarily (for taxable years beginning before January 1, 2021) suspending the application of the 80%-of-income limitation on the use of net operating losses, which was enacted as part of the Tax Cuts and Jobs Act of 2017. The CARES Act also provides that net operating losses

arising in any taxable year beginning after December 31, 2017, and before January 1, 2021 are generally eligible to be carried back up to five years.

On June 29, 2020, Assembly Bill 85 (A.B. 85) was signed into California law. A.B. 85 provides for a three-year suspension of the use of net operating losses for medium and large businesses and a three-year cap on the use of business incentive tax credits to offset no more than $5.0 million of tax per year. A.B. 85 suspends the use of net operating losses for taxable years 2020, 2021 and 2022 for certain taxpayers with taxable income of $1.0 million or more. The carryover period for any net operating losses that are suspended under this provision will be extended. A.B. 85 also requires that business incentive tax credits including carryovers may not reduce the applicable tax by more than $5.0 million for taxable years 2020, 2021 and 2022.

In December 2020, the Consolidated Appropriations Act, 2021 (CAA) was signed into law. The CAA included additional funding through tax credits as part of its economic package for 2021.

The enactment of the FFCR Act, CARES Act and A.B. 85 and CAA did not result in any material adjustments to our income tax provision for the year-ended December 31, 2020 or to our net deferred tax assets as of December 31, 2020. Given our history of losses, we do not expect the provisions of the FFCR Act, CARES Act and A.B. 85 to have a material impact on our annual effective tax rate or consolidated financial statements in 2020; however, we will continue to evaluate the impact of tax legislation and will update our disclosures as additional information and interpretive guidance becomes available.

U.K.'s Research and Development (R&D) Tax Relief Scheme

We carry out extensive research and development activities that benefit from U.K.'s small and medium-sized enterprises (SME) R&D tax relief scheme, whereby an entity has an option to receive an enhanced U.K. 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 U.K. 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.

Foreign Currency Translation and Transactions

We have certain foreign operations where their functional currency was determined to be their local currency. For these foreign subsidiaries, the local currency of their monetary assets and liabilities are translated to U.S. Dollars at the rates of exchange in effect on the balance sheet date, and local currency revenues and expenses are translated to U.S. Dollars at average rates of exchange in effect during the period. The resulting translation gains or losses are included in our consolidated statements of comprehensive loss as a component of other comprehensive income (loss) and in the consolidated statements of stockholders' equity. We also recognize gains and losses on transactions that are denominated in a currency other than the respective subsidiary's functional currency in other income (expense), net in the consolidated statements of operations.

Other Comprehensive Income (Loss)

Components of other comprehensive income (loss) include changes in fair value of our available-for-sale marketable securities, reclassification adjustments from realization of gain (loss) on sale of marketable securities included in net loss and foreign currency translation adjustments.

Stock-Based Compensation

We recognize 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 expense is recognized on a straight-line basis over the requisite service period. We account for forfeitures as they occur. Stock-based compensation is classified in the accompanying statements of operations based on the function to which the related services are provided. From time to time, we may grant broad-based restricted stock units to employees, including executive officers, that vest upon the satisfaction of both service-based and performance-based vesting conditions. We recognize stock-based compensation over the requisite service period for awards with a performance condition if the performance condition is deemed probable of being met. As a result, our stock-based

compensation expense may experience fluctuations, which may impact our reported financial results and period-to-period comparisons of our consolidated statements of operations.

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 represents the estimated length of time over which we expect an option will be outstanding. We used the simplified method, as provided for under the applicable guidance for entities with a limited history of relevant stock option exercise activity, to estimate the expected term.
- Expected volatility—The expected volatility was calculated based on our historical stock prices over the expected term.
- 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 expected term of the option.
- Expected dividend yield—The expected dividend yield was based on our historical practice and anticipated dividends over the expected term of the option.

Valuation of Restricted Stock Units

The fair value of each restricted stock unit was based on our closing stock price on the date of grant.

Net Loss per Share

Basic net loss per share is calculated by dividing the net loss by the weighted average number of shares of common stock outstanding during the period, without consideration of common stock equivalents. Diluted net loss per share is the same as basic net loss per share, since the effects of potentially dilutive securities are antidilutive given our net loss.

Accounting Pronouncements Recently Adopted

Accounting Standards Update (ASU) 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* revises the measurement of credit losses for most financial instruments measured at amortized cost, including trade receivables, from an incurred loss methodology to an expected loss methodology which results in earlier recognition of credit losses. Under the incurred loss model, a loss is not recognized until it is probable that the loss-causing event has already occurred. The standard introduces a forward-looking expected credit loss model that requires an estimate of the expected credit losses over the life of the instrument by considering all relevant information including historical experience, current conditions, and reasonable and supportable forecasts that affect collectability. In addition, the standard also modifies the impairment model for available-for-sale debt securities, which are measured at fair value, by eliminating the consideration for the length of time fair value has been less than amortized cost when assessing credit loss for a debt security and provides for reversals of credit losses through income upon credit improvement. The standard became effective for us beginning January 1, 2020. Based on the composition of our investment portfolio, which reflects our primary investment objective of capital preservation, the adoption of this standard did not have a material impact on our consolidated financial statements or related disclosures.

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. The implied fair value for a reporting unit is determined in the same manner as the amount of goodwill recognized in a business acquisition of the reporting unit. Under the standard, an entity shall 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 standard became effective for us beginning January 1, 2020. The adoption of this standard did not have a material impact on our consolidated financial statements or related disclosures; however, any prospective goodwill impairment losses recognized will be measured in accordance with the updated guidance.

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 range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. This standard became effective for us beginning January 1, 2020 and the adoption of this standard did not have a material impact on our consolidated financial statements. For the new disclosures regarding our Level 3 fair value measurements, see Note 8, *Fair Value Measurements* to these consolidated financial statements.

ASU 2019-12, *Simplifying the Accounting for Income Taxes (Topic 740) (ASU 2019-12)* removes certain exceptions to the general principles in Topic 740 related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. The new guidance also simplifies aspects of the accounting for franchise taxes and enacted changes in tax laws or rates and clarifies the accounting for transactions that result in a step-up in the tax basis of goodwill. This ASU is effective for us for all interim and annual periods beginning January 1, 2021, with early adoption permitted. We early adopted ASU 2019-12 beginning January 1, 2020 on a prospective basis. The adoption of this standard did not have a material impact on our consolidated financial statements and related disclosures.

The only aspect of ASU 2019-12 that is currently applicable to us is the removal of the exception related to intraperiod tax allocation. Beginning January 1, 2020, we have applied the general methodology regarding the intraperiod allocation of tax expense for reporting periods where we have a loss from continuing operations by determining the amount of taxes attributable to continuing operations without regard to the tax effect of other items, including changes in unrealized gains related to marketable securities.

Accounting Pronouncements Issued But Not Yet Effective

ASU 2020-06, Debt — *Debt with Conversion and Other Options (subtopic 470-20) and Derivatives and Hedging — Contracts in Entity's Own Equity (subtopic 815-40)* (ASU 2020-06), reduces the number of accounting models in ASC 470-20 that require separate accounting for embedded conversion features, which we followed in accounting for the issuance of our convertible senior notes (see Note 9). ASU 2020-06 will be effective for our fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. However, early adoption is permitted in certain circumstances for fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. When effective, we expect the elimination of the requirement to separately account for the conversion feature into its equity component by recording amounts as debt discount related to our senior convertible notes will result in a decrease to our interest expense over the expected life of the financial instrument. In addition, interest expense is expected to be closer to the stated coupon rate of the Convertible Senior Notes.

As we intend to settle conversions by paying the conversion value in cash up to the principal amount being converted and any excess in shares, we expect to be eligible to use the treasury stock method to reflect the shares underlying the notes in our diluted earnings per share. Under this method, if the conversion value of the notes exceeds their principal amount for a reporting period, then we will calculate our diluted earnings per share assuming that all the notes were converted and that we issued shares of our common stock to settle the excess. However, if reflecting the notes in diluted earnings per share in this manner is anti-dilutive, or if the conversion value of the notes does not exceed their principal amount for a reporting period, then the shares underlying the notes will not be reflected in our diluted earnings per share. Upon adoption of ASU 2020-06, we also expect to lose the ability to use the treasury stock method, which would cause our diluted earnings per share to decline. For example, ASU 2020-06 eliminates the treasury stock method for convertible instruments that can be settled in whole or in part with equity and instead require application of the "if-converted" method. Under that method, diluted earnings per share would generally be calculated assuming that all the notes were converted solely into shares of common stock at the beginning of the reporting period, unless the result would be anti-dilutive. The application of the if-converted method could reduce our reported diluted earnings per share. We have not yet made a determination on whether to elect early adoption of this ASU.

Note 3 — Revenues

Net Product Sales

For the year ended December 31, 2020, we recorded net product sales of $9.6 million, which consisted of commercial sales of Fintepla following the FDA's approval in June 2020 for marketing in the U.S.

Revenue from product sales is recorded net of applicable provisions for rebates, prompt pay discounts, distribution-related fees, patient program assistance, amongst others. The following table summarizes the provisions, and credits/payments, for sales-related deductions.

(In thousands)	Rebates	Trade Discounts, Distributor Fees and Other	Total
Balance at December 31, 2019	$ —	$ —	$ —
Provisions	1,203	380	1,583
Credits/payments	(42)	(251)	(293)
Balance at December 31, 2020	$ 1,161	$ 129	$ 1,290

Collaboration Revenue

In March 2019, we entered into an agreement (Shinyaku Agreement) with Nippon Shinyaku Co., Ltd. (Shinyaku) for the exclusive distribution of Fintepla in Japan for the treatment of Dravet syndrome and LGS. As part of the Shinyaku Agreement, we are responsible for completing the global clinical development and all regulatory approval activities for Fintepla to support the submission of new drug applications in Japan for Dravet syndrome and LGS. Shinyaku will be responsible for the commercialization activities including the promotion, marketing, sale and distribution of Fintepla in Japan. Upon regulatory approval of Fintepla in Japan, Shinyaku will also act as our exclusive distributor for commercial shipment and distribution of Fintepla in Japan. If we pursue global development of Fintepla for indications other than Dravet syndrome or LGS, Shinyaku has the option to participate in the development for such indications in Japan, subject to cost sharing requirements pursuant to the agreement. Activities under the Shinyaku Agreement will be governed by a joint steering committee (JSC) consisting of three representatives from each party to the agreement. All decisions of the JSC are to be made by a unanimous vote with tie-breaking rights provided to each party for certain matters related to development, regulatory approval and commercialization.

Shinyaku has agreed to support development and regulatory approval of Fintepla in Japan by actively participating in the design of non-clinical, clinical and manufacturing requirements needed for regulatory submission, actively planning and participating in product labeling decisions and discussions with the Japanese Ministry of Health, Labor and Welfare (MHLW) and obtained distribution exclusivity through the payment of $20.0 million, of which $17.0 million had been received as of December 31, 2020 with the remainder expected to be received in 2021. We will be actively running the clinical trials, performing manufacturing validation activities, preparing regulatory filings and holding discussions with MHLW, and negotiating pricing. We and Shinyaku have agreed to proportionally share the Japan specific development costs that may arise outside of the initial development plan and any post-approval clinical study costs in Japan. In addition, we can earn up to $66.0 million from Shinyaku for the achievement of certain regulatory milestones related to the treatment of Dravet syndrome and the treatment of LGS.

After regulatory approval of Fintepla in Japan has been obtained, we have agreed to supply Shinyaku with Fintepla upon receipt of purchase orders at our actual manufacturing cost plus a fixed transfer price mark-up, a fixed percentage of Shinyaku's net sales of Fintepla in Japan for such fiscal year, and a net price mark-up based on a percent of the applicable aggregate sales of Fintepla by Shinyaku for such fiscal year. The net price mark-up percentage increases with Shinyaku’s sales of Fintepla annual net sales in Japan and ranges between mid-twenties and is capped at a low thirties of the aggregate annual net sales for an applicable fiscal year.

In addition, we can earn up to an additional $42.5 million tied to the achievement of certain net sales milestones by Shinyaku through the term of the agreement.

The Shinyaku Agreement expires in September of 2045, unless earlier terminated by either party for a change in control, a material breach, bankruptcy, dissolution, or winding up of such other party. The Shinyaku Agreement may be also terminated by either party: (1) with one year prior written notice to the other party on or after the date of the first commercial sale of a competing generic version of the Fintepla in Japan, (2) if, prior to the launch of the Fintepla in Japan, a party has a good faith concern, based on credible evidence, that such launch is not likely to be possible with commercially reasonable efforts, or (3) if a party believes Fintepla poses a substantial safety concern. We may also terminate the agreement following the second anniversary of the first commercial sale of the Fintepla in Japan if Shinyaku has failed to achieve or maintain certain diligence obligations under the Shinyaku Agreement. Shinyaku may also terminate the agreement if, prior to the launch of the Fintepla in Japan, Shinyaku has a good faith concern that Fintepla will not be commercially viable in Japan.

We concluded that collaborative activities under the Shinyaku Agreement prior to regulatory approval are within the scope of the collaborative arrangements guidance as both parties are active participants and are exposed to significant risks and rewards dependent on the success of commercializing Fintepla in Japan. Shinyaku is not a customer as it does not obtain an output of our development and regulatory approval activities for Fintepla as they were not provided a license to its intellectual property or the ability to manufacture the product, and we do not consider performing development and regulatory approval services to be a part of our ongoing activities.

We considered the revenue from contracts with customers guidance by analogy in determining the unit of account, and the recognition and measurement of such unit of account for collaborative activities under the Shinyaku Agreement and concluded that there are two development programs akin to performance obligations related to collaborative activities for development and regulatory approval efforts for Dravet and LGS. Participation on the JSC was concluded to be both quantitatively and qualitatively immaterial in the context of the Shinyaku Agreement. We are the principal as it relates to the collaborative development and regulatory approval activities primarily because we are responsible for the acceptability of the results of the work of the third-party vendors that are used to assist us in performing such activities. Therefore, such collaboration revenue has been presented on a gross basis in our consolidated statements of operations apart from research and development expenses incurred.

The initial collaboration consideration allocated on a relative standalone selling price basis to each associated development program was determined using the most likely method to consist solely of the fixed consideration payments of $20.0 million. Analogizing to the revenue from contracts with customers variable consideration guidance, all potential regulatory milestone payment consideration will be included in the collaboration consideration if and when it is probable that a significant reversal in the amount of cumulative collaboration consideration recognized will not occur when the uncertainty associated with the variable collaboration consideration is subsequently resolved. We determined at contract inception and as of December 31, 2020, this consideration should be fully constrained, as the achievement of the events tied to these regulatory milestone payments was highly dependent on factors outside of our control.

Collaboration revenue is being recognized over time as the collaborative activities related to each development program are rendered. We determined an input method is a reasonable representative depiction of the performance of the collaborative activities under the Shinyaku Agreement. The method of measuring progress towards completion incorporates actual internal and external costs incurred, relative to total internal and external costs expected to be incurred over an estimated period to satisfy the collaborative activities. The period over which total costs are estimated reflects our estimate of the period over which it will perform the collaborative activities for each development program. Changes in estimates of total internal and external costs expected to be incurred are recognized in the period of change as a cumulative catch-up adjustment to collaboration revenue.

As of December 31, 2020, we had received $17.0 million of the $20.0 million in fixed consideration under the arrangement. For the years ended December 31, 2020 and 2019, we recognized collaboration revenue of $4.1 million and $3.6 million, respectively. As of December 31, 2020, the deferred revenue balance of $10.8 million included a $1.5 million collaboration receivable recorded within other current assets related to the $20.0 million fixed consideration under the arrangement. The final payment of $1.5 million will be payable to us in March 2021. Deferred revenue, which is classified as either current or net of current portion in the consolidated balance sheets based on the period over which the collaboration revenue is expected to be recognized. We expect to recognize collaboration revenue related to these collaborative activities through 2023.

We concluded that the supply of Fintepla to Shinyaku will be within the scope of the revenue from contracts with customers guidance if regulatory approval in Japan occurs and when a purchase order is received from Shinyaku. Such activity is considered to be a vendor customer relationship as Shinyaku will be a party that has contracted with an us to obtain goods or services that are an output of our ordinary activities in exchange for consideration and selling approved commercial product to a customer is expected to be part of our ongoing activities. Each purchase order for a shipment of Fintepla will be identified as a separate performance obligation as we did not grant Shinyaku intellectual property rights. The agreed upon price for the supply of Fintepla (cost plus a fixed transfer price mark-up, fixed percentage of aggregate sales of Fintepla by Shinyaku per year, the net price mark-up and sales milestones) to Shinyaku does not represent a material right, and therefore is not a performance obligation, and such pricing on an aggregate basis represents the standalone selling price a distributor would typically pay for such a product in that region or market. There are also no minimum purchase commitments. The transaction price to be allocated to the performance obligation will include the fixed consideration associated with the cost-plus price of Fintepla and variable consideration associated with a fixed percentage of aggregate sales of Fintepla by Shinyaku per year, the net price mark-up and sales milestones subject to the constraint. To date,

Shinyaku has not provided us with any purchase orders and thus no revenue has been recognized for the supply of Fintepla.

Note 4 — Acquisitions

Asset Acquisition of Modis

On September 6, 2019, the date the transaction closed, we acquired all of the outstanding equity interests of Modis, a privately-held biopharmaceutical company, to expand our late-stage development pipeline. Modis was formed in May 2016 through a collaboration with academic experts in mitochondrial biology. Modis holds an exclusive worldwide license from Columbia University in New York City (Columbia) to certain intellectual property rights owned or controlled by Columbia to develop and commercialize MT1621. MT1621 is an investigational deoxynucleoside substrate enhancement therapy (SET) for the treatment of TK2d, an inherited mitochondrial DNA depletion disease that predominantly affects children and is often fatal. Aggregate upfront consideration transferred of approximately $246.5 million consisted of $175.5 million in cash payments made and 1,595,025 unregistered shares of our common stock issued to the outstanding shareholders of Modis as well as employee award holders under the legacy Modis 2017 Stock Plan (Modis Plan). The fair value of common stock issued as acquisition consideration was $68.1 million on the date the transaction closed. Also included in the aggregate upfront consideration transferred were $3.5 million of transaction costs incurred, reduced by a net working capital adjustment receivable of $0.6 million. Pursuant to the terms of the Modis purchase agreement, certain unvested awards held by employees under the Modis Plan converted into the right to receive a pro-rata share of the purchase consideration at the date of acquisition, with no future service requirement. A component of the total consideration transferred was attributed to the unvested awards with a fair value of $4.9 million and was accounted for as a separate transaction from the asset acquisition. This amount was immediately expensed and included in acquired in-process research and development and related costs in the consolidated statements of operations for the year ended December 31, 2019.

Of the upfront cash consideration, $25.0 million was deposited into an escrow account to fund post-closing net working capital adjustments, and general representations and warranties for a one-year period, which was subsequently released in 2020. In addition, the former shareholders of Modis were eligible to receive milestone payments consisting of $100.0 million upon FDA approval and $50.0 million upon EMA approval of MT1621, as well as a 5% royalty on any future net sales of specified Modis products. The upfront cash consideration was funded by cash and marketable securities on hand. The shares of our common stock provided as consideration were subsequently registered under our existing shelf registration statement on Form S-3 (No. 333-220759).

We determined substantially all of the fair value of Modis was concentrated in a single IPR&D asset group, which included license rights, clinical trial data, clinical trial development plans, research and development materials, formulations and intellectual property related to MT1621. Accordingly, the acquired set of assets and activities did not meet the definition of a business. As a result, we accounted for the transaction as an asset acquisition and allocated the remaining upfront consideration transferred to the identifiable tangible and intangible assets acquired and liabilities assumed based on their relative fair values resulting in $244.5 million being assigned to the IPR&D asset associated with MT1621 and $2.8 million for assumed net liabilities.

As of the acquisition date, Modis had completed a pivotal Phase 2 retrospective treatment clinical trial study (RETRO) of MT1621 substrate enhancement therapy in patients with TK2d and commenced a Phase 2 prospective, open-label extension clinical trial study of patients with TK2d. As the MT1621 program had not yet reached technological feasibility and had no alternative future use, the purchased IPR&D asset was expensed immediately subsequent to the acquisition within our consolidated statements of operations. As we had no tax basis in the acquired IPR&D asset, and the acquired IPR&D asset was expensed prior to the measurement of any deferred taxes, no deferred taxes were recognized for the initial differences between the amounts recognized for financial reporting and tax purposes.

The milestone payments due upon FDA or EMA approval and royalty payments on future net sales of MT1621 products were determined to be contingent consideration and not subject to derivative accounting. Any contingent consideration will be recognized when the contingency is resolved and the consideration becomes payable. For the years ended December 31, 2020 and 2019, no such amounts were deemed to be payable.

The nature of the remaining efforts for completion of the MT1621 program primarily consist of performing clinical trials and validating contract manufacturing abilities, the cost, length and success of which are extremely difficult to determine. Numerous risks and uncertainties can delay or stop clinical development of a pharmaceutical

product prior to the receipt of marketing approval, including, but not limited to, results from clinical trials that do not support continuing development, issues related to manufacturing or intellectual property protection, and other events or circumstances that cause unanticipated delays, technical problems or other difficulties. Given these risks and uncertainties, there can be no assurance that the development of MT1621 will be successfully completed. If the development of MT1621 is not successful, in whole or in part, or completed in a timely manner, we may not realize the expected financial benefits from the development of MT1621.

Note 5 — Strategic License Agreements

Fintepla

Brabant

In October 2014, we acquired Brabant in a business acquisition and obtained worldwide development and commercialization rights to Fintepla, one of our lead product candidates. Under the terms of the acquisition, 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 milestones and $45.0 million in sales-based milestones that have been accounted for as contingent consideration under purchase accounting for an acquisition of a business. To date all regulatory milestones have been earned of which $35.0 million have been paid with the remaining $15.0 million included in other current liabilities on the consolidated balance sheet as the contingency has been resolved.

Universities of Antwerp and Leuven in Belgium (the Universities)

In addition, we have a collaboration and license agreement with the 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 low-dose 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 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 we (a) do 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 we become insolvent or makes 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.

MT1621

License Agreement with Columbia University

As a result of our acquisition of Modis in September 2019, we became party to the Exclusive License Agreement, by and between Modis and the Trustees of Columbia University in the City of New York, dated as of September 26, 2016, related to MT1621. We are required to use commercially reasonable efforts to develop and commercialize licensed products worldwide, including to meet certain development and commercialization milestones within specified periods of time. Upon the achievement of certain regulatory and commercial milestones, we are required to pay Columbia University up to $2.9 million and $25.0 million, respectively, as well as tiered royalties on sales for each licensed product, at percentages ranging from the mid-single digits to the high single-digits. The royalty obligations and License Agreement will expire on a country-by-country and product-by-product basis upon the later of (i) 15 years after the first bona fide commercial sale of a licensed product, (ii) the expiration of the last to expire valid patent claim covering a licensed product in a country or (iii) expiration of any regulatory exclusivity covering such licensed product. The License Agreement may be terminated by either by Columbia or by us in the event of an uncured material breach by the other party, or by Columbia in the event we are subject to specified bankruptcy, insolvency or similar circumstances. We can terminate the License Agreement either in its entirety or on a product-by-product and country-by-country basis, upon specified prior written notice to Columbia, provided we are not exploiting licensed products in such countries.

Other License Agreement Assumed

We also became party to a license agreement between two other research institutions related to MT1621 where we may be required to pay up to $3.0 million for research, development and regulatory milestone events and up to $10.0 million for certain sales milestone events. We are also required to pay tiered royalties ranging from low to mid-single digits on net sales of licensed product.

Tevard Collaboration, Option and License Agreement

In October 2019, we entered into an option agreement with Tevard Biosciences (Tevard), a privately-held company focused on tRNA-based gene therapies. Under the agreement, Tevard granted us an option to license exclusive rights related to a preclinical development program to identify and develop novel tRNA-based gene therapies for Dravet syndrome. During 2020, we extended the option period to exercise our license rights prior to entering into a collaboration, option and license agreement with Tevard. Payments made under the option agreement were nonrefundable, but may be credited against the upfront payment due if we exercise our option on the preclinical development program. Payments made under the option agreement of $2.0 million in 2019 and $5.5 million in 2020 were included in acquired IPR&D expense and related costs in our consolidated statement of operations.

In December 2020, we exercised the option on the Dravet syndrome program and entered into a collaboration, option and license agreement with Tevard (the Tevard Agreement). The financial terms of the Tevard Agreement included an upfront payment of $5.2 million. In connection with the transaction, we also purchased a convertible promissory note issued by Tevard in the amount of $5.0 million. The note matures in December 2022 and carries interest at 3.5% per year. The note will automatically convert into equity securities issued by Tevard in their next equity financing transaction at a conversion price equal to the price paid per share by other investors of the financing transaction.

In addition to the upfront payments, we have agreed to fund Tevard's early discovery activities under the licensed Dravet syndrome program in accordance with the development plan as determined by the parties to the agreement. Once Tevard completes the early discovery activities for a program, we will be responsible for any potential future development and commercialization activities. Tevard is also eligible to receive additional development, regulatory and commercial-related milestone payments of up to $100.0 million for the Dravet program, as well as tiered royalties on future net sales in the single digits that result from the collaboration. We are also entitled to rights of negotiation and rights of first refusal to potentially obtain licenses to compounds subsequently discovered and developed by Tevard. The agreement, if not terminated sooner, would expire upon the expiration of all applicable royalty terms under the agreement with respect to a licensed program or product; however, we have the unilateral right to terminate the agreement with 180 days advanced notice

At the inception of the agreement and through December 31, 2020, we determined Tevard is a VIE in which we held variable interests through our licensed Dravet syndrome program and convertible promissory note. We determined that we are not the primary beneficiary of Tevard as we do not have voting control or other forms of power to direct activities that most significantly impact Tevard's economic performance.

In accounting for the Tevard Agreement, we excluded from consideration all prior payments made under the option agreement, which was previously expensed to acquired IPR&D. Upon entering the Tevard Agreement, we made an upfront payment of $10.2 million in exchange for a license to the Dravet syndrome program and the convertible promissory note. The upfront payment was allocated between the acquired IPR&D asset and the convertible promissory note based on their relative fair values of $5.2 million and $5.0 million, respectively. The estimated fair value of the acquired IPR&D asset was determined based on information from discussions with Tevard's management team regarding the potential of the Dravet syndrome program as well as our management team's expectations regarding the timing, future cost and commercial potential for the program. The estimated fair value of the convertible promissory note was determined based on a discounted cash flow analysis, adjusted for credit and market risk, and consideration of the fair value of the embedded conversion feature with a conversion price not more favorable than other investors participating in an equity financing transaction.

The $5.2 million of consideration allocated to the IPR&D asset was determined to have no alternative future use and was immediately charged to acquired IPR&D expense in our consolidated statements of operations and classified as cash used in investing activities on the consolidated statements of cash flows. The $5.0 million of consideration allocated to the convertible promissory note was included in other noncurrent assets on our consolidated balance sheet and carried at amortized costs and classified as cash used in investing activities on the

consolidated statements of cash flows. Payments made to fund Tevard's costs incurred under the Dravet syndrome program after the execution of the Tevard Agreement is reflected as research and development expense in our statements of operations. For the year ended December 31, 2020, amounts recorded as research and development expense associated with funding the Dravet syndrome program were $0.7 million.

At each reporting period, we evaluate the note receivable for current expected credit loss by considering factors such as historical experience, market data, issuer-specific factors, and current economic conditions. As of December 31, 2020, no provision for current expected credit losses was deemed necessary based on the expected timing of an equity financing that would result in the automatic conversion of the note to equity securities of Tevard and their existing cash on hand was sufficient to meet their operating requirements prior to the consummation of a financing transaction.

As of December 31, 2020, we do not have any current legal or contractual obligations to provide financing to Tevard and our maximum exposure to future loss is limited to the $5.0 million note receivable. While we have committed to fund the Dravet syndrome development program for Tevard's early discovery activities, our obligation to fund these efforts is contingent upon continued involvement in the program and/or the lack of any adverse events which could cause the discontinuance of the program. Our exposure to future losses is limited as we have the unilateral right to terminate the agreement with 180 days advanced notice.

Note 6 — Cash, Cash Equivalents and Marketable Securities

The following table summarizes the amortized cost and fair value of our cash, cash equivalents and marketable securities by major investment category as of December 31, 2020 and 2019:

	December 31, 2020			
(In thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Current assets:				
Cash	$ 23,887	$ —	$ —	$ 23,887
Cash equivalents:				
Money market funds	80,986	—	—	80,986
Commercial paper	61,043	—	—	61,043
Certificate of deposits	1,000	—	—	1,000
Total cash equivalents	143,029	—	—	143,029
Total cash and cash equivalents	166,916	—	—	166,916
Marketable securities:				
U.S. Treasuries	43,050	1	(1)	43,050
Commercial paper	210,986	—	—	210,986
Certificate of deposits	44,480	—	—	44,480
U.S. Government-sponsored enterprises debt securities	6,200	17	—	6,217
Corporate debt securities	33,288	172	—	33,460
Total marketable securities	338,004	190	(1)	338,193
Total cash, cash equivalents and marketable securities	$ 504,920	$ 190	$ (1)	$ 505,109

(In thousands)	December 31, 2019			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Current assets:				
Cash	$ 43,058	$ —	$ —	$ 43,058
Cash equivalents:				
Money market funds	11,527	—	—	11,527
Commercial paper	7,485	—	—	7,485
Total cash and cash equivalents	62,070	—	—	62,070
Marketable securities:				
Commercial paper	73,366	—	—	73,366
Corporate debt securities	74,038	381	(2)	74,417
Certificates of deposit	41,302	—	—	41,302
Total marketable securities	188,706	381	(2)	189,085
Total cash, cash equivalents and marketable securities	$ 250,776	$ 381	$ (2)	$ 251,155

The following table summarizes the amortized cost and fair value of marketable securities based on stated effective maturities as of December 31, 2020:

(In thousands)	Amortized Cost	Estimated Fair Value
Due within one year	$ 331,804	$ 331,976
Due between one and two years	6,200	6,217
Total	$ 338,004	$ 338,193

We regularly review our available-for-sale marketable securities in an unrealized loss position and evaluate the current expected credit loss by considering factors such as historical experience, market data, issuer-specific factors, and current economic conditions. As of December 31, 2020, no provision for current expected credit losses was required as the fair value of each individual security in an unrealized loss position exceeded its amortized cost by a de minimis amount.

Accrued interest receivable on available-for-sale marketable securities are recorded within prepaid expenses and other current assets on our consolidated balance sheets and was $0.3 million and $0.6 million at December 31, 2020 and 2019, respectively.

See Note 7 for further information regarding the fair value of our financial instruments.

Note 7 — 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, 2020 and 2019:

(In thousands)	December 31, 2020 Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 80,986	$ —	$ —	$ 80,986
Commercial paper	—	61,043	—	61,043
Certificate of deposits	—	1,000	—	1,000
Marketable securities:				
U.S. Treasuries	—	43,050	—	43,050
Commercial paper	—	210,986	—	210,986
Certificate of deposits	—	44,480	—	44,480
U.S. Government-sponsored enterprises debt securities	—	6,217	—	6,217
Corporate debt securities	—	33,460	—	33,460
Total assets[1]	$ 80,986	$ 400,236	$ —	$ 481,222
Liabilities:				
Common stock warrant liabilities[3]	$ —	$ —	$ —	$ —
Contingent consideration liabilities[2]	—	—	42,400	42,400
Total liabilities	$ —	$ —	$ 42,400	$ 42,400

(In thousands)	December 31, 2019 Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 11,527	$ —	$ —	$ 11,527
Commercial paper	—	7,485	—	7,485
Marketable securities:				
Commercial paper	—	73,366	—	73,366
Corporate debt securities	—	74,417	—	74,417
Certificates of deposit	—	41,302	—	41,302
Total assets[1]	$ 11,527	$ 196,570	$ —	$ 208,097
Liabilities:				
Common stock warrant liabilities[3]	$ —	$ —	$ 198	$ 198
Contingent consideration liabilities[2]	—	—	63,800	63,800
Total liabilities	$ —	$ —	$ 63,998	$ 63,998

(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) In connection with the acquisition of Brabant in 2014 (See Note 5), we may be required to pay future consideration that is contingent upon the achievement of specified development, regulatory approval or sales-based milestone events. We estimate 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, we remeasure these liabilities by performing a review of the assumptions discussed above and record an adjustment to reflect any changes in the estimated fair value of our contingent consideration liabilities. In the absence of any significant changes in key assumptions during a reporting period, the fair value of the contingent consideration liability is expected to increase each period with the recognition of change in fair value of contingent consideration resulting from the passage of time at the applicable discount rate as we approach the payment dates of the contingent consideration. Significant judgment is used in determining Level 3 inputs and fair value measurements as of a reporting date. Updates to assumptions could have a significant impact on our 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. As of December 31, 2020, we classified $8.8 million of the total contingent consideration liabilities of $42.4 million as current liabilities. The balance sheet classification between current and non-current liabilities was based upon our reasonable expectation as to the timing of settlement of the remaining sales-based milestones.

(3) Represents the fair value of common stock warrants outstanding that may require cash settlement under certain circumstances. As of December 31, 2020 and 2019, common stock warrant liabilities consists 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.

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, 2020 and 2019:

(In thousands)	Contingent Consideration
Balance at December 31, 2018	$ 78,200
Settlements	(20,000)
Changes in fair value	5,600
Balance at December 31, 2019	63,800
Settlements	(30,000)
Changes in fair value	8,600
Balance at December 31, 2020	$ 42,400

The following table summarizes the significant unobservable inputs used in the fair value measurement of our contingent consideration liabilities as of December 31, 2020.

Fair Value as of December 31, 2020 (in thousands)	Valuation Technique	Unobservable Input	Range	Weighted Average[1]
		Discount rate	2.5% —3.5%	3.1%
$42,400	Discounted cash flow	Probability of payment	100%	100%
		Projected year of payment	2021 — 2030	2022

(1) Unobservable inputs were weighted by the relative fair value of the contingent consideration liability.

The weighted average discount rate was calculated based on the relative fair value of our contingent consideration obligations. Significant increases or decreases in projected revenues, probabilities of payment, discount rates or the time until payment is made would have resulted in a significantly lower or higher fair value measurement as of December 31, 2020.

Periodic changes in the estimated fair value of contingent consideration are included within operating expenses in the consolidated statements of operations.

Convertible Senior Notes

As of December 31, 2020, the estimated fair value of our Convertible Senior Notes was approximately $260.5 million and was determined based on a binomial lattice model with Level 2 inputs. When determining the estimated fair value of our Senior Convertible Notes, we utilize a binomial lattice model which incorporates the terms and conditions of the Senior Convertible Notes and market-based risk measurement that are indirectly observable, such as credit risk. The lattice model produces an estimated fair value based on changes in the price of the underlying common stock price over successive periods of time. An estimated yield based on comparable non-convertible debt instruments in the market is used to discount the cash flows.

Note 8 — Other Balance Sheet Details

Inventory

Our inventory balance consists of the following:

(In thousands)	December 31, 2020
Raw materials	$ 391
Work in process	243
Finished goods	392
Total	$ 1,026

As of December 31, 2020, our inventory balance reflects the cost of post-approval manufacturing activities related to our product. Prior to receiving FDA approval for Fintepla, we recorded all manufacturing product costs as research and development expense. As of December 31, 2020, no write-downs of inventory were deemed necessary.

Property and Equipment, Net

Property and equipment, net consists of the following:

	December 31,	
(In thousands)	2020	2019
Computer equipment and software	$ 429	$ 291
Leasehold improvements	9,835	9,431
Furniture and fixtures	1,266	978
Total	11,530	10,700
Less accumulated depreciation	(2,806)	(1,276)
Property and equipment, net	$ 8,724	$ 9,424

Depreciation expense for 2020, 2019 and 2018 was $1.5 million, $1.3 million, and $0.2 million, respectively.

Accrued and Other Current Liabilities

Accrued and other current liabilities consist of the following:

(In thousands)	December 31, 2020	December 31, 2019
Accrued clinical trial costs	$ 16,477	$ 16,555
Accrued contract manufacturing costs	2,761	2,546
Accrued compensation	10,917	7,179
Accrued milestone payment	15,000	—
Other accrued liabilities	9,809	3,639
Common stock warrant liabilities	—	198
Total	$ 54,964	$ 30,117

Note 9 – Intangible Asset

The following table provides details of the carrying amount of our intangible asset:

(In thousands)	December 31, 2020	December 31, 2019
Finite-lived intangible asset	$ 102,500	$ —
Accumulated amortization	(3,942)	—
Indefinite-lived IPR&D intangible asset	—	102,500
Net carrying value	$ 98,558	$ 102,500

Our intangible asset consist of worldwide development, commercialization and related intellectual property rights including patents and licenses for our product, Fintepla (fenfluramine; formerly referred to as ZX008), which at the time of our acquisition in October 2014 and as of December 31, 2019, was classified as an indefinite-lived IPR&D asset. Upon FDA approval of Fintepla in June 2020, this indefinite-lived asset was reclassified to a finite-lived intangible asset subject to amortization.

In July 2020, we commercially launched Fintepla and commenced amortization of this asset on a straight-line basis over its estimated useful life. Due to the inherent subjectivity of forecasting the timing in which the cash flows may be generated from this intangible asset over a long-term time horizon, we concluded the pattern of economic benefit cannot be reliably determined. As such, we elected to use the straight-line method of amortization for this intangible asset.

In estimating the useful life of the finite-lived Fintepla intangible asset, we considered the estimated period over which the asset will contribute directly or indirectly to our future cash flows, the strength of issued or licensed patents and related period of intellectual property protection, the availability of competitor products treating similar indications and the impact of patent expiry on the sustainability of future operating cash flows of the asset. Based on these factors, we estimated the useful life of the finite-lived intangible asset to be 13 years. As of December 31, 2020, the carrying value of the intangible asset will be amortized over its estimated remaining useful life of 12.5 years as follows:

(In thousands)	Amortization Expense
2021	$ 7,885
2022	7,885
2023	7,885
2024	7,885
2025	7,885
Thereafter	59,133
Total	$ 98,558

Note 10 – Convertible Senior Notes

Between September 2020 and October 2020, we issued $230.0 million principal amount of 2.75% convertible senior notes due 2027 in a private offering (collectively, the Convertible Senior Notes or Notes). Total proceeds realized from the sale of the Notes, net of issuance costs of $7.5 million, were $222.5 million. The Notes are governed by an indenture (Indenture), dated as of September 28, 2020, between Zogenix and U.S. Bank National Association, as trustee. Under the Indenture, the Notes are senior, unsecured obligations of Zogenix, are equal in right of payment with its future senior, unsecured indebtedness of Zogenix, and structurally subordinated to all indebtedness and liabilities of its subsidiaries. The principal amount of the Notes was issued at par value and the Notes accrue interest at a rate of 2.75% per year, payable semi-annually in arrears on April 1 and October 1 of each year, beginning on April 1, 2021. The Notes mature on October 1, 2027, unless earlier converted by the holders or redeemed or repurchased by us in accordance with their terms prior to such date. The Indenture contains customary terms and covenants, including certain events of default upon which the Notes may be due and payable immediately, but does not contain any financial covenants.

The Notes are convertible, subject to certain conditions described below, into shares of our common stock at an initial conversion rate of 41.1794 shares per $1,000 principal amount of the Notes, which represents an initial conversion price of approximately $24.28 per share, subject to adjustments upon the occurrence of certain events. Certain corporate events described in the Indenture may increase the conversion rate for holders who elect to convert their Notes in connection with such corporate event should they occur. We also may choose to repurchase outstanding Notes through open-market transactions, including through Rule 10b5-1 trading plan to facilitate open-market repurchases, or otherwise, from time to time.

Holders may convert the Notes in multiples of $1,000 principal amount at any time prior to October 1, 2027, but only in the following circumstances:

- during any calendar quarter ending after December 31, 2020, if our closing stock price exceeds 130% of the conversion price on each of at least 20 trading days of the last 30 consecutive trading days of the immediately preceding calendar quarter;
- during the five consecutive business day period after any 10 consecutive trading day period in which the Notes' trading price is less than 98% of the product of our closing stock price times the conversion rate; or
- the occurrence of certain corporate events, such as a change of control, merger, default or liquidation.

In addition, holders may also convert their Notes at their option at any time beginning on July 1, 2027 until the close of business on the second scheduled trading day immediately before the maturity date for the Notes, without regard to the foregoing circumstances.

Upon conversion, we will pay or deliver, as the case may be, cash, shares of our common stock or a combination thereof at our election.

We may not redeem the Notes prior to October 7, 2024. On or after October 7, 2024, the Notes are redeemable for cash, in whole or in part (subject to minimum redemption amounts), at our option at any time, and from time to time, before the 40th scheduled trading day immediately before October 1, 2027, at a cash redemption price equal to 100% of the principal amount of the Notes to be redeemed, plus accrued and unpaid interest, if any, but only if our closing stock price exceeds 130% of the conversion price on (1) each of at least 20 trading days, whether or not consecutive, during the 30 consecutive trading days ending on, and including, the trading day immediately before the date we send the related redemption notice; and (2) the trading day immediately before the date we send such notice. In addition, calling any note for redemption will constitute a make-whole fundamental change with respect to that Note, in which case the conversion rate applicable to the conversion of that Note will be increased in certain circumstances if it is converted after it is called for redemption.

The Indenture contains representations and warranties by us, indemnification provisions in favor of the lenders and customary affirmative and negative covenants related to timing filings and reporting, and events of default. As of December 31, 2020, we were in compliance with all covenants under the Indenture.

In accounting for the issuance of the Notes, we performed an assessment of all embedded features of the debt instrument to determine if (i) such features should be bifurcated and separately accounted for, and (ii) if bifurcation requirements are met, whether such features should be classified and accounted for as equity or liability instruments. If the embedded feature meets the requirements to be bifurcated and accounted for as a liability, the

fair value of the embedded feature is measured initially, included as a liability on the consolidated balance sheets and re-measured to fair value at each reporting period.

We determined the embedded conversion feature in the Notes is not required to be separately accounted for as a derivative liability instrument because it is considered to be indexed to our common stock. However, since the Notes may be settled with a combination of cash and shares, at our election, we are required to separate the Notes into debt and equity components. The value assigned to the debt component is the estimated fair value, as of the issuance date, of a similar debt instrument issued by us without the conversion feature. The difference between the full principal amount of the Notes and this estimated fair value was recorded as a debt discount on the Notes, with a corresponding offset to additional paid-in capital (the equity component). In addition, debt issuance costs associated with the Notes were allocated to the debt and equity components in proportion to the allocation of the full principal amount to those components.

At issuance, the debt component of the Notes was estimated to have a fair value of $152.1 million based on contractual cash flows discounted at our estimated non-convertible debt borrowing rate of 9.7%. Our determination of an appropriate discount rate was based on a yield curve derived from then-recent publicly-traded bond offerings with a similar term for companies with similar credit ratings to us (Level 2 inputs). As a result, the equity component of $77.9 million, which represents the difference between the proceeds from the issuance of the Notes and the fair value of the debt component, was recognized as a debt discount. In addition, debt issuance costs of $7.5 million related to the issuance of the Notes were comprised of $4.9 million attributable to the debt component, and recorded as debt discount, with the remaining $2.5 million attributable to the equity component and netted with the equity component discussed above resulting in $75.3 million recorded to additional paid-in capital within stockholders' equity on the consolidated balance sheet. The debt discount and issuance costs of $82.8 million are being amortized as interest expense over the expected term of the Notes of seven years using the effective interest rate of 9.9%. The equity component is not remeasured as long as it continues to meet the conditions for equity classification. As of December 31, 2020, the outstanding Notes were not subject to conversion under the Indenture and no principal is due until 2027. At December 31, 2020, the Notes had a weighted-average remaining term of approximately 6.7 years and the equity component continues to meet the conditions for equity classification.

The following table provides information on our Convertible Senior Notes balance as of December 31, 2020:

(In thousands)	December 31, 2020
Liability component	
Principal amount of Convertible Senior Notes	$ 230,000
Less: Unamortized debt discount and issuance costs	(80,647)
Net carrying amount	$ 149,353
Equity component - net carrying value	$ 75,333

Interest expense related to the Convertible Senior Notes was included in other income (expense), net on the consolidated statements of operations as follows:

(In thousands)	Year Ended December 31, 2020
Contractual coupon interest	$ 1,600
Amortization of debt discount and issuance costs	2,143
Total interest expense	$ 3,743

Note 11 — Leases

We have non-cancelable operating leases consisting of administrative and research and development office space for our Emeryville, California headquarters and Maidenhead, United Kingdom that will expire in expires in May 2027 and February 2025, respectively. We also maintain limited office space in Ireland, Germany, Italy and Japan. Our Emeryville lease includes a renewal option for an additional five years, which was not included in our determination of the lease term under the legacy lease standard as renewal was not reasonably assured at the inception of the lease. Other non-cancellable leases recorded on our consolidated balance sheets include the

former headquarters of Modis' in Oakland, California, which expires in July 2021 and a lease related to our former headquarters located in San Diego, which we subleased to an unrelated third party under a coterminous agreement, until its expiration in March 2020.

We do not have any material finance leases or service contracts with lease arrangements. Our lease agreements do not contain any material residual value guarantees or material restrictive covenants.

Information regarding operating lease expense and other select lease information are as follows:

	Year Ended December 31,	
(In thousands)	**2020**	**2019**
Components of lease costs:		
Operating lease cost	$ 1,989	$ 2,045
Short-term lease cost	444	851
Sublease income	(115)	(580)
Total lease expense	$ 2,318	$ 2,316

Other Lease information

	Year Ended December 31,	
(In thousands)	**2020**	**2019**
Cash paid for amounts included in the measurement of lease liabilities	$ 2,178	$ 1,842
Right-of-use lease assets obtained in exchange for new lease liabilities, noncash	$ 1,156	$ 354

Supplemental balance sheet information

	December 31,	
(In thousands)	**2020**	**2019**
Right-of-use assets	$ 7,748	$ 7,774
Current portion of operating lease liabilities	1,688	1,322
Operating lease liabilities, net of current portion	10,314	10,752
Total operating lease liabilities	$ 12,002	$ 12,074
Weighted average remaining lease term (in years)	6.0	7.2
Weighted average discount rate, weighted based on the remaining balance of lease payments	6.2 %	6.0 %

Maturities of operating lease liabilities as of December 31, 2020 are as follows:

(In thousands)	**Operating Leases**
2021	$ 2,327
2022	2,265
2023	2,321
2024	2,330
2025	2,070
After 2025	3,031
Total lease payments	14,344
Less: imputed interest	(2,342)
Total operating lease liabilities	$ 12,002

Note 12 — Commitments and Contingencies

Legal Matters

We may become involved in various legal proceedings and claims that arise in the ordinary course of business. We currently do not believe that the ultimate outcome of any of the matters is probable or reasonably estimable, or that these matters will have a material adverse effect on our business. However, such matters are subject to uncertainty and there can be no assurance that such legal proceedings will not have a material adverse effect on our business, consolidated results of operations, financial position or cash flows.

Indemnification Agreements

In the ordinary course of business, we may provide indemnification of varying scope and terms to vendors, lessors, customers and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. These indemnities include indemnities to our directors and officers to the maximum extent permitted under applicable Delaware law. The maximum potential amount of future payments that we could be required to make under these indemnification agreements is, in many cases, unlimited. We have not incurred any material costs as a result of such indemnifications and is not currently aware of any indemnification claims.

Unconditional Purchase Obligations

We have supply agreements for the manufacture of active pharmaceutical ingredient (API) used in Fintepla and procurement of raw materials (other than the API) used to formulate, fill, test and release an oral solution of Fintepla. As of December 31, 2020, annual minimum purchase commitments under these supply agreements were not material.

In addition, we enter into contracts in the normal course of business with CROs for preclinical studies and clinical trials and contract manufacturing organizations for the manufacture of drug materials. The contracts are cancellable, with varying provisions regarding termination. If a contract with a specific vendor were to be cancelled, we would only be obligated for costs of products or services that have been incurred by the vendor prior the effective date of cancellation, plus applicable cancellation fees.

Note 13 — Stockholders' Equity

Preferred Stock

We have 10.0 million shares of preferred stock authorized for issuance, par value of $0.001 per share. As of December 31, 2020 and 2019, no shares of preferred stock were issued and outstanding.

Common Stock

On May 21, 2019, our stockholders approved and we filed an amendment to our Fifth Amended and Restated Certificate of Incorporation, as amended, to increase the total number of authorized shares of common stock from 50.0 million to 100.0 million. Each holder of our common stock, par value of $0.001 per share, is entitled to one vote for each share of such stock held. As of December 31, 2020 and 2019, there were 55.7 million and 45.3 million shares of common stock issued and outstanding.

The following table presents common stock reserved for future issuance for the following financial instruments:

	December 31,	
(In thousands)	2020	2019
Stock options and RSUs outstanding	5,703	4,692
Warrants to purchase common stock	28	28
Reserved for future grants under employee equity plans	3,899	4,926
Reserved for issuance upon conversion of Convertible Senior Notes	12,313	—
Total	21,943	9,646

At December 31, 2020, we had approximately 22.3 million shares of authorized and unreserved common stock available for issuance.

Sale of Common Stock

At-the-Market Offerings

We have an at-the-market sales agreement (the ATM Sales Agreement) with Cantor Fitzgerald & Co. (Cantor) pursuant to which Cantor agreed to act as a sales agent in connection with sales of our common stock from time to time pursuant to an effective registration statement.

In December 2017, we filed a prospectus supplement to our automatic "shelf" registration statement on Form S-3 registering the offering, issuance and sale of up to $75.0 million in gross aggregate proceeds of common stock under the ATM Sales Agreement. During 2019 and 2018, we sold approximately 0.9 million and 0.7 million shares of common stock, respectively, resulting in net proceeds of approximately $42.6 million and $30.3 million, respectively, after deducting commissions and other offering costs.

In June 2020, we filed a prospectus supplement to our automatic "shelf" registration statement on Form S-3 registering the offering, issuance and sale of up to $200.0 million in gross aggregate proceeds of our common stock under the ATM Sales Agreement. During 2020, we sold approximately 0.2 million shares of common stock and realized net proceeds of approximately $4.9 million, after deducting commissions and other offering costs.

Underwritten Public Offerings

In August 2018, we completed an underwritten public offering of 6.0 million shares of our common stock at an offering price of $52.00 per share. Net proceeds realized from the offering amounted to approximately $292.9 million, after deducting commissions and other offering expenses.

In March 2020, we completed an underwritten public offering of 9.8 million shares of our common stock at an offering price of $23.50 per share, including 1.3 million shares sold pursuant to the underwriters' full exercise of their option to purchase additional shares. Net proceeds realized from the offering amounted to approximately $221.7 million, after deducting commissions and other offering costs.

Accumulated Other Comprehensive Income

A summary of changes in the balances of each component of accumulated other comprehensive loss, net of tax, follows:

(In thousands)	Net Unrealized Gains (Losses) on Marketable Securities	Foreign Currency Translation Adjustments	Accumulated Other Comprehensive Income
Balance at December 31, 2017	$ —	$ —	$ —
Amounts arising during the period	3	—	3
Balance at December 31, 2018	3	—	3
Amounts arising during the period	702	—	702
Reclassification adjustments	(326)	—	(326)
Balance at December 31, 2019	379	—	379
Amounts arising during the period	(197)	(260)	(457)
Reclassification adjustments	7	—	7
Balance at December 31, 2020	$ 189	$ (260)	$ (71)

Note 14 — Stock-Based Compensation

Summary of Equity Incentive Plans

2010 Plan

Our 2010 Equity Incentive Award Plan (2010 Plan), which was previously amended in June 2012, provides for the grant 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.

On May 21, 2019, our stockholders approved the amendment and restatement of our 2010 Plan (2010 Restated Plan). The 2010 Restated Plan included the following material changes: (1) an increase in the aggregate number of shares available for issuance under the plan from 7.5 million to 11.5 million shares; (2) elimination of the evergreen provision that provided for automatic annual increases based on 4% of common stock issued and outstanding as of each January 1; and (3) the extension of the expiration date of the plan to March 2029.

As of December 31, 2020, approximately 3.4 million shares remained available for future grants. Subsequent to the 2010 Restated Plan's effective date on May 21, 2019, all future equity awards will be issued from this plan (other than shares available for purchase under our 2010 Employee Stock Purchase Plan).

Inducement Plan

In December 2013, our board of directors adopted the Employment Inducement Equity Incentive Award Plan (Inducement Plan) and initially reserved 337,500 shares of common stock for issuance, which was subsequently increased to 637,500 shares in May 2018. The Inducement Plan is a non-shareholder approved stock plan adopted pursuant to the "inducement exception" provided under Nasdaq listing rules. The Inducement Plan was used exclusively for the issuance of non-statutory stock options and restricted stock units to certain new hires who satisfy the requirements to be granted inducement grants under Nasdaq rules as an inducement material to the individual's entry into employment with us. The terms of the Inducement Plan are substantially similar to the terms of our 2010 Restated Plan. Subsequent to the effective date of our 2010 Restated Plan on May 21, 2019, we no longer issue grants under the Inducement Plan.

Employee Stock Purchase Plan

In November 2010, our board of directors adopted an Employee Stock Purchase Plan (ESPP), which allows employees to purchase shares of our common stock during specified offering periods at a discount to the fair market value at the time of purchase. In May 2020, our shareholders approved an amendment and restatement of the ESPP, which became effective on May 29, 2020. The ESPP was amended to increase the aggregate number of shares authorized for issuance from 375,000 to 875,000 shares and to eliminate the annual evergreen feature, which automatically added 31,250 shares to the aggregate shares authorized for issuance on January 1 of each year under the plan. In addition, the expiration date of the ESPP was modified from October 2020 to the date that all shares authorized have been issued.

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 1st and December 1st of a calendar year.

Common stock may be purchased under the ESPP at a price equal to 85% of the fair market value of our common 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 our 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 a preceding offering period with a 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 5,000 shares. In addition, the Internal Revenue Code limits purchases under an ESPP to $25,000 worth of stock in any one calendar year, valued as of the first day of an offering period. As of December 31, 2020, approximately 0.5 million shares of common stock were available for future purchase.

Equity Incentive Plan Activity

The following sections summarize activity under our equity incentive plans.

Stock Options

The following table summarizes our stock option activity for 2020:

	Shares (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2019	4,253	$ 29.59	6.8	$ 96,524
Granted	1,647	$ 27.41		
Exercised	(274)	$ 16.06		
Canceled	(315)	$ 38.00		
Outstanding at December 31, 2020	5,311	$ 29.12	7.1	$ 14,131
Exercisable at December 31, 2020	3,061	$ 25.08	5.8	$ 13,515

The total intrinsic value of options exercised during 2020, 2019 and 2018 was $5.1 million, $22.4 million and $11.8 million, respectively.

Restricted Stock Units (RSUs)

The following table summarizes the Company's restricted stock unit activity for 2020:

	Shares (in thousands)	Weighted Average Fair Value per RSU at Grant Date
Nonvested at December 31, 2019	439	$ 36.97
Granted	218	$ 27.34
Vested	(220)	$ 26.39
Canceled	(44)	$ 38.15
Nonvested at December 31, 2020	393	$ 37.68

The total intrinsic value of RSUs vested during 2020, 2019 and 2018 was $5.7 million, $1.9 million and $4.2 million, respectively. In June 2020, approximately 128,000 shares of performance-based restricted stock units (PSU's) granted in March 2017 vested upon satisfaction of both a service-period condition and a performance condition, the latter of which was satisfied following the FDA's approval of Fintepla in June 2020. As a result, a $1.4 million charge representing the PSUs' fair value on the date of grant was expensed upon satisfaction of the performance condition. Previously, no compensation expense for such PSUs was recognized as we determined the performance condition is not probable of achievement until the event actually occurs.

ESPP

Employees purchased 51,745 shares, 28,146 shares and 32,679 shares under our ESPP during 2020, 2019 and 2018, respectively.

Valuation of Equity Awards

We use the Black-Scholes option-pricing model for determining the estimated fair value and stock-based compensation related to stock options and ESPP awards. A summary of the assumptions used to estimate the fair values of stock option grants for the years presented is as follows:

	Year Ended December 31,		
	2020	2019	2018
Risk free interest rate	0.3% to 1.8%	1.4% to 2.6%	2.3% to 3.0%
Expected term	5.3 to 6.1 years	5.3 to 6.1 years	5.3 to 6.1 years
Expected volatility	73.2% to 76.7%	73.5% to 82.3%	80.1% to 85.2%
Expected dividend yield	—%	—%	—%
Weighted-average fair value of option on grant date	$17.86	$32.64	$30.87

The fair value of ESPP awards was not material for all periods presented.

Stock-Based Compensation Expense Allocation

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

	Year Ended December 31,		
(In thousands)	2020	2019	2018
Research and development	12,139	8,293	6,317
Selling, general and administrative	17,037	12,954	9,175
Total	$ 29,176	$ 21,247	$ 15,492

As of December 31, 2020, there was approximately $60.6 million of total unrecognized compensation costs related to outstanding equity awards scheduled to be recognized over a weighted average period of 2.7 years.

Note 15 – Net Loss Per Share

Basic net loss per share is calculated by dividing net loss by the weighted average number of shares outstanding for the period. Diluted net loss per share is calculated by dividing net loss by the weighted average number of shares of common stock and potential dilutive common stock equivalents outstanding during the period if the effect is dilutive. Our potentially dilutive shares of common stock include outstanding stock options, restricted stock units, warrants to purchase common stock and rights under our Senior Convertible Notes.

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

	Year Ended December 31,		
	2020	2019	2018
Numerator			
Net loss	$ (209,383)	$ (419,503)	$ (123,914)
Denominator			
Weighted average common shares outstanding, basic and diluted	53,706	43,078	37,884
Net loss per share, basic and diluted	$ (3.90)	$ (9.74)	$ (3.27)

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

	Year Ended December 31,		
(In thousands)	2020	2019	2018
Shares subject to outstanding common stock options	4,966	4,085	3,770
Shares subject to outstanding restricted stock units	464	382	289
Shares subject to outstanding warrants to purchase common stock	28	28	33
Shares issuable upon conversion of Convertible Senior Notes	4,415	—	—
Total	9,873	4,495	4,092

Note 16 — Employee Benefit Plans

We maintain defined contribution retirement plans for our employees. We established a 401(k) Plan for our U.S. employees and a defined benefit pension plan for our U.K. employees by which participants may defer taxation on a portion of their earnings, subject to a maximum amount under each applicable plan. We may make discretionary matching contributions to the plans on behalf of participants in any plan year. Any discretionary matching contributions made on behalf of participants become immediately vested and non-forfeitable to the participant. Total expense recognized by us for discretionary matching contributions made in 2020, 2019 and 2018 was $1.2 million, $0.5 million, and $0.2 million, respectively.

Note 17 — Income Taxes

For financial reporting purposes, the components of loss from continuing operations before income taxes are presented in the following table.

	December 31,		
(In thousands)	2020	2019	2018
United States	$ (170,812)	$ (325,769)	$ (35,838)
Foreign	(55,996)	(93,734)	(87,878)
Total	$ (226,808)	$ (419,503)	$ (123,716)

The following table summarizes carryforwards of net operating losses and tax credits as of December 31, 2020.

(in millions)	Amount
Federal net operating losses	$ 526.9
State net operating losses	343.2
Foreign net operating losses	290.7
Federal research and development credits	6.4
State research and development credits	4.2
Orphan drug research and development credits	2.0

At December 31, 2020, our federal, state, and foreign (primarily related to the U.K.) net operating loss carryforwards, including the acquired net operating losses from our acquisition of Modis, were approximately $526.9 million, $343.2 million and $290.7 million, respectively, which may be subject to limitations as described below. If not utilized, a significant portion of our federal net operating loss carryforwards incurred prior to 2018 will begin to expire in 2029 and the state net operating 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. However, the deductibility of such federal net operating losses is limited to 80% of taxable income. As of December 31, 2020, of the $526.9 million in total federal net operating loss carryforwards, $272.3 million do not expire. It is uncertain if and to what extent various states will conform to the Tax Act. In the U.K, our net operating loss carryforwards do not expire, but the use of net operating loss carryforwards in relation to U.K. taxable income incurred on or after April 1, 2017 will be limited each year to £5.0 million plus an incremental 50% of U.K. taxable income, subject to a regulatory established allowance per group.

In addition, we have federal and California research and development income tax credit carryforwards of approximately $6.4 million and $4.2 million. If not utilized, the federal research and development income tax credit carryforwards will begin to expire in 2031. The California research and development income tax credit carryforwards do not expire and can be carried forward indefinitely. As of December 31, 2020, we had federal orphan drug tax credit carryforwards of $2.0 million, which begin to expire in 2036. 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 we file tax returns. We are currently not under audit by any tax jurisdiction.

As of December 31, 2020, we have experienced at least three ownership changes. The first ownership change occurred in August 2006 and resulted in a reduction to our net operating loss carryforwards of $1.9 million. We had a second ownership change in September 2011 which resulted in reductions to our federal net operating loss carryforwards of $121.1 million, research and development income tax credits of $3.0 million, and California net

operating loss carryforwards of $53.3 million. We 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. We recently completed an evaluation of the potential effect of Section 382 on our ability to utilize our net operating losses, including those acquired from our acquisition of Modis. Any operating losses and other tax attributes generated by us subsequent to January 2014, including those acquired from our acquisition of Modis, are currently not subject to any IRC Section 382 limitations. Pursuant to the IRC, the use of our 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 income tax provision to amounts computed by applying the statutory federal income tax rate to loss from continuing operations before income taxes is shown as follows (in thousands):

	December 31,		
	2020	2019	2018
Income tax at federal statutory rate	$ (47,630)	$ (88,096)	$ (26,022)
State taxes, net of federal benefit	(4,316)	(65)	(8)
Non-deductible acquired IPR&D charge and other expenses[(1)]	—	52,044	—
Change in valuation allowance	40,039	21,155	16,949
Impact of foreign rate change on deferred taxes	(2,950)	1,887	1,961
Other permanent differences	3,993	4,101	(701)
State tax rate benefit	(1,346)	(18)	169
Foreign rate differential	752	1,883	1,731
Stock-based compensation	1,180	(2,674)	(1,344)
Net operating losses surrendered under U.K.'s R&D tax relief scheme	—	9,349	6,322
State apportionment adjustments	(2,673)	48	—
Impact of foreign exchange rate differences	(4,532)	—	—
Credits and other	58	386	943
Income tax benefit	$ (17,425)	$ —	$ —

(1) Amounts attributable to our asset acquisition of Modis. See Note 4 for additional information.

The significant components of deferred tax assets (liabilities) are as follows:

	December 31,	
(In thousands)	2020	2019
Deferred tax assets:		
Federal, state and foreign net operating loss carryforwards	$ 186,963	$ 134,009
Capitalized research and development	486	925
Accrued expenses	2,498	1,311
Research and development credits	5,343	5,343
Amortization	2,949	1,028
Lease liability	2,534	2,547
Stock-based compensation	7,878	6,464
Other, net	2,690	1,979
Total deferred tax assets	211,341	153,606
Less: valuation allowance	(176,594)	(151,544)
Total deferred tax assets, net of valuation allowance	$ 34,747	$ 2,062
Deferred tax liabilities:		
Operating lease right-of-use asset	$ (1,585)	$ (1,640)
IPR&D	(15,857)	(17,425)
Discount on Notes	(17,305)	—
Depreciation	—	(422)
Total deferred tax liabilities	(34,747)	(19,487)
Total net deferred tax liabilities	$ —	$ (17,425)

For the year ended December 31, 2020, income tax benefit of $17.4 million resulted from a change in our valuation allowance balance associated with the completion of our in-process research and development program for Fintepla. Prior to regulatory approval of Fintepla in June 2020, our indefinite-lived asset was not subject to amortization. Upon completion of the IPR&D program, the indefinite-lived intangible asset was reclassified to an intangible asset subject to amortization over its estimated useful life. As a result, future reversals of deferred tax liabilities related to finite-lived intangible assets provided a source of income when assessing the realizability of our U.K. net operating loss carryforwards. We therefore recorded a $17.4 million income tax benefit in 2020 with a corresponding reduction to our valuation allowance on our U.K. deferred tax assets. The income tax benefit included the effects of foreign exchange differences on remeasurement of the deferred tax liability. An immaterial portion of the adjustment for foreign exchange differences was related to prior periods. For the years ended December 31, 2019 and 2018, no income tax provision was recorded due to recurring losses and our assessment a full valuation allowance should be established against any net deferred tax assets due to the uncertainty regarding our ability to realize them in the future. The increase in valuation allowance of $25.1 million during 2020 was primarily attributable to the tax effect of our net loss exceeding the $17.4 million release of the valuation allowance on our U.K. deferred tax assets noted above. The increase in valuation allowance of $33.5 million during 2019 was attributable to our current year taxable loss and deferred tax assets related to acquired net operating loss carryovers from our acquisition of Modis.

As of December 31, 2020 and 2019, we have established a full valuation allowance against our U.S. and foreign deferred tax assets that are in excess of our reversing taxable temporary differences in those jurisdictions as we determined it is more likely than not that the tax benefit will not be realized.

We recognize 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 our unrecognized tax benefits (in thousands):

	December 31,		
	2020	2019	2018
Beginning balance of unrecognized tax benefits	$ 3,541	$ 1,487	$ 2,030
Gross increases based on tax positions related to current year	—	1,495	—
Gross increases based on tax positions related to prior years	97	559	91
Gross decreases based on tax positions related to prior years	—	—	(634)
Settlements with taxing authorities	—	—	—
Expiration of statute of limitations	—	—	—
Ending balance of unrecognized tax benefits	$ 3,638	$ 3,541	$ 1,487

As at December 31, 2020 and 2019, there were no unrecognized tax benefits that, if recognized, would affect our effective tax rate as any tax benefit would increase a deferred tax asset, which is currently offset by a full valuation allowance.

We record interest and, if applicable, penalties related to income tax matters as a component of income tax expense. No interest or penalties have been recorded for all periods presented. We do not expect any significant increases or decreases to our unrecognized tax benefits in the next twelve months.

Note 18 — U.K.'s R&D Tax Relief Scheme

We conduct extensive research and development activities that benefit from U.K.'s small and medium-sized enterprises (SMEs) R&D tax relief scheme. Under this tax relief scheme, a SME can make an election (i) to receive an enhanced U.K. tax deduction on its eligible R&D activities or, when an SME entity is in a net operating loss position, or (ii) to surrender net operating losses that arise from its eligible R&D activities in exchange for a cash payment from the U.K. 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 us 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 by submitting a claim for a discrete tax year and collectability is deemed probable and reasonably assured.

In December 2019, we elected to surrender net operating losses by submitting claims to receive cash payments of $9.9 million and $9.8 million related to our 2017 and 2018 tax years, respectively. For the year ended December 31, 2020, we recognized income and collected cash of $19.7 million upon approval of our submitted claims by the U.K. tax authorities as a component of other income, net on the consolidated statement of operations. Other income, net on the consolidated statement of operations for 2018 included $10.1 million for claims related to our 2015 and 2016 U.K. tax years. For our 2019 tax year, we have not yet decided whether to seek tax relief by surrendering some of our losses for a tax credit cash rebate claim or electing to receive enhanced U.K. tax deductions on our eligible research and development activities. Under U.K's tax legislation, there is a two-year window after the end of a tax year to seek relief under this scheme.

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, 2020 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, 2020, 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, 2020, 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, 2020, 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, 2020, 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, 2020 and 2019, 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, 2020, and the related notes and our report dated March 1, 2021 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
March 1, 2021

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 2021 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, 2020, 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 AND 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 ACCOUNTANT 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

We have filed the following documents as part of this Annual Report on Form 10-K:

(1) Consolidated Financial Statements

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Consolidated Balance Sheets	87
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(2) Financial Statement Schedules

All financial statement schedules have been omitted, since the required information is not applicable or is not present in amounts sufficient to require submission of the schedule, or because the information required is included in the consolidated financial statements and accompanying notes included in this Form 10-K.

(3) Exhibits

The exhibits required by Item 601 of Regulation S-K are listed below.

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	
2.2*	Agreement and Plan of Merger, dated August 23, 2019, by and among Zogenix, Inc., Xena Merger Sub, Inc., Modis Therapeutics, Inc. and Shareholder Representative Services, LLC, as the shareholders' representative	8-K	001-34962	August 26, 2019	2.1	
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	Certificate of Amendment of Fifth Amended and Restated Certificate of Incorporation	10-Q	001-34962	August 6, 2019	3.4	
3.5	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 Healthcare Royalty Partners (formerly Cowen Healthcare Royalty Partners II, L.P.)	10-Q	001-34962	August 12, 2011	4.12	
4.3	Indenture, dated as of September 28, 2020, between Zogenix, Inc. and U.S. Bank National Association, as trustee	8-K	001-34962	September 28, 2020	4.1	
4.4	Form of Global Note representing the 2.75% Convertible Senior Notes due 2027	8-K	001-34962	September 28, 2020	4.1	
4.5	Description of Registered Securities	10-K	001-34962	March 2, 2020	4.3	
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, as amended through May 22, 2019	8-K	001-34962	May 22, 2019	10.1	
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#	Form of Stock Option Grant Notice and Stock Option Agreement under the 2010 Equity Incentive Award Plan					

Exhibit No.	Description	Incorporated by Reference				Filed Herewith
		Form	File Number	Date of Filing	Exhibit No.	
10.7#	Employment Inducement Equity Incentive Award Plan and form of stock option agreement thereunder	8-K	001-34962	December 5, 2013	10.1	
10.8#	Annual Incentive Plan	10-Q	001-34962	May 11, 2015	10.3	
10.9#	Independent Director Compensation Policy as amended and restated effective March 14, 2018	10-Q	001-34962	May 9, 2018	10.1	
10.10#	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	
10.11#	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	
10.12#	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	
10.13#	Employment Agreement dated January 16, 2017, by and between the Registrant and Michael P. Smith	10-Q	001-34962	May 4, 2017	10.2	
10.14#	Employment Agreement dated July 2, 2018, by and between the Registrant and Ashish Sagrolikar	10-Q	001-34962	November 8, 2018	10.1	
10.15#	Employment Agreement dated April 20, 2020, by and between the Registrant and Shawnte M. Mitchell	10-Q	001-34962	August 6, 2020	10.1	
10.16†	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	
10.17	Lease Agreement, dated October 1, 2018, by and between the Registrant and Emery Station West, LLC	10-K	001-34962	February 28, 2019	10.21	
10.18	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	
10.19+	Manufacturing and Supply Agreement dated January 31, 2019 by and between Zogenix International Limited and Aptuit (Oxford) Limited	10-Q	001-34962	May 9, 2019	10.1	
10.20+	Distributorship Agreement dated March 18, 2019 by and between the Registrant and Nippon Shinyaku Company, Ltd.	10-Q	001-34962	May 9, 2019	10.2	
10.21+	Exclusive License Agreement by and between the Trustees of Columbia University and Modis Therapeutics, Inc. (as successor-in-interest to Meves Pharmaceuticals, LLC), dated September 26, 2016	10-Q	001-34962	November 7, 2019	10.1	
10.22+	Amendment No. 1 to Exclusive License Agreement by and between the Trustees of Columbia University and Modis Therapeutics, Inc., dated December 5, 2019	10-K	001-34962	March 2, 2020	10.22	

Exhibit No.	Description	Incorporated by Reference				Filed Herewith
		Form	File Number	Date of Filing	Exhibit No.	
10.23	Supply Agreement, by and between the Registrant and Penn Pharmaceutical Services Limited, trading as PCI Pharma Services, dated July 17, 2019	10-Q	001-34962	November 7, 2019	10.2	
10.24+	Collaboration, Option and License Agreement by and between Tevard Biosciences, Inc. and Zogenix, Inc.					X
21.1	Subsidiaries of the Registrant					X
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)					
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)					
101	Inline XBRL Document Set for the consolidated financial statements and accompanying notes in Part II, Item 8, “Financial Statements” of this Annual Report on Form 10-K.					X
104	Inline XBRL for the cover page of this Annual Report on Form 10-K, included in the Exhibit 101 Inline XBRL Document Set.					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

* Confidential portions of this Exhibit were redacted pursuant to Item 601(b)(2) of Regulation S-K and Zogenix Inc. agrees to furnish supplementally to the Securities and Exchange Commission a copy of any redacted information or omitted schedule and/or exhibit upon request.

+ Confidential portions of this Exhibit were redacted pursuant to Item 601(b)(10) of Regulation S-K and Zogenix Inc. agrees to furnish supplementally to the Securities and Exchange Commission a copy of any redacted information or omitted schedule and/or exhibit upon request.

# Indicates management contract or compensatory plan.

‡ Furnished herewith.

ITEM 16. FORM 10-K SUMMARY

None.

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.

March 1, 2021

By: /s/ STEPHEN J. FARR, PH.D.

Stephen J. Farr, Ph.D.

President and Chief Executive Officer

March 1, 2021

By: /s/ MICHAEL P. SMITH

Michael P. Smith

Executive Vice President, Chief Financial Officer and Treasurer

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.

Name	Title	Date
/s/ STEPHEN J. FARR, PH.D. **Stephen J. Farr, Ph.D.**	President, Chief Executive Officer and Director (Principal Executive Officer)	March 1, 2021
/s/ MICHAEL P. SMITH **Michael P. Smith**	Executive Vice President, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	March 1, 2021
/s/ CAM L. GARNER **Cam L. Garner**	Chairman of the Board	March 1, 2021
/s/ LOUIS C. BOCK **Louis C. Bock**	Director	March 1, 2021
/s/ JAMES B. BREITMEYER, M.D., PH.D. **James B. Breitmeyer, M.D., Ph.D**	Director	March 1, 2021
/s/ ERLE T. MAST **Erle T. Mast**	Director	March 1, 2021
/s/ CAROLINE M. LOEWY **Caroline M. Loewy**	Director	March 1, 2021
/s/ MARY E. STUTTS **Mary E. Stutts**	Director	March 1, 2021
/s/ RENEE TANNENBAUM, PHARM.D. **Renee Tannenbaum, Pharm.D.**	Director	March 1, 2021
/s/ DENELLE J. WAYNICK **Denelle J. Waynick**	Director	March 1, 2021
/s/ MARK WIGGINS **Mark Wiggins**	Director	March 1, 2021

Exhibit 10.24

CERTAIN INFORMATION (INDICATED BY ASTERISKS) HAS BEEN OMITTED FROM THIS DOCUMENT BECAUSE IT IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED

COLLABORATION, OPTION AND LICENSE AGREEMENT

by and between

TEVARD BIOSCIENCES, INC.

AND

ZOGENIX, INC.

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This COLLABORATION, OPTION, AND LICENSE AGREEMENT (the "Agreement") is entered into and made effective as of December 3, 2020 (the "Effective Date") by and between Tevard Biosciences, Inc., a Delaware corporation ("Tevard"); and Zogenix, Inc., a Delaware corporation ("Zogenix"). Tevard and Zogenix are each referred to herein by name or as a "Party" or, collectively, as "Parties."

RECITALS

WHEREAS, Tevard is a biotechnology company developing novel therapeutic platforms to target Dravet Syndrome and other rare diseases with high unmet need;

WHEREAS, Zogenix is a is a pharmaceutical company developing and commercializing, inter alia, transformative central nervous system (CNS) therapies for people living with serious and life-threatening rare CNS disorders and medical conditions, including CNS therapies to address rare, or "orphan" childhood-onset epilepsy disorders;

WHEREAS, the Parties desire to establish a strategic partnership to discover, develop, and commercialize novel medicines for epilepsy disorders and epileptic encephalopathies, including childhood-onset genetic epilepsy disorders.

NOW, THEREFORE, in consideration of the premises and mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto agree as follows:

ARTICLE 1
DEFINITIONS

1.1 Defined Terms. As used in this Agreement, the following terms will have the meanings set forth in this Article 1 unless context dictates otherwise:

"Affiliate" means any Person that, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with a Party to this Agreement, regardless of whether such Affiliate is or becomes an Affiliate on or after the Effective Date. A Person shall be deemed to "control" another Person if it (a) owns, directly or indirectly, beneficially or legally, at least fifty percent (50%) of the outstanding voting securities or capital stock of such other Person, or has other comparable ownership interest with respect to any Person other than a corporation; or (b) has the power, whether pursuant to contract, ownership of securities or otherwise, to direct the management and policies of the Person.

"Aggregate Option Agreement Payments" means the aggregate amount of payments made by Zogenix to Tevard as of the Effective Date pursuant to that certain Option Agreement For Exclusive License, dated as of October 14, 2019, and amended on May 13, 2020, August 12, 2020, September 23, 2020 and October 23, 2020, by and between Tevard and Zogenix.

"Applicable Laws" means all applicable Laws, including without limitation, all good clinical practices, good manufacturing practices, and all applicable standards or guidelines promulgated by the appropriate Regulatory Authority.

"Biosimilar Application" means an application or submission filed with a Regulatory Authority for marketing authorization of a "biosimilar" or "interchangeable" product pursuant to Section 351(k) of the Public Health Service Act (42 U.S.C. § 262(k)).

"Books and Records" means, in whatever media, any and all books and records, documents, reports, and accounts in connection with or related to: any costs Tevard or Zogenix is obligated to reimburse or pay to the other Party under this Agreement; as well as any other books and records as may be required from time to time by Applicable Laws or this Agreement.

“BPCIA” means the Biologics Price Competition and Innovation Act of 2009, as amended.

“Business Day” means a day on which banking institutions in New York, New York, United States are open for business, excluding any Saturday or Sunday.

“Calendar Quarter” means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31; provided, however, that (i) the first Calendar Quarter of this Agreement shall commence on the Effective Date and end at the end of the Calendar Quarter in which the Effective Date occurs and (ii) the last Calendar Quarter of this Agreement shall commence at the commencement of such Calendar Quarter and end on the date of expiration or termination of this Agreement.

“Calendar Year” means each successive period of twelve (12) months commencing on January 1 and ending on December 31; provided, however, that (i) the first Calendar Year of this Agreement shall commence on the Effective Date and end on December 31 of the same year and (ii) the last Calendar Year of this Agreement shall commence on January 1 of the Calendar Year in which this Agreement terminates or expires and end on the date of expiration or termination of this Agreement.

“cGMP” means all applicable standards relating to Manufacturing practices for pharmaceuticals, biologics, intermediates, bulk products or Licensed Products, including (a) the principles set forth in the FDA’s current Good Manufacturing Practices, 21 CFR Parts 210 and 211 and The Rules Governing Medicinal Products in the European Community, Volume IV, Good Manufacturing Practice for Medicinal Products, as each may be amended from time to time or (b) Laws promulgated by any Governmental Authority having jurisdiction over the Manufacture of a product.

“Change of Control” means, with respect to Tevard, (a) a merger or consolidation of Tevard with a Third Party which results in the voting securities of Tevard outstanding immediately prior thereto ceasing to represent at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger or consolidation, (b) a transaction or series of related transactions in which a Third Party, together with its Affiliates, becomes the owner of fifty percent (50%) or more of the combined voting power of Tevard’s outstanding securities other than through issuances by Tevard of securities of Tevard in a bona fide financing transaction or series of related bona fide financing transactions, or (c) the sale or other transfer to a Third Party of all or substantially all of Tevard’s assets or all or substantially all of Tevard’s business to which this Agreement relates.

“Clinical Trial” means a human clinical trial, including any Phase 1 Clinical Trial, Phase 2 Clinical Trial, and/or Phase 3 Clinical Trial, including a Pivotal Registration Trial.

“CMC” means chemistry, manufacturing and controls.

“Commercialization” and “Commercialize” means all activities undertaken after Regulatory Approval relating to continuing medical education, marketing, promotion (including advertising or detailing) and any other offering for sale, distribution, importation, and sale of the product.

“Commercially Reasonable Efforts” means [***].

“Competitive Product” means, with respect to a Licensed Product or Tevard Product, a Third Party therapeutic agent that either (a) may be used for the diagnosis, amelioration, mitigation, prevention, treatment and/or cure of Epilepsy, (b) results in improved transcription, translation, expression, function or activity of the same Target as such Licensed Product or Tevard Product, or (c) may be used to treat the same Indication for which such Licensed Product or Tevard Product is approved. For clarity, Generic Products are Competitive Products.

“Confidential Information” is defined in Section 9.1.

“Control,” “Controls,” “Controlled” or “Controlling” means, with respect to any intellectual property, possession of the right (whether through ownership or license (other than by operation of this Agreement) or control over an Affiliate with such right) to grant the licenses or sublicenses as provided herein without violating the terms of any agreement or other arrangement with any Third Party.

“Core Option Package Criteria” means the core data package criteria for each Option Package, as set forth on Exhibit B. In no event will Core Option Package Criteria require Tevard activities beyond generating and evaluating in vitro data.

“Corrective Therapeutic Agent” means any agent (which may comprise one or more components) that can be used to [***].

“Cover,” “Covering” or “Covered” means, with respect to a product, agent, composition, technology, process or method that, in the absence of ownership of or a license granted under a Patent, the manufacture, use (where such use is for the treatment of an Indication approved by the applicable Regulatory Authority), offer for sale, or sale of such product, agent or composition, would infringe such Patent (or, in the case of a Patent that has not yet issued, would infringe such Patent if it were to issue).

“Develop” or “Development” means all activities relating to research, development, manufacturing development, including manufacturing of a compound or product, test method development and stability testing, formulation, process development, production process, manufacturing scale-up, and manufacturing for use in non-clinical and clinical studies, non-clinical and preclinical testing and trials, clinical testing and trials, including Clinical Trials, toxicology testing, modification, optimization and animal efficacy testing of pharmaceutical compounds, statistical analysis, publication and presentation of study results and reporting, preparation and submission to Regulatory Authorities of applications (including any CMC information) and maintenance of such applications following approval.

“Development Costs” means the FTE Costs and the Out-of-Pocket Expenses incurred by a Party or any of its Affiliates after the Effective Date (or after October 14, 2019 for the Dravet Syndrome Program) that are specifically attributable to the Development of a Product and are consistent with the approved Development Plan, including, without limitation, the costs of preclinical Development, preclinical supply and manufacturing (including CMC), Clinical Trials and submissions to Regulatory Authorities, but, excluding any royalties, milestones or other payments due under the In-Licenses.

“Development Product” means any therapeutic agent in the Field, including any Corrective Therapeutic Agent, regardless of stage of development (e.g., preclinical or clinical trials), Developed by Tevard as part of a Development Program, prior to Zogenix’s exercise (if ever) of its Option to license such Development Product.

“Development Program” means a program initially undertaken by Tevard pursuant to this Agreement to Develop therapeutic agents (including therapeutic agents in Development prior to the Effective Date) concerning a Target(s) and an Indication for Epilepsy, including, without limitation, the Dravet Syndrome Program and the Second Program and any Subsequent Option Program. A Development Program can potentially result in one or more Products covering one or more Indications in the Field.

“DOJ” means the Antitrust Division of the United States Department of Justice.

“Dollars” or “$” means the legal tender of the U.S.

“Dravet Syndrome” means a disease also known as Severe Myoclonic Epilepsy of Infancy (SMEI).

“Dravet Syndrome Program” means the Licensed Development Program to Develop a Licensed Product for the treatment of Dravet Syndrome.

“EMA” means the European Medicines Agency, and any successor entity thereto.

“Epilepsy” means all epilepsy disorders or epileptic encephalopathies, including Dravet syndrome and Lennox-Gastaut syndrome.

“Executive Officers” means the Chief Executive Officer of each Party, or his or her designee.

“FDA” means the U.S. Food and Drug Administration, and any successor entity thereto.

“Field” means all uses, including diagnosis, amelioration, mitigation, prevention, treatment and/or cure, related to Epilepsy, but, for clarity, not related to [***].

“First Commercial Sale” means, with respect to a Licensed Product or a Tevard Product and a country, the first sale of such Licensed Product or Tevard Product, as applicable, made by the applicable Party, its Affiliates, Licensees, or Sublicensees to a Third Party in such country for end use or consumption in such country after any necessary Regulatory Approval (but, for clarity, excluding any sales for Clinical Trials or compassionate use programs); provided, however, that in no event will any sale or distribution of the Licensed Product or a Tevard Product for pre-launch activities or use in a Clinical Trial be deemed a First Commercial Sale.

“FTC” means the United States Federal Trade Commission.

“FTE” means one (1) person (or the equivalent of one (1) person) working full time for one (1) twelve (12) month period in a Development, regulatory or other relevant capacity (excluding persons employed in general and administrative, non-technical management or other non-technical capacities) employed or contracted by Tevard or Zogenix or any of their Affiliates and assigned to perform specified work, with such commitment of time and effort to constitute one (1) employee performing such work on a full-time basis, which for purposes hereof shall be two thousand (2,000) hours per year. No additional payment shall be made with respect to any person who works more than two thousand (2,000) hours per year and any person who devotes less than two thousand (2,000) hours per year shall be treated as an FTE on a pro rata basis based upon the actual number of hours worked divided by two thousand (2,000).

“FTE Costs” means the FTE Rate multiplied by the applicable number of FTEs who perform a specified activity pursuant to this Agreement and, if applicable, in accordance with the Research Plan and Budget.

“FTE Rate” means [***] per FTE for the period commencing on the Effective Date and ending December 31, 2020. On January 1, 2021 and on January 1st of each subsequent Calendar Year, the foregoing rate shall be increased for the Calendar Year then commencing by the percentage increase, if any, over the annual period in the Consumer Price Index (U.S. Bureau of Labor Statistics for all urban consumers, U.S. city average, all items) of the immediately prior Calendar Year, and as mutually agreed upon by the Parties .

“GAAP” means U.S. generally accepted accounting principles, consistently applied.

“Generic Product” means, with respect to a Licensed Product or Tevard Product in any country in the Territory, any Competitive Product that (i) is approved by the FDA as a “biosimilar” or “interchangeable” product pursuant to Section 351(k) of the Public Health Service Act (42 U.S.C. § 262(k)), (ii) is approved by the FDA pursuant to an Abbreviated New Drug Application as defined in the Federal Food, Drug, and

Cosmetic Act referencing the Licensed Product, or (iii) is approved pursuant to any abbreviated route of approval similar to (i) or (ii) in any other countries in the Territory.

"Generic Product Competition" means (a) with respect to a Licensed Product or Tevard Product in the Territory, if during a Calendar Quarter, one or more Generic Product(s) is commercially available in such country and such Generic Product(s) has a market share of twenty percent (20%) or more of the aggregate market in such country of such Licensed Product or Tevard Product and the Generic Product(s) (based on sales of units of such Licensed Product or Tevard Product and such Generic Product(s), as reported by IMS International, or if such data are not available, such other reliable data source as reasonably determined by the Parties) or (b) with respect to a Licensed Product or Tevard Product in any other country in the Territory, if during a Calendar Quarter, one or more Generic Product(s) is commercially available in such country and such Generic Product(s) reduces the Net Sales of such Licensed Product or Tevard Product in such country by at least twenty percent (20%) as compared to the Net Sales in such country from the Calendar Quarter immediately preceding the commercial availability of such Generic Product(s).

"Genetic Material" means [***] DNA [***] and [***] RNA [***].

"Governmental Authority" means any United States federal, state or local or any foreign government, or political subdivision thereof, or any multinational organization or authority or any authority, agency, division, board or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, any court or tribunal (or any department, bureau or division thereof), or any governmental arbitrator or arbitral body.

"In-License" means (a) the Tevard In-Licenses and (b) any Third Party license agreements that become In-Licenses pursuant to Section 6.5.3(b).

"Inbound Licensor" means the licensor(s) under an In-License.

"IND" means an investigational new drug application submitted to the FDA pursuant to Part 312 of Title 21 of the U.S. Code of Federal Regulations, including any amendments thereto. References herein to IND shall include, to the extent applicable, any comparable filing(s) outside the U.S. for the investigation of any product in any other country or group of countries (such as a Clinical Trial application in the European Union).

"Indication" means the intended use of a Product for the diagnosis, amelioration, mitigation, prevention, treatment and/or cure of a distinct recognized human disease, disorder or condition, or of a manifestation of a recognized human disease, disorder or condition, or for the relief of symptoms associated with a recognized human disease, disorder or condition, and which, if approved in the U.S., would be reflected in the "Indications and Usage" section of labeling pursuant to 21 C.F.R. §201.57(c)(2) or, to the extent applicable, any comparable labeling section outside the U.S. For clarity, a Product may have one or more than one Indication.

"Initiation" means, with respect to a Clinical Trial, the administration of the first dose to a human in such Clinical Trial.

"Invention" means any new and useful process, article of manufacture, compound, composition of matter, formulation or apparatus, or any improvement thereof, discovery or finding, whether or not patentable.

"Joint IP" means, collectively, Joint Patents and Joint Know-How.

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“Joint Know-How” means, with respect to a Development Program, all Know-How developed jointly by or on behalf of Tevard and Zogenix in the course of activities conducted pursuant to such Development Program. The Joint Know-How shall not be Tevard Know-How or Zogenix Know-How.

“Joint Patents” means, with respect to a Development Program, all Patents that claim an Invention conceived jointly by or on behalf of Tevard and Zogenix in the course of performing activities conducted pursuant to such Development Program. The Joint Patents shall not be Tevard Patents or Zogenix Patents.

“Know-How” means any confidential ideas, Inventions, know-how, trade secrets, data, specifications, instructions, processes, formulas, technology, expert opinions and information, including biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, clinical, safety, manufacturing and quality control data or information.

“Law” or “Laws” means all laws, statutes, rules, regulations, treaties, orders, judgments, guidelines, or ordinances having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision.

“Licensed Development Program” means any Development Program for which Zogenix has exercised its Option. For clarity, the Dravet Syndrome Program is a Licensed Development Program as of the Effective Date.

“Licensed Product” means any therapeutic composition to be used in the Field containing a Corrective Therapeutic Agent, that is (i) Developed by Tevard pursuant to a Development Program for which Zogenix has exercised its Option or (ii) Developed by Zogenix pursuant to a Licensed Development Program.

“Licensee” means, with respect to a particular Licensed Product or Tevard Product, a Third Party to whom Tevard or Zogenix, as applicable, has granted a license under any Know-How or Patents Controlled by the granting Party, but excluding any Third Party acting solely as a distributor.

“Manufacture” means all activities related to the manufacturing of a compound or product, including test method development and stability testing, formulation, process development, production process, manufacturing scale-up, manufacturing for use in non-clinical and clinical studies, manufacturing for commercial sale, packaging, release of product, quality assurance/quality control development, quality control testing (including in-process, in-process release and stability testing) and release of product or any component or ingredient thereof, and regulatory activities related to all of the foregoing.

“Net Sales” shall mean, with respect to a Licensed Product or Tevard Product in a country in the Territory, the gross amount invoiced for sale or other disposition of such Licensed Product or Tevard Product in such country by a Party, its Affiliates, Licensees, or Sublicensees to Third Parties (including distributors, wholesalers and end users), less the following deductions accounted for in accordance with GAAP:

(a) sales returns and allowances actually paid, granted or accrued on the Licensed Product, including trade quantity, prompt pay and cash discounts and adjustments, granted on account of price adjustments or billing errors;

(b) credits or allowances given or made for rejection, recall, return or wastage replacement of, and for uncollectible amounts on, Licensed Products or Tevard Products or for rebates or retroactive price reductions;

(c) price reductions, reimbursements, rebates and chargeback payments granted to managed health care organizations, pharmacies and other retailers, group purchasing organizations or other buying groups, health maintenance organizations, health insurance providers, patient assistance or similar programs,

pharmacy benefit managers (or equivalents thereof), national, state/provincial, local, and other governments, their agencies and purchasers and reimbursers, or to trade customers (including Medicare, Medicaid, managed care and similar types of rebates and chargebacks);

(d) costs of outbound freight, insurance, and other transportation charges to the extent separately invoiced to the customer and included in gross amounts invoiced, as well as discounts, chargeback payments, rebates and reimbursements granted to, and inventory management fees or similar fees for bona fide services provided by, wholesalers, distributors, warehousing chains and other Third Parties related to the warehousing or distribution of such Licensed Product or Tevard Product;

(e) taxes, duties or other governmental charges (including any tax such as a value added or similar tax, other than any taxes based on income) relating to the sale of such Licensed Product, as adjusted for rebates and refunds, including pharmaceutical excise taxes;

(f) the portion of administrative fees paid during the relevant time period to group purchasing organizations or pharmaceutical benefit managers relating to such Licensed Product;

(g) that portion of the annual fee on prescription drug manufacturers imposed by the Patient Protection and Affordable Care Act that a Party or its Affiliates allocates to sales of the Licensed Products or Tevard Products in accordance with such Party's or its Affiliate's standard policies and procedures consistently applied across its products; and

(h) any other deductions not otherwise itemized above but which are hereinafter consistently applied across Zogenix's or Tevard's products as a result of a change in Applicable Law or GAAP;

to the extent such deductions: (i) are applicable and in accordance with standard allocation procedures, (ii) have not already been deducted or excluded, (iii) are incurred in the ordinary course of business in type and amount consistent with good industry practice, and (iv) except with respect to the uncollectible amounts and pharmaceutical excise taxes described in subsections (b) and (e) above, are determined in accordance with GAAP. Net Sales shall not be imputed to transfers of Licensed Product or Tevard Product without consideration or for nominal consideration for use in any clinical trial, or for any bona fide charitable, compassionate use or indigent patient program purpose or as a sample. For the avoidance of doubt, in the case of any transfer of any Licensed Product or Tevard Product between or among a Party and its Affiliates, Licensees, or Sublicensees for resale, Net Sales shall be determined based on the sale made by such Affiliate, Licensee, or Sublicensee to a Third Party. In the case of any sale for value, such as barter or counter-trade, of a Licensed Product or Tevard Product, or part thereof, other than in an arm's length transaction exclusively for cash, Net Sales shall be deemed to be the Net Sales at which substantially similar quantities of such Licensed Product and Tevard Product are sold for cash in an arm's length transaction in the relevant country.

Notwithstanding anything to contrary contained herein, the following shall not be considered Net Sales for purposes of this Agreement: sales of (w) a Generic Product by any Licensee or Sublicensee that has received a license from a Party in settlement of any dispute or pursuant to any judgment (provided that, any actual monies received by a Party or its Affiliates from such settlement after a deduction of such Party's Out-of-Pocket costs and expenses shall be treated as Net Sales in accordance with Section 8.3.2(f)), (x) a Licensed Product, Tevard Product, or generic or biosimilar product by a Licensee or Sublicensee pursuant to a compulsory license (provided that, any actual monies received by a Party or its Affiliates pursuant to such compulsory license shall be treated as Net Sales) or (y) a Licensed Product or Tevard Product as to which a Party or its Affiliate, Licensee, or Sublicensee does not receive any consideration tied to sales of such Licensed Product or Tevard Product. If a Party appoints a distributor to sell an authorized Generic Product

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of a Licensed Product or Tevard Product, then only the consideration actually paid to such Party or its Affiliate by such distributor shall be included in the calculation of Net Sales.

In the event that any Licensed Product is sold in combination with one or more products which are themselves not Licensed Products under this Agreement for a single price, the Net Sales for such Licensed Product shall be calculated by multiplying the sales price of such combination sale by the fraction A/(A+B) where A is the fair market value of the Licensed Product and B is the fair market value of the other product(s) in the combination sale. If the fair market value for any product sold in combination with a Licensed Product cannot be reasonably determined, the price attributed to such product will be based on the relative cost of goods for such product, as determined in accordance with GAAP. In addition, in the event that any Licensed Product is sold with any other product(s) or if any giveaways, discounts, rebates or charge-backs (whether as part of a customer loyalty, bundling or "loss leader" program, or otherwise) are provided for any Licensed Product to promote or sell other products or otherwise, the Net Sales for such Licensed Product shall be no less than the fair market value of such Licensed Product on a stand-alone basis (excluding any such discounts, rebates or charge-backs).

"Option Exercise Fee" means the fee applicable to Zogenix's exercise of an Option, if any, as set forth in the table in Section 6.3.

"Option Package" means, with respect to a given Development Program, the results and data to be delivered to Zogenix pursuant to this Agreement, which results and data shall be reasonably sufficient for Zogenix to evaluate each category of the Option Package Criteria determined in advance for such Development Program.

"Option Package Criteria" means the Core Option Package Criteria, which may be customized for each Development Program by the JDC pursuant to Section 3.1.4, prior to the commencement of a Development Program, or by the JDC and/or the Parties from time to time thereafter by mutual agreement.

"Out-of-Pocket Expenses" means, with respect to the Development of a Product, a Party's actual, reasonably incurred, documented, out-of-pocket expenses of any nature or kind incurred in performing or having performed Development activities to the extent not included in the FTE Costs.

"Patent" means (a) all patents and patent applications in any country or supranational jurisdiction in the Territory, (b) any substitutions, divisionals, continuations, continuations-in-part, provisional applications, reissues, renewals, registrations, confirmations, re-examinations, extensions, supplementary protection certificates and the like of any such patents or patent applications, and (c) foreign counterparts of any of the foregoing.

"Patent-Based Exclusivity" means, (i) with respect to a Licensed Product in a country in the Territory, that at least one Valid Claim of the Tevard Patents or the Joint Patents Covers such Licensed Product in such country or (ii) with respect to a Tevard Product in a country in the Territory, that at least one Valid Claim of the Zogenix Patents or the Joint Patents Covers such Tevard Product in such country.

"Person" means any individual, partnership, joint venture, limited liability company, corporation, firm, trust, association, unincorporated organization, governmental authority or agency, or any other entity not specifically listed herein.

"Phase 1 Clinical Trial" means a human clinical trial of a product in any country, the principal purpose of which is a preliminary determination of safety in healthy individuals or patients, that would satisfy in all material respects the requirements of 21 C.F.R. 312.21(a), or a similar clinical study prescribed by the relevant Regulatory Authorities in a country other than the United States, but excluding so-called "phase 0 trials" conducted using small doses in fewer than twenty (20) people.

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“Phase 2 Clinical Trial” means a human clinical trial of a product in any country that would satisfy the requirements in all material respects of 21 C.F.R. 312.21(b) and is intended to explore a variety of doses, dose response, and duration of effect, and to generate initial evidence of clinical safety and activity in a target patient population, or a similar clinical study prescribed by the relevant Regulatory Authorities in a country other than the United States.

“Phase 3 Clinical Trial” means a human clinical trial of a product in any country that would satisfy the requirements in all material respects of 21 C.F.R. 312.21(c) and is intended to (a) establish that the product is safe and efficacious for its intended use, (b) define warnings, precautions and adverse reactions that are associated with the product in the dosage range to be prescribed, and (c) support Regulatory Approval for such product.

“Pivotal Registration Trial” means any Phase 3 Clinical Trial or any a human clinical trial conducted for inclusion in (i) that portion of the FDA submission and approval process which provides for the continued trials of a product on sufficient numbers of human patients to generate safety and efficacy data to support Regulatory Approval in the proposed Indication, or (ii) equivalent Regulatory Authority submissions with similar requirements in a country other than the United States.

“Product” means a Development Product or a Licensed Product.

“Product Transfer” means, with respect to a Licensed Product that was Developed under a Development Program, the transfer of Development responsibility from Tevard to Zogenix following achievement by Tevard of the Product Transfer Criteria for such Licensed Product.

“Product Transfer Criteria” means the criteria to be met for each Licensed Product before transfer of Development responsibilities from Tevard to Zogenix, such criteria to be determined by the JDC pursuant to Section 3.1.4 and set forth in Exhibit G, as may be amended from time to time by the JDC or the mutual agreement of the Parties.

“Product Transfer Package” means, with respect to a given Licensed Product, the results and data to be delivered to the JDC pursuant to this Agreement, which results and data shall be reasonably sufficient for the JDC to evaluate each category of the Product Transfer Criteria determined in advance for such Licensed Product.

“Prosecution and Maintenance” or “Prosecute and Maintain” means, with regard to a Patent, the preparation, filing, prosecution of an application for such Patent and maintenance of such Patent, as well as requests for patent term adjustments and patent term extensions, and post-grant proceedings including re-examinations, reissues, appeals, and with respect to such Patent, together with the initiation or defense of interferences, the initiation or defense of oppositions and other similar proceedings with respect to the particular Patent, and any appeals therefrom. For clarification, “Prosecution and Maintenance” or “Prosecute and Maintain” shall not include any other enforcement actions taken with respect to a Patent.

“Protected Therapeutic Agent” is defined in Section 7.4.

“Regulatory Application” means (a) a Biologics License Application or a New Drug Application for any Licensed Product or Tevard Product filed with the FDA to obtain Regulatory Approval in the United States, or (b) any corresponding applications or submissions filed with the relevant Regulatory Authorities to obtain Regulatory Approvals in any other country or region in the Territory.

“Regulatory Approval” means the approval, license or authorization of the applicable Regulatory Authority for the marketing and sale of a Product for a particular Indication in a country in the Territory, including where required or reasonably prudent to obtain, pricing and reimbursement approvals.

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“Regulatory Authority” means the FDA in the U.S. or any health regulatory authority in another country in the Territory that is a counterpart to the FDA and holds responsibility for granting Regulatory Approval in such country, including the EMA and any successor(s) thereto.

“Regulatory-Based Exclusivity” means with respect to a Licensed Product or Tevard Product in a country in the Territory, that, with respect to such Licensed Product or Tevard Product, (a) Zogenix or Tevard, as applicable or any of such Party’s Affiliates, Licensees, or Sublicensees has been granted the exclusive legal right by a Regulatory Authority (or is otherwise entitled to the exclusive legal right by operation of Applicable Law) in such country to market and sell the Licensed Product or Tevard Product, as applicable, in such country, or (b) the data and information submitted by Zogenix or Tevard as applicable or any of such Party’s Affiliates, Licensees, or Sublicensees to the relevant Regulatory Authority for purposes of obtaining Regulatory Approval may not be disclosed, referenced, used or relied upon in any way by the relevant Regulatory Authority (including by relying upon the Regulatory Authority’s previous findings regarding the safety or effectiveness of the Licensed Product) to support the Regulatory Approval or marketing of any product by a Third Party.

“Research Term” means five (5) years from the Effective Date unless otherwise extended by mutual agreement of the Parties.

“Safety Concern” means any toxicity, serious adverse event, or other safety finding in any preclinical or clinical studies that leads to a good faith determination by any Party, data monitoring committee or by Regulatory Authorities that the Licensed Product exposes or could reasonably likely expose humans to an unacceptable safety risk in relation to therapeutic benefit.

“Second Program” means a Development Program, other than the Dravet Syndrome Program, to Develop a Product for the treatment of a disease or disorder in the Field other than Dravet Syndrome.

“Sublicensee” means, with respect to a particular Licensed Product or Tevard Product, a Third Party to whom Zogenix or Tevard, as applicable, has granted a sublicense under any Know-How or Patents licensed to such Party pursuant to this Agreement, but excluding any Third Party acting solely as a distributor or manufacturer.

“Subsequent Option Program” means a Development Program, other than the Dravet Syndrome Program and the Second Program, to Develop a Product for a different Target(s) than the Dravet Syndrome Program and the Second Program Target(s), and for a disease or disorder in the Field. For avoidance of doubt, there can be more than one Subsequent Option Program.

“Target” means [***] or otherwise associated with any disease or disorder in the Field or that may be the target of a research program to diagnose, ameliorate, mitigate, prevent, treat and/or cure any disease or disorder in the Field. An initial Target list is attached hereto as Exhibit A.

“Territory” means the entire world.

“Tevard In-Licenses” means the license agreements set forth on Exhibit C, as such exhibit may be amended from time to time in accordance with this Agreement.

“Tevard IP” means, collectively, the Tevard Patents and Tevard Know-How.

“Tevard Know-How” means, with respect to a Development Program, all Know-How which is Controlled by Tevard or its Affiliates at any time during the Term, that either (a) relates to the Target(s), Indications(s), or Corrective Therapeutic Agent, including suppression of premature termination codon(s) and rescue translation approaches, used (or intended to be used) in the conduct of such Development Program, (b) is reasonably necessary or useful to Develop, Commercialize or Manufacture any Product

arising out of or resulting from such Development Program or (c) is developed solely by or on behalf of Tevard in the course of activities conducted pursuant to such Development Program.

"Tevard Option Information Package" means an information package provided by Zogenix to Tevard consisting of a copy of the first IND filed for the applicable Dravet Syndrome Program and a preliminary, non-binding plan and, for the next [***], a budget for the clinical Development of Licensed Products under the Dravet Syndrome Program, which plan and budget have been prepared in good faith by Zogenix.

"Tevard Patents" means, with respect to a Development Program, all Patents owned or Controlled by Tevard or its Affiliates at any time during the Term to the extent any Invention Covered by such Patent is reasonably necessary or useful to Develop, Commercialize or Manufacture any Product under, or conceived in the course of performing activities conducted pursuant to, such Development Program. All Patents owned or Controlled by Tevard or its Affiliates related to the Dravet Syndrome Program or Covering any Products thereunder shall be set forth on Exhibit E.

"Tevard Product" means any agent, including a Corrective Therapeutic Agent that is Developed or Commercialized by Tevard under a Tevard Program.

"Tevard Program" means (a) a Development Program for which Zogenix does not exercise its Option before expiration or termination of the Option Period or (b) a Development Program terminated by Zogenix pursuant to Section 5.3.2, Section 12.2 or Section 12.4 or by Tevard pursuant to Section 12.3.1(b) or Section 12.5.

"Third Party" means any Person other than Tevard or Zogenix that is not an Affiliate of Tevard or of Zogenix.

"United States" or "U.S." means the United States of America and all of its territories and possessions.

"Valid Claim" means (a) a claim of an issued Joint Patent, Tevard Patent and/or Zogenix Patent, that has not expired, lapsed, been cancelled or abandoned, or been dedicated to the public, disclaimed, or held unenforceable, invalid, or cancelled by a court or administrative agency of competent jurisdiction in an order or decision from which no appeal has been or can be taken, including through opposition, reexamination, reissue or disclaimer, or (b) a claim of a pending patent application of a Joint Patent, Tevard Patent and/or Zogenix Patent that is filed and being prosecuted in good faith and that has not been finally abandoned or finally rejected and which has been pending for no more than five (5) years from the date of filing of the earliest patent application to which such pending patent application claims priority. (For clarity, a claim of an issued patent that ceased to be a Valid Claim before it issued because it had been pending for more than five (5) years from the date of filing of the earliest patent application to which such pending patent application claims priority, but subsequently issued and is otherwise described by clause (a) of the foregoing sentence shall again be considered to be a Valid Claim once it issues.)

"Zogenix Development Program" means any Licensed Development Program for which there has been a Product Transfer.

"Zogenix IP" means, collectively, the Zogenix Patents and Zogenix Know-How.

"Zogenix Know-How" means, with respect to a Development Program, all Know-How which is Controlled by Zogenix or its Affiliates at any time during the Term, that either (a) relates to therapeutic approaches used (or intended to be used) in the conduct of such Development Program, (b) is reasonably necessary or useful to Develop, Commercialize or Manufacture any Product arising out of or resulting from such Development Program or (c) is developed solely by or on behalf of Zogenix in the course of activities conducted pursuant to such Development Program.

“Zogenix Patents” means, with respect to a Development Program, all Patents that claim an Invention conceived solely by or on behalf of Zogenix, its Affiliates, Licensees, or Sublicensees in the course of performing activities conducted pursuant to such Development Program.

1.2 Additional Definitions. Each of the following definitions is set forth in the section of this Agreement indicated below:

Definitions	**Sections**
Additional Third Party IP	Section 6.5.3(b)(i)
Agreement	Preamble
Arbitration Request	Section 13.3
Bankruptcy Code	Section 4.6
Breaching Party	Section 12.3.1
Chairperson	Section 3.1.1
Claims	Section 11.1
Confidential Information	Section 9.1
Defense Proceeding	8.2.1(a)
Development Plan	Section 2.1.2
Disclosing Party	Section 9.1
Tevard Option	Section 5.2.1
Effective Date	Preamble
Existing Confidentiality Agreements	Section 9.1.4
Indemnified Party	Section 11.3
Indemnifying Party	Section 11.3
Joint Development Committee or JDC	Section 3.1
Losses	Section 11.1
Manufacturing Technology Transfer	Section 2.6.1
Milestone Event	Section 6.4.1(a)
Non-Breaching Party	Section 12.3.1
Option	Section 4.1.1
Optioned Dravet Product	Section 5.2.2
Option Period	Section 4.1.2
Party or Parties	Preamble
Payee	Section 6.8
Payor	Section 6.8
Program Selection	Section 2.1.4
Receiving Party	Section 9.1
Royalty Term	6.5.3(a)
Securities Laws	Section 9.3.3
Terminal Exercise Disqualification Programs	Section 4.1.2
Tevard	Preamble
Tevard Indemnitee	Section 11.1
Tevard Pre-Payment	Section 5.2.2(a)
Tevard-Prosecuted Joint Patents	Section 8.2.3(c)
Transition Plan	Section 4.3.1
University Patents	Section 6.5.3(d)
UPC	Section 8.3.2(g)
VAT	Section 6.12
Withholding Taxes	Section 6.11

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Zogenix Preamble
Zogenix Indemnitee Section 11.2
Zogenix-Prosecuted Joint Patents Section 8.3.2(a)

ARTICLE 2
RESEARCH AND DEVELOPMENT

Section 2.1 Development Programs.

2.1.1 Development Responsibilities. During the period of time in which any Development Program is under Development, the Parties will cooperate with each other to provide reasonable support in the conduct of all activities that are reasonably necessary or useful for the Development of such Development Program in the Territory. Notwithstanding the foregoing, Tevard shall have responsibility for the Development of each Product under a Development Program until the Product Transfer of a Product, and Zogenix shall have responsibility for the Development of such Product under a Licensed Development Program and/or Zogenix Development Program thereafter. Each Party will be responsible for conducting the activities assigned to it in each Development Plan under the direction and supervision of the JDC. Each Party will be responsible for selection and supervision of its personnel assigned to tasks related to Development activities. The JDC will be responsible for making, and have authority to make, all decisions, and undertake any actions necessary as a result of such decisions, regarding Development (including additional preclinical and clinical Development and testing) with respect to each Development Program in accordance with Article 3, all in a manner consistent with this Agreement and the applicable Development Plan.

2.1.2 Development Plans. Tevard shall prepare and deliver to the JDC, for the JDC's review and approval, a written Development plan (the "Development Plan"), including the associated budget (the "Budget"), for the Dravet Syndrome Program, the Second Program and any Subsequent Option Programs setting forth the discovery and research activities to be conducted by Tevard in connection therewith in accordance with a timeline and sufficient to meet the Option Package Criteria to be prepared by the JDC. The initial Development Plan for the Dravet Syndrome Program is attached hereto as Exhibit H, and the initial Development Plans for the Second Program and Subsequent Option Programs will be attached hereto as Exhibit I and Exhibit J, respectively, upon approval of such Development Plans by the JDC. The JDC will, on an annual basis, prepare and approve updates to the Development Plans by September 30 of each Calendar Year for each year of the Research Term. From time to time in between such annual updates, the JDC may amend the Development Plans, consistent with the principles set forth in this Section 2.1. In the event of a conflict between the terms of this Agreement and a Development Plan, the terms of this Agreement shall govern. Without limiting the foregoing, the Development Plans shall include development milestones, anticipated timelines therefor and a Budget. The Budget shall include a reasonable level of detail, including an estimated breakdown of FTEs by category (including categories of personnel whose working time will be fully dedicated to the Development Program and personnel whose working time will be partially dedicated to the Development Program). For clarity, the FTE breakdown estimate shall be for budgeting purposes only and shall not restrict Tevard's ability to move scientists within and between the FTE categories at its reasonable discretion, provided that Tevard does not exceed the Budget and maintains the minimum level of total FTEs.

2.1.3 Development Diligence. Pursuant to this Agreement and as further provided in this Article 2, during the Research Term, Tevard shall use Commercially Reasonable Efforts to (i) (A) Develop the Dravet Syndrome Program, (B) Develop a Second Program, and (C) if Tevard conducts such Development activities, Develop any Subsequent Option Programs, in each case (A) – (C) until the Product Transfer of the applicable Product arising under such Development Program; (ii) achieve the development milestones

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and meet the timelines set forth in each Development Plan; (iii) deliver to Zogenix Option Packages for the Second Program and all Subsequent Option Programs, as mutually agreed by the Parties in accordance with Section 2.2; and (iv) deliver to the JDC for review and approval Product Transfer Packages for (A) the Dravet Syndrome Program, (B) a Second Program, and (C) if Tevard conducts such Development activities, any Subsequent Option Programs.

2.1.4 Selection of Development Program Targets and Indications. From time to time after the Effective Date, Tevard and the JDC will discuss and consider potential Targets, and Tevard shall provide to Zogenix any information or data reasonably requested by Zogenix related to any current Targets and Indications and Development by Tevard related thereto, for the purpose of evaluating such Targets and Indications for any Development Program for which Tevard conducts Development activities (other than the Dravet Syndrome Program). Zogenix may select any such Target and Indication for the Second Program and, if applicable, any Subsequent Option Program at its discretion but subject to the review and approval of the JDC ("Program Selection"). Upon such approval by the JDC, Tevard shall direct the Second Program and, if applicable, any Subsequent Option Program with respect to the relevant Targets and Indications.

2.1.5 Development Costs.

(a) Zogenix shall be responsible for the Development Costs incurred in connection with the Dravet Syndrome Program from and after the Effective Date and in accordance with the applicable Development Plan, including the Budget. In addition, Zogenix shall be responsible for the Development Costs incurred by Tevard in connection with the Dravet Syndrome Program during the period beginning October 14, 2019 and ending on the Effective Date ("Prior Development Costs") which Prior Development Costs the Parties hereby agree equals [***].

(b) Tevard shall be responsible for the Development Costs incurred in connection with the Second Program unless and until Program Selection by Zogenix. Zogenix shall (i) be responsible for the Development Costs incurred in accordance with the applicable Development Plan, including the Budget, in connection with the Second Program after Program Selection and (ii) shall reimburse Tevard for all of the Development Costs it incurred in accordance with the applicable Development Plan, including the Budget, in connection with the Second Program until Program Selection by Zogenix.

(c) Tevard shall be responsible for the Development Costs incurred in connection with any Subsequent Option Program(s) unless and until Program Selection by Zogenix. Zogenix shall be responsible for the Development Costs incurred in accordance with the applicable Development Plan, including the Budget, in connection with a Subsequent Option Program after Program Selection and (ii) shall reimburse Tevard for all of the Development Costs it incurred in accordance with the applicable Development Plan, including the Budget, in connection with the Subsequent Option Program until Program Selection by Zogenix.

2.1.6 Development Program Funding. In consideration of Tevard's performance of its obligations under the Development Plan for each Development Program upon the terms and conditions contained herein, Zogenix shall pay Tevard the Development Costs as set forth in Section 2.1.5 and this Section 2.1.6 and in accordance with the applicable Budget.

(a) At least ten (10) days prior to the start of any Calendar Quarter, and subject to receipt of a corresponding invoice from Tevard, Zogenix will pay Tevard the estimated amount set forth in the Budget for the corresponding Calendar Quarter (each such quarterly payment is referred to herein as an "Estimated Pre-Payment").

(b) Starting with the first Calendar Year following the Effective Date and within thirty (30) days after (i) the end of each Calendar Year during the Research Term and (ii) the date of termination or

expiration of the Research Term, Tevard shall perform a true-up for all FTE Costs and Out-of-Pocket Expenses actually incurred during the applicable Calendar Year (or partial Calendar Year in the event of termination or expiration) with respect to which Estimated Pre-Payments have been paid by Zogenix to reconcile the FTE Costs and Out-of-Pocket Expenses that were actually incurred during such Calendar Year (or partial Calendar Year) with the Development Costs that were paid by Zogenix with respect thereto. The true-up for the first full Calendar Year following the Effective Date shall include the Calendar Quarter of the previous year. Tevard shall provide to Zogenix its cost accounting documentation and other information reasonably requested by Zogenix to document the reconciliation.

(c) Each Party shall make reconciling payments to the other as necessary to effect such true-up with respect to the FTE Costs and Out-of-Pocket Expenses for such Calendar Year (or partial Calendar Year). If Zogenix is required to make a payment to Tevard to effect such reconciliation, then Zogenix shall provide such payment to Tevard within twenty-one (21) days of the determination of such payment. If Tevard is required to make a payment to Zogenix to effect such reconciliation, Tevard shall offset such amount against future amounts owed by Zogenix to Tevard pursuant to this Section 2.1.6. If either Party is required to make a payment to effect such reconciliation following the expiration or termination of the Research Program Term, such Party shall make such payment directly to the other Party within thirty (30) days following receipt of the reconciliation.

(d) Tevard shall keep for at least two (2) years from the end of the Calendar Year to which they pertain complete and accurate records of the FTE Costs and Out-of-Pocket Expenses with respect to Development Program activities in reasonably sufficient detail to allow the accuracy of the amounts charged to Zogenix to be confirmed ("Funding Records"). Upon the written request of Zogenix and not more than once in each Calendar Year, Tevard shall permit an independent certified public accounting firm of nationally recognized standing selected by Zogenix and reasonably acceptable to Tevard, at Zogenix's expense, to have access during normal business hours to such of the Funding Records of Tevard as may be reasonably necessary to verify the accuracy of the amounts charged to Zogenix hereunder for any Calendar Year ending not more than twenty-four (24) months prior to the date of such request. The accounting firm shall disclose to Zogenix and Tevard only whether the amounts charged to Zogenix are correct or incorrect and the amount of any discrepancy. No other information shall be provided to Zogenix. If such accounting firm identifies a discrepancy made during such period, the appropriate Party shall pay the other Party the amount of the discrepancy according to Section 2.1.6(c). The fees charged by such accounting firm shall be paid by Zogenix; provided, however, that if such audit uncovers an overcharge to Zogenix of an amount that exceeds the greater of One Hundred Thousand Dollars ($100,000) and seven and one-half percent (7.5%) of the total amounts owed for the Calendar Year in question, the fees of such accounting firm shall be paid by Tevard.

Section 2.2 Delivery and Evaluation of Option Packages for Development Programs.

2.2.1 Delivery of Option Package. On a Development Program-by-Development Program basis, promptly after generating and analyzing data that Tevard believes, in its reasonable opinion, to satisfy the applicable Option Package Criteria, Tevard shall provide the Option Package for the applicable Development Program to Zogenix. The first such Option Package shall be for the Second Program.

2.2.2 Evaluation of Option Package. The JDC shall evaluate each delivered Option Package within thirty (30) days after its receipt to determine whether the data contained therein satisfy in all material respects the applicable Option Package Criteria.

(a) If the JDC determines that the Option Package satisfies the Option Package Criteria, then the Option Period with respect to the applicable Development Program as provided in Section 4.1.2 shall

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commence on the date the JDC makes such determination, which date shall be communicated to Tevard and Zogenix within five (5) Business Days.

(b) If the JDC determines that the Option Package does not satisfy the Option Package Criteria, then unless the Parties agree to amend the applicable Option Package Criteria such that the submitted Option Package meets such amended Option Package Criteria or Zogenix elects to accept the Option Package as delivered by Tevard, Tevard shall continue to use Commercially Reasonable Efforts to Develop or supplement such Option Package until the applicable Option Package Criteria have been satisfied.

(c) Tevard shall not present or transfer any Option Package or any data or information related to any Development Program to any Third Party, or offer to grant or grant any Third Party any rights or license under such Development Program prior to such Development Program either becoming a Tevard Program or becoming a Terminal Exercise Disqualification Program.

2.2.3 Obligations from and after Delivery of the Option Package. Tevard shall continue to conduct Development activities with respect to each Product arising under a Development Program for which an Option Package has been delivered and Option exercised with respect to each such Licensed Product(s) until Product Transfer, and Tevard shall continue to conduct Development activities with respect to every other Product arising under any other Development Program until the earlier of (i) expiration of the Option Period without such Option being exercised and (ii) Product Transfer for such Development Program.

Section 2.3 Regulatory Matters; Compliance.

2.3.1 Compliance & Data Integrity. All of the Development activities to be conducted by Tevard and Zogenix under this Agreement shall be conducted in all material respects in compliance with Applicable Laws, including all applicable cGMP requirements, good laboratory practice requirements and good clinical practice requirements. Tevard and Zogenix shall carry out the Development Programs so as to collect and record any data generated therefrom in a manner consistent with all applicable regulatory requirements.

2.3.2 Regulatory Filings. Tevard shall control and maintain in its possession all regulatory filings, data and information related to each Development Program until the exercise by Zogenix of its Option to such Development Program. As soon as reasonably practicable after Zogenix’s exercise of the Option pursuant to Section 4.1 with respect to each Development Program (including with respect to the Dravet Syndrome Program, which is deemed exercised as of the Effective Date pursuant to Section 4.1.3), but in no event longer than thirty (30) days thereafter, Tevard shall assign and transfer to Zogenix all right, title and interest in and to and sponsorship of and responsibility for all regulatory filings and data and information for the applicable Licensed Products under such Development Programs. Subject to the provisions of Article 9, Tevard may maintain an archival copy in its files of such regulatory filings and data and information for the applicable Licensed Products under such Development Programs, provided that such data and information shall be deemed the Confidential Information of Zogenix. Within ten (10) Business Days after the foregoing date, Tevard shall provide Zogenix with copies of such regulatory filings and all pre-clinical and clinical data and information. Thereafter, Zogenix shall own, prepare, file, be responsible for, and maintain all regulatory filings and Regulatory Approvals for such Licensed Products.

Section 2.4 Subcontracting. Zogenix shall have the right to engage Affiliates or Third Party subcontractors to perform certain of its obligations under this Agreement. Tevard shall have the right to subcontract its obligations under this Agreement to any Third Party subcontractors, provided that such subcontractors are pre-approved in the applicable Development Plan or are pre-approved in writing by the JDC. Any Affiliate or subcontractor to be engaged by a Party to perform a Party’s obligations set forth in this Agreement shall meet the qualifications typically required by such Party for the performance of work similar in scope and complexity to the subcontracted activity; provided that, any Party engaging an Affiliate

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or subcontractor hereunder shall remain principally responsible and obligated for such activities. In addition, each Party engaging a subcontractor with respect to its obligations under any Development Program shall in all cases retain or obtain exclusive Control of any and all Know-How, Patents or other intellectual property created by or used with the relevant Party's permission by such subcontractor directly related to such subcontracted activity under the applicable Development Program. Each Party shall ensure that any subcontractor engaged by it will be bound by confidentiality provisions at least as stringent as those set forth in Article 9.

Section 2.5 Records and Audits. Tevard shall, and shall require its Affiliates and permitted subcontractors to, maintain materially complete, current and accurate hard and/or electronic copies of records of all work conducted under each Development Program including, all work conducted to prepare Option Packages, and all results, data, developments and Know-How made in conducting such activities, during the Term and for a period of three (3) years thereafter or longer if required by Applicable Law. Such records shall accurately reflect all such work done and results achieved and shall be in reasonably sufficient detail and in good scientific manner appropriate for applicable patent, Development, and regulatory purposes. Zogenix shall have the right to receive and retain a copy of all such records upon delivery of a written request to Tevard. Zogenix shall also have the right to conduct reasonable audits with respect to all facilities, operations and laboratories (and any records related thereto) operated by Tevard, its Affiliates or its permitted subcontractors, where Development activities are conducted, as is reasonably necessary solely for the purposes of verifying Tevard's compliance with this Agreement and applicable good laboratory practices, good clinical practices and other regulatory requirements in each country in the Territory, and verifying such Affiliates' or subcontractors performance under the applicable subcontract, including through audit of any applicable books, records, data or other information of such subcontractor. The foregoing audit shall be conducted during Tevard's normal business hours and without unreasonable disruption of Tevard's general business operations and only following seven (7) Business Days prior written notice being delivered to Tevard.

Section 2.6 Manufacture and Supply.

2.6.1 Manufacturing Responsibility. Each Development Plan shall specify the Manufacturing activities to be performed by each Party with respect to the applicable Product. Tevard shall be entitled to participate on any manufacturing subcommittee established by the JDC pursuant to Article 3. Promptly following Product Transfer with respect to any Licensed Product, the Parties shall mutually agree upon a reasonable Manufacturing technology transfer plan to provide for the orderly transition of Manufacturing activities and technology for such Licensed Product to Zogenix or its designee (the "Manufacturing Technology Transfer"). Until the completion of the Manufacturing Technology Transfer with respect to such Licensed Product, Tevard shall be responsible for providing Manufacturing-related services to Zogenix at Zogenix's continued cost and expense, including but not limited to the supply of quantities of such Licensed Product as requested by Zogenix for technical, non-clinical and clinical Development in the Territory. As part of the Manufacturing Technology Transfer, Tevard shall deliver, at its sole cost and expense, to Zogenix (or its designee) all manufacturing batch records, Development reports, analytical results, filings and correspondence with any Regulatory Authority (including notes or minutes of any meetings with any Regulatory Authority), raw material and excipient sourcing information, quality audit findings and any other relevant technical information in Tevard's possession and/or control relating to the applicable Licensed Product, and Tevard will reasonably assist (or cause its permitted subcontractors to reasonably assist) Zogenix in the transfer of manufacturing activities to a contract manufacturing organization designated by Zogenix. Subject to the provisions of Article 9, Tevard may maintain an archival copy in its files of such information and records for the applicable Licensed Products, provided that such information and records shall be deemed the Confidential Information of Zogenix, and provided further that Tevard shall be permitted to use such manufacturing-related information for its own Development of

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Tevard Products under a Tevard Program notwithstanding such manufacturing-related information being Zogenix Confidential Information. Tevard shall reasonably cooperate with Zogenix to transition the Manufacture of the applicable Licensed Product to a contract manufacturing organization designated by Zogenix and to scale up such Manufacture for Commercialization of such Product. Zogenix shall have the right to control all Manufacturing-related activities for Development and Commercialization of such Licensed Product in the Territory, at its sole cost and expense.

2.6.2 Manufacturing Approvals. Tevard shall be responsible for obtaining and maintaining Regulatory Approval for the Manufacture of Products until the date of the Manufacturing Technology Transfer. Thereafter, Zogenix or its designee shall be responsible for obtaining and maintaining such Regulatory Approvals.

2.6.3 Compliance with Applicable Law. Each Party shall Manufacture, or have an Affiliate or subcontractor Manufacture, all Products hereunder in full compliance with all aspects of Applicable Law, the applicable specifications, and all applicable FDA (or foreign equivalent) requirements, including without limitation then-current cGMP, as applicable.

2.6.4 Capital Costs. Unless otherwise mutually agreed upon in writing between the Parties, each Party shall be solely responsible for all capital costs incurred by it in connection with the Manufacture of Products, including without limitation building out Manufacturing capacity for and final packaging of such Products.

ARTICLE 3

MANAGEMENT OF THE COLLABORATION

Section 3.1 Joint Development Committee and Subcommittees. The Parties shall establish a joint development committee (the “Joint Development Committee” or “JDC”) as more fully described in this Article 3. Subject to Section 3.1.7, the JDC shall have review, oversight and decision-making responsibilities for all Development activities performed under this Agreement, as more specifically provided herein, and each Party agrees to keep the JDC informed of its progress and activities under the programs developed under this Agreement. For clarity, Tevard shall keep the JDC informed of all Development activities in the Field, including activities with respect to the evaluation or Development of any Target or any Corrective Therapeutic Agent.

3.1.1 Membership. The JDC shall be comprised of three (3) representatives (or such other equal number of representatives from each Party as the Parties may agree) from each of Zogenix and Tevard. Each Party shall provide the other with a list of its initial members of the JDC no later than thirty (30) days prior to the first scheduled meeting of the JDC, which shall be no later than sixty (60) days after the Effective Date. Each Party may replace any or all of its representatives on the JDC at any time upon written notice to the other Party in accordance with Section 13.8. Each representative of a Party shall have relevant expertise in pharmaceutical drug discovery and Development, and be suitable in seniority and experience and have been delegated the authority to make decisions on behalf of the applicable Party with respect to matters within the scope of the JDC’s responsibilities. Any member of the JDC may designate a substitute to attend and perform the functions of that member at any meeting of the JDC. Each Party may, in its reasonable discretion, invite non-member representatives of such Party to attend meetings of the JDC as non-voting participants, subject to the confidentiality obligations of Article 9. The Parties shall designate a chairperson (the “Chairperson”) to oversee the operation of the JDC, which chairperson may be replaced or substituted as may be mutually agreed upon by the Parties.

3.1.2 Meetings; Reports.

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(a) Prior to the expiration of the Research Term, the JDC shall meet at least once each Calendar Quarter, and more or less frequently as the Parties mutually deem appropriate, on such dates and at such places and times as provided herein or as the Parties shall agree. After conclusion of the Research Term and, on a Licensed Development Program-by-Licensed Development Program basis, prior to the First Commercial Sale of each applicable Licensed Product, the JDC shall meet at least once each Calendar Quarter in order (i) to support ongoing collaboration, communication, and information exchange among the Parties and (ii) for each Party to provide the other Party with an update regarding such Party's Development of Products. Meetings of the JDC that are held in person shall alternate between the offices of the Parties, or such other location as the Parties may agree. JDC meetings may be conducted by telephone, videoconference or in person. The members of the JDC also may be polled or consulted from time to time by means of telecommunications, video conferences, electronic mail or correspondence, as deemed necessary or appropriate. Each Party will bear all expenses it incurs in regard to participating in all meetings of the JDC, including all travel and living expenses. Each Party may also call for special meetings of the JDC to discuss particular matters requested by such Party. The Collaboration Managers shall provide the members of the JDC with no less than ten (10) Business Days' notification of each regularly scheduled meeting and, to the extent reasonably practicable under the circumstances, no less than five (5) Business Days' notification of any special meetings called by either Party.

(b) Tevard shall provide Zogenix with a written report summarizing (to the extent applicable) the activities of Tevard and its Affiliates, Licensees and Sublicensees with respect to the Development of Products and, if applicable, Licensed Products. Such written report shall be provided to Zogenix at least ten (10) Business Days prior to each JDC meeting and shall include: (i) material information, data, and results relating to such Development activities, (ii) discussion of any proposed material changes to any Development Plan, and (iii) the status of regulatory filings and information regarding meetings with Regulatory Authorities, if any.

3.1.3 Minutes. The Chairperson shall appoint one (1) representative in attendance at each meeting to prepare and circulate accurate minutes of each meeting of the JDC, with such appointment effective upon approval by Tevard, such approval not to be unreasonably withheld, setting forth, inter alia, an overview of the discussions at the meeting and a list of any actions, decisions or determinations approved by the JDC and a list of any issues to be resolved by the Executive Officers pursuant to Section 3.1.5. Draft minutes shall be circulated to all JDC representatives for review and comment within five (5) Business Days after the applicable meeting. The JDC representatives will have ten (10) Business Days from the date of circulation of such draft minutes to provide comments. The JDC representative preparing the minutes will incorporate timely received comments. Such minutes shall be effective only after approval by both Parties in writing. With the sole exception of specific items of the meeting minutes to which the members cannot agree and that are escalated to the Executive Officers as provided in Section 3.1.5, definitive minutes of all JDC meetings shall be finalized no later than thirty (30) days after the meeting to which the minutes pertain. If, at any time during the preparation and finalization of the JDC minutes, the Parties do not agree on any issue with respect to the minutes, such issue shall be resolved by the escalation process set forth in Section 3.1.5. The decision resulting from the escalation process shall be recorded by the Collaboration Manager in amended finalized minutes for such meeting.

3.1.4 Responsibilities. The JDC shall perform the following functions, subject to the final decision-making authority of the respective Parties as set forth in Section 3.1.5:

(a) discuss and mutually agree upon the addition of potential Targets (and upon JDC agreement Exhibit A shall be deemed to be updated accordingly), the type or types of Epilepsy to be treated, and the initial Indication(s) for a Corrective Therapeutic Agent to be Developed under the Second Program and any Subsequent Option Programs in accordance with Section 2.1.4;

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(b) review and agree upon target product profile, delivery technology, applicable nucleic acid or peptide sequence(s), other applicable technology, and applicable intellectual property related to each Development Program, including Licensed Development Program and Zogenix Development Program, or reasonably expected to cover any Licensed Products developed thereunder (including applicable Tevard Patents, In-Licenses and any necessary or useful intellectual property Controlled by a Third Party);

(c) prior to the commencement of each Development Program, customize the Core Option Package Criteria to establish the Option Package Criteria for such Development Program, provided that, notwithstanding Section 3.1.5, such customization of such criteria shall require the mutual written agreement of both Parties and, provided further, that if the JDC fails to reach consensus, the issue shall be escalated to the Executive Officers of the Parties for resolution of such criteria pursuant to Section 3.1.5, and neither party shall have final decision-making authority over such decision. The Parties agree that within forty-five (45) days after the date of this Agreement, the JDC shall determine the Option Package Criteria for the Second Program;

(d) discuss and mutually agree upon a list of approved Third Party subcontractors that Tevard may utilize for Development or Manufacturing work;

(e) review and provide comments on each Development Plan, including Budget, submitted by Tevard pursuant to Section 2.1.2 and approve such Development Plan or recommend amendments or revisions thereto;

(f) review, monitor progress, and discuss recommendations under each Development Program and review and discuss the reports provided by Tevard pursuant to Section 3.1.2(b), and discuss any Development Programs under Development by Tevard, including the evaluation of data generated during the course of Tevard's Development efforts under each such Development Program and any recommendations thereof;

(g) discuss and mutually agree upon the Product Transfer Criteria and any modifications or updates thereto for each Licensed Development Program, provided that if the JDC fails to reach consensus, the issue shall be escalated to the Executive Officers of the Parties for resolution of such criteria pursuant to Section 3.1.5, and neither party shall have final decision-making authority over such decision;

(h) evaluate each delivered Product Transfer Package to determine whether the data contained therein satisfy the applicable Product Transfer Criteria;

(i) provide a forum for determining a publication strategy in relation to the Development Programs and approve proposed publications;

(j) review and monitor all Corrective Therapeutic Agents Developed under the Dravet Syndrome Program, Second Program and any Subsequent Option Programs, and discuss and mutually agree upon the lists of Protected Therapeutic Agents nominated by Zogenix, including the First Restricted List, the Second Restricted List, the Third Restricted List, and the Fourth Restricted List, and any additions or replacements to such lists nominated by Zogenix; and

(k) such other responsibilities as may be assigned to the JDC pursuant to this Agreement or as may be mutually agreed upon by the Parties from time to time.

For clarity, the JDC shall not have any authority beyond the specific matters set forth in this Section 3.1.4, and in particular shall not have any power to amend or modify the terms of this Agreement.

3.1.5 Decision Making. Except as otherwise provided herein, including, without limitation, Section 3.1.7, with respect to a given Development Program, all decisions of the JDC shall be made by consensus,

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with each Party having one vote. If the JDC cannot agree on a matter within its authority hereunder within thirty (30) days after it has met and attempted to reach such decision, then, either Party may, by written notice to the other, have such issue referred to the Executive Officers for resolution. The Parties' respective Executive Officers shall meet within fifteen (15) days after such matter is referred to them, and shall negotiate in good faith to resolve the matter. If the Executive Officers are unable to resolve the matter within thirty (30) days after the matter is referred to them, then the issue shall be finally resolved as follows:

(a) Tevard shall have final decision-making authority with respect to any disputes with respect to all Development Programs for which Zogenix has not exercised its Option; except (i) for matters set forth in Sections 3.1.4(a) or 3.1.4(b), for which neither Party shall have final decision-making authority and (ii) as otherwise set forth in Section 3.1.4(c), for which decision-making authority shall be as set forth therein.

(b) Zogenix shall have final decision-making authority with respect to any disputes following the exercise of its Option and with respect to all Licensed Development Programs, including disputes concerning the Development and Commercialization of Licensed Products thereunder.

(c) Any dispute regarding a matter within the JDC's authority with respect to which final decision-making authority is not otherwise specified in this Section 3.1.5, if not resolved by escalation to the respective Executive Officers of the Parties, shall be finally decided by Zogenix.

3.1.6 Dissolution on Change of Control. Zogenix may, in its sole discretion, dissolve the JDC in the event of a Change of Control of Tevard. Tevard will provide Zogenix written notice within ten (10) days of undergoing any Change of Control.

3.1.7 Termination of JDC role after Product Transfer — except for the Dravet Syndrome Program and except with respect to Protected Therapeutic Agents. Notwithstanding anything to the contrary in this Agreement, with respect to each Development Program except for the Dravet Syndrome Program and except with respect to Section 3.1.4(j), upon Initiation of any Clinical Trial for any Product arising under such Development Program: (i) the jurisdiction and authority of the JDC with respect to such Product shall cease; (ii) all rights of Tevard under this Article 3 with respect to such Product shall be of no further force or effect; and (iii) Zogenix shall have sole decision-making authority with respect to such Product, and Zogenix shall have no further obligation to present any matter with respect to such Product to the JDC or to Tevard, whether for their respective review, approval or otherwise. For the avoidance of doubt, the jurisdiction and authority of the JDC and rights of Tevard with respect to each of the other Products arising under such Development Program shall continue as provided under this Article 3 for so long as such Products remain under Development pursuant to this Agreement, until the Initiation of any Clinical Trial for each such Product.

3.1.8 Termination of JDC role after Expiration of Tevard Option for the Dravet Syndrome Program. Notwithstanding anything to the contrary in this Agreement, with respect to the Dravet Syndrome Program but not with respect to Section 3.1.4(j), upon the expiration of the Tevard Option pursuant to Section 5.2.1 or the cancellation of the Tevard Option in accordance with Section 5.2.3 or 5.2.4 (i) the jurisdiction and authority of the JDC with respect to the Dravet Syndrome Program shall cease; (ii) all rights of Tevard under this Article 3 shall be of no further force or effect; and (iii) Zogenix shall have sole decision-making authority with respect to all matters related to the Dravet Syndrome Program and the Products Developed thereunder without any obligation to present such matters to the JDC or to Tevard, whether for their respective review, approval or otherwise.

3.1.9 Termination of the JDC role with respect to Protected Therapeutic Agents. Notwithstanding anything to the contrary in this Agreement, on a Licensed Development Program-by-Licensed Development Program basis, the jurisdiction and authority of the JDC solely with respect to Section 3.1.4(j) shall continue

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until five (5) years after the first Regulatory Approval of a Licensed Product Developed under such Licensed Development Program.

ARTICLE 4

GRANT OF RIGHTS TO ZOGENIX

Section 4.1 Zogenix Options.

4.1.1 Option Grant. Subject to the provisions of this Section 4.1, Tevard hereby grants to Zogenix the exclusive option, exercisable on a Development Program-by-Development Program basis at Zogenix's sole discretion, to obtain the exclusive license set forth in Section 4.2.1 as to the Second Program and all Subsequent Option Programs and all Products arising therefrom (each, an "Option").

4.1.2 Option Exercise Period. Zogenix shall have the right to exercise its Option with respect to the Second Program and all Subsequent Option Programs at any time after the Effective Date until as follows (the "Option Period"):

(a) if Tevard delivers an Option Package for such Development Program during the Research Term, the date that is ninety (90) days after the Parties' agreement that the applicable Option Package satisfies the Option Package Criteria therefor;

(b) if Tevard delivers an Option Package for such Development Program during the Research Term but the Parties do not agree that such Option Package satisfies the Option Package Criteria, and the Research Term has expired before Tevard has updated and redelivered an Option Package that the Parties agree does satisfy the Option Package Criteria, then:

(i) if Tevard has agreed to update and redeliver such Option Package after the Research Term, the date that is ninety (90) days after the Parties' agree that the updated and redelivered Option Package for such Development Program satisfies the Option Package Criteria, or

(ii) if Tevard has not agreed to update and redeliver such Option Package after the Research Term, the date that is forty-five (45) days after the expiration of the Research Term;

(c) if Tevard has not provided an Option Package prior to the end of the Research Term, the date that is forty-five (45) days after the expiration of the Research Term; provided that, this clause (c) shall not apply to any Development Program that is terminated by the mutual agreement in writing of the Parties (such programs, the "Terminal Exercise Disqualification Programs").

(d) If Zogenix exercises an Option with respect to a Development Program prior to Tevard's delivery or redelivery, as applicable, of an Option Package therefor, then Tevard shall be deemed to have delivered an Option Package for such Development Program for purposes of determining whether Tevard has satisfied its obligation to deliver Option Packages pursuant to Section 2.1.3.

4.1.3 Deemed Exercise of Option to Dravet Syndrome Program. Zogenix's option with respect to the Dravet Syndrome Program shall be deemed exercised as of the Effective Date.

4.1.4 Exercise of Option to Second Program and any Subsequent Option Programs. Zogenix shall have the right to exercise the Option with respect to the Second Program and any Subsequent Option Programs by written notice to Tevard and payment of the applicable Option Exercise Fee as set forth in

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Section 6.3, if any. Upon Zogenix's exercise of an Option with respect to the Second Program or any Subsequent Option Programs and receipt by Tevard of the applicable Option Exercise Fee, if any, (i) such Second Program or any Subsequent Option Programs shall be designated as a Licensed Development Program and (ii) the applicable Development Products shall be designated as Licensed Products.

4.1.5 Expiration or Termination of Option. With respect to a particular Second Program or any Subsequent Option Program, if Zogenix does not exercise the Option within the applicable Option Period then, as of the expiration of the Option Period (a) such Option shall terminate and be of no further force or effect, (b) the applicable Second Program or Subsequent Option Program shall become a Tevard Program, and (c) the provisions of Section 5.3.1 shall apply.

Section 4.2 License Grants.

4.2.1 License with respect to the Dravet Syndrome Program. Tevard hereby grants to Zogenix, and Zogenix hereby accepts and receives, the exclusive right and license (even as to Tevard and its Affiliates) in the Territory and in the Field, with the right to grant sublicenses (subject to Section 4.2.5), under the Tevard IP and Tevard's interest in the Joint IP, to Develop, Manufacture, Commercialize, make, have made, use, offer for sale, sell and import Licensed Products arising from the Dravet Syndrome Program.

4.2.2 Licenses with respect to the Second Program and the Subsequent Option Programs. Upon Zogenix's exercise of an Option for the Second Program and any Subsequent Option Programs pursuant to Section 4.1, Tevard hereby grants to Zogenix, and Zogenix shall have, the exclusive right and license (even as to Tevard and its Affiliates) in the Territory and in the Field, with the right to grant sublicenses (subject to Section 4.2.5), under the Tevard IP and Tevard's interest in the Joint IP, to Develop, Commercialize, make, have made, use, offer for sale, sell and import Licensed Products arising from such Development Program.

4.2.3 Tevard In-License.

(a) Zogenix acknowledges and agrees that the rights, licenses and sublicenses granted by Tevard to Zogenix in this Agreement (including any sublicense rights) are subject to the terms of the Tevard In-Licenses set forth in Exhibit C. Upon exercise by Zogenix of its Option with respect to a Development Program, and from time to time thereafter, the Parties shall mutually agree upon any required amendments to Exhibit C.

(b) During the Term, Tevard shall maintain each of the Tevard In-Licenses in good standing and shall not take any action, or omit or fail to take any action (including making necessary payments), which would result in a breach or early termination of any such In-Licenses or any rights thereunder. Tevard covenants that it shall not amend, modify or supplement the terms of, or waive any rights under, any Tevard In-License without the prior written consent of Zogenix, which consent will not unreasonably be denied. Tevard shall promptly notify Zogenix upon receipt by Tevard of any notice from any Inbound Licensor of any actual or alleged breach under any In-License that could result in the termination of such agreement or a material reduction or other material limitation in Tevard's rights thereunder, and Tevard shall promptly cure any such breach within the allotted cure period and if it is unwilling or unable to do so, Tevard shall timely notify Zogenix and Zogenix shall have the right to cure such breach on Tevard's behalf.

4.2.4 Termination of Tevard In-Licenses. Zogenix acknowledges and agrees that, if any of the licenses granted to Tevard under the Tevard In-Licenses is terminated, in whole or in part, including due to any failure by Tevard and Zogenix, and their Affiliates and Sublicensees, to meet any of the diligence obligations (including any diligence milestone) set forth therein, then Zogenix's sublicense under such terminated license(s) may terminate. In instances where an Tevard In-License provides a right for Zogenix to receive a direct license from such Inbound Licensor in event of termination of such Tevard In-License, Tevard shall reasonably cooperate with Zogenix in obtaining such direct license. In instances where a

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Tevard In-License does not already provide a right for Zogenix to receive a direct license from such Inbound Licensor, Tevard will use Commercially Reasonable Efforts to secure written statements from each Inbound Licensor declaring that, should the Tevard In-License be terminated, the applicable Inbound Licensor shall provide prompt notice thereof to Zogenix and shall grant a direct license to Zogenix on the same terms as those set forth in (a) this Agreement, or (b) the Tevard In-License, in each case which apply to the Inbound Licensor's intellectual property that is sublicensed to Zogenix under the Tevard In-License.

4.2.5 Zogenix's Sublicensing Rights. Subject to Section 4.2.3(a), Zogenix shall have the right to grant sublicenses under the rights granted to it under Sections 4.2.1 and 4.2.2 to any of its Affiliates and Third Parties. If Zogenix grants a sublicense, the terms and conditions of this Agreement that are applicable to Sublicensees shall apply to such Sublicensee to the same extent as they apply to Zogenix. Zogenix assumes full responsibility, and shall remain liable, for causing the performance of all obligations of each Zogenix Affiliate and Sublicensee to which it grants a sublicense, and will itself pay and account to Tevard for all payments due under this Agreement by reason of operation of any such sublicense.

4.2.6 No Grant of Rights to Third Parties. Except for any rights previously granted by Tevard to the Inbound Licensors pursuant to the Tevard In-Licenses, Tevard shall not itself exercise, nor grant to any Third Party, rights to the Tevard IP or Tevard's interest in the Joint IP that are inconsistent with or that would interfere with the grant of the rights, Option and licenses granted or potentially to be granted to Zogenix hereunder.

Section 4.3 Product Transfer.

4.3.1 On a Licensed Product-by-Licensed Product basis, promptly after generating and analyzing data that Tevard believes, in its reasonable opinion, to satisfy the applicable Product Transfer Criteria, Tevard shall provide a Product Transfer Package to the JDC. The JDC shall evaluate such Product Transfer Package promptly to determine whether the data satisfy the applicable Product Transfer Criteria.

4.3.2 As soon as reasonably practicable after the JDC determines that the Product Transfer Criteria for a Licensed Product have been achieved, the Parties shall agree to a plan to transfer to Zogenix (or its designee) all Development activities then being undertaken by Tevard with respect to such Licensed Product ("Transition Plan"). Tevard shall transition all such activities to Zogenix in accordance with the Transition Plan at Zogenix's cost and expense with respect to such transition activities. Without limiting the foregoing, Tevard shall disclose and deliver to Zogenix all tangible embodiments of all Tevard Know-How or Joint Know-How in its possession and Control that are useful or necessary to research, develop, make, use, sell, offer for sale or import the applicable Licensed Product, in each case to the extent not provided to Zogenix prior to such achievement of the Product Transfer Criteria, and all Books and Records related to such Licensed Product (provided that, with respect to any Books and Records related to both such Licensed Product and any other Products remaining with Tevard, Tevard may retain copies of such Books and Records for use in another Licensed Development Program, which copies shall be subject to the confidentiality covenants set forth in Article 9, provided that Tevard may disclose such Books and Records to an Inbound Licensor solely to the extent required under an In-License). Tevard shall make such Tevard Know-How or Joint Know-How available in a mutually agreed upon format and where feasible in electronic form; provided that, if Zogenix requests a form other than the form in which Tevard otherwise maintains such Tevard Know-How or Joint Know-How then Zogenix shall reimburse Tevard for all Out of Pocket Expenses incurred by Tevard in converting such Tevard Know-How or Joint Know-How to the form requested by Zogenix.

4.3.3 Without limiting the foregoing, Tevard will provide reasonable assistance to Zogenix or its designee in connection with understanding and using the Tevard Know-How within the scope of the licenses granted under Section 4.2.1 at Tevard's cost and expense. In providing Tevard Know-How or Joint Know-

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How under Section 4.3.1, Tevard shall deliver written and electronic materials to Zogenix, and assistance from its professional staff for meetings, telephone calls, and other reasonable assistance as requested by Zogenix to enable it to understand and use such Know-How.

Section 4.4 Rights Retained by the Parties. Any rights of Tevard or Zogenix, as the case may be, not expressly granted to the other Party pursuant to this Agreement shall be retained by such Party.

Section 4.5 Government Rights. To the extent that the Tevard IP was supported under a United States Government funding agreement, then (a) the United States Government has been or will be granted licensing rights as required under the terms of those federal agreements, (b) all rights and requirements of the United States Government and others under Public Law 96-517, and Public Law 98-620, including but not limited to government purpose license, march-in rights, and obligations to provide materials to other researchers shall remain and shall in no way be affected by this Agreement and any right granted in this Agreement greater than that permitted under Public Law 96-517, or Public Law 98-620, shall be subject to modification as may be required to conform to the provisions of those statutes, and (c) products sold in the United States of America, embodying or produced through use of Tevard IP, will be manufactured substantially in the United States of America, unless a waiver has been obtained from the federal funding agency under whose funding agreement the Tevard IP was generated.

Section 4.6 Section 365(n) of the Bankruptcy Code. All rights and licenses granted pursuant to any section of this Agreement, including pursuant to Section 4.2, are rights and licenses to “intellectual property” (as defined in Section 101(35A) of title 11 of the United States Code (the “Bankruptcy Code”)). Each Party shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code.

ARTICLE 5

POST-EXERCISE ACTIVITIES

Section 5.1 Zogenix Development and Commercialization.

5.1.1 Zogenix, either itself or by and through its Affiliates, Licensees, Sublicensees, or contractors, shall control all Development (except as provided in Section 2.1.1), Manufacturing and Commercialization activities in connection with Licensed Products arising under Zogenix Development Programs. Zogenix shall have sole decision-making authority with respect to the Development, Manufacturing and Commercialization of any Licensed Product within a Zogenix Development Program, provided that, Tevard shall remain primarily responsible for conducting, and shall use Commercially Reasonable Efforts to conduct, the Development Programs with respect to each Product arising thereunder up to Product Transfer, provided further that Zogenix shall have final decision-making authority with respect to such additional Development activities (including any Development budget) and Tevard shall not submit any regulatory filings with respect thereto without Zogenix’s prior written approval thereof. Zogenix shall reimburse Tevard for all Development Costs incurred by Tevard in conducting such post-exercise activities consistent with the approved Development Plan and Budget in accordance with Section 2.1.6, and Tevard shall incorporate any input of Zogenix regarding the conduct of such activities.

5.1.2 Zogenix shall use Commercially Reasonable Efforts to Develop and obtain Regulatory Approval for at least one (1) Licensed Product and, after receiving the applicable Regulatory Approval, to Commercialize at least one (1) Licensed Product.

5.1.3 Notwithstanding Section 5.1.1 and subject to the reasonable availability of Tevard resources, in addition to its obligation under Section 4.3, Tevard shall continue to provide Development support for any stage of Development for Zogenix Development Programs as reasonably requested by Zogenix. Prior to beginning any such Development support, Tevard shall prepare a reasonable budget for Zogenix’s review

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and approval. Zogenix shall reimburse Tevard for all Development Costs incurred by Tevard or any of its Affiliates in performing activities requested by Zogenix under this Section 5.1.3 within forty-five (45) days after Zogenix's receipt of each Tevard invoice therefor provided such expenses are consistent with the approved budget.

Section 5.2 Tevard Option.

5.2.1 Tevard's Option to Participate in Clinical Development of Dravet Syndrome Program. At any time after [***] but at [***] before Initiation of [***] Zogenix shall provide to Tevard the Tevard Option Information Package. Within ninety (90) days of Zogenix providing such Tevard Option Information Package, Tevard shall have the right to elect, by written notice to Zogenix, to receive an enhanced royalty on sales of Licensed Products from the Dravet Syndrome Program and to share in the Development Costs of the Dravet Syndrome Program as further provided in this Section 5.2 (the "Tevard Option"). Upon the expiration of such ninety (90)-day election period, the Tevard Option shall expire and be of no further effect.

5.2.2 Effects of Exercising Tevard Option. If Tevard exercises the Tevard Option, then (a) Tevard shall be liable for and shall reimburse Zogenix for [***] of all Development Costs incurred by Zogenix in connection with the Dravet Syndrome Program after Tevard's exercise of the Tevard Option, including any Pivotal Registration Trials and post-marketing studies; and (b) the royalty rates payable by Zogenix to Tevard on Net Sales of Licensed Products under the optioned Dravet Syndrome Program ("Optioned Dravet Product") shall increase as provided in Section 6.5.1.

(a) Within thirty (30) days following Tevard's exercise of the Tevard Option, and thereafter at least thirty (30) days prior to the start of any Calendar Year, and subject to receipt of a corresponding invoice from Zogenix, Tevard will pay Zogenix the amount set forth in such invoice, which shall be the estimated [***] of Zogenix's Development Costs expected to be incurred by Zogenix in connection with the Dravet Syndrome for the corresponding Calendar Year (or partial Calendar Year) (each such payment is referred to herein as a "Tevard Pre-Payment").

(b) Within thirty (30) days after the end of each Calendar Year (or partial Calendar Year) following Tevard's exercise of the Tevard Option, Zogenix shall perform a true-up for all FTE Costs and Out-of-Pocket Expenses actually incurred during the applicable Calendar Year (or partial Calendar Year) with respect to which Tevard Pre-Payments have been paid by Tevard to reconcile the FTE Costs and Out-of-Pocket Expenses that were actually incurred during such Calendar Year (or partial Calendar Year) with the Tevard Pre-Payment that was paid by Tevard with respect thereto. Zogenix shall provide to Tevard its cost accounting documentation and other information reasonably requested by Tevard to document the reconciliation.

(c) Each Party shall make reconciling payments to the other as necessary to effect such true-up with respect to the FTE Costs and Out-of-Pocket Expenses for such Calendar Year (or partial Calendar Year). If Tevard is required to make a payment to Zogenix to effect such reconciliation, then Tevard shall provide such payment to Zogenix within twenty-one (21) days of the determination of such payment. If Zogenix is required to make a payment to Tevard to effect such reconciliation, Zogenix shall offset such amount against future amounts owed by Tevard to Zogenix pursuant to this Section 5.2.2.

5.2.3 Failure to Make Tevard Pre-Payment. If Tevard fails to make a Tevard Pre-Payment when due, Zogenix shall provide Tevard with written notice of such failure (a "Pre-Payment Failure Notice"). Timely upon receipt of such a Pre-Payment Failure Notice, Tevard may provide written notice to Zogenix detailing any amounts in dispute, which dispute Zogenix and Tevard shall seek to resolve in accordance with Section 13.1. If Tevard fails to make an undisputed Tevard Pre-Payment (or the undisputed amount of a Tevard

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Pre-Payment) within sixty (60) days following receipt of a Pre-Payment Failure Notice, Tevard's exercise of the Tevard Option shall be deemed cancelled as if such exercise had not occurred. Tevard shall not be entitled to any refund or credit for amounts that it may have paid as Tevard Pre-Payments prior to cancellation (other than amounts that may be payable or creditable to Tevard as a final reconciliation) and Tevard shall not be entitled to any increased royalty rates on Net Sales of Licensed Products and the Optioned Dravet Product shall be deemed a Licensed Product.

5.2.4 Cancellation of Tevard Option. Tevard may cancel its exercise of the Tevard Option for any or no reason by providing [***] written notice of such cancellation to Zogenix. For the avoidance of doubt, if Tevard elects to cancel its exercise of the Tevard Option for convenience as set forth in this Section 5.2.4, Tevard shall be obligated to make any Tevard Pre-Payment that comes due during such [***] notice period, and Tevard shall not be entitled to any refund or credit for amounts that it may have paid as Tevard Pre-Payments prior to cancellation (other than amounts that may be payable or creditable to Tevard as a final reconciliation) and Tevard shall not be entitled to any increased royalty rates on Net Sales of Licensed Products and the Optioned Dravet Product shall be deemed a Licensed Product.

5.2.5 Responsibility for Development and Commercialization. Tevard's exercise of the Tevard Option shall not alter Zogenix's right to control all Development, Manufacturing and Commercialization activities under the Dravet Syndrome Program or Zogenix's obligations hereunder with respect to such Development, Manufacturing and Commercialization.

Section 5.3 Tevard Programs.

5.3.1 Tevard Program. If the Option Period for an Option with respect to a particular Development Program expires without exercise by Zogenix, then (i) such Development Program shall become a Tevard Program and the applicable Development Products shall become Tevard Products for which Tevard shall, subject to Article 7, have the right (but not the obligation), in its sole discretion, to Develop, Manufacture and Commercialize such Tevard Product in the Territory inside and outside the Field, alone or through any Affiliate and, after the Research Term, with any Third Party, Licensee or Sublicensee, (ii) the obligations of Tevard and rights of Zogenix under Article 2 with respect to such Development Program will terminate, and (iii) Zogenix will have no further obligations to make any milestone, royalty or other payments to Tevard under Article 6 with respect to such Development Program, except for any such obligations that accrued prior to the date such Development Program became a Tevard Program.

5.3.2 Zogenix Development Termination. After exercising an Option with respect to a particular Development Program, Zogenix may terminate this Agreement with respect to such Licensed Development Program pursuant to Section 12.2. Upon such termination, the Licensed Products within such Licensed Development Program shall be deemed Tevard Products for the remainder of the Term, such Licensed Development Program shall be deemed a Tevard Program for the remainder of the Term and Sections 12.6.2(c), 12.6.2(e) and 12.6.2(f) and the restrictions of Article 7 shall apply.

5.3.3 License with respect to the Tevard Program. Zogenix hereby grants to Tevard, and Tevard hereby accepts and receives, the exclusive right and license (even as to Zogenix and its Affiliates) in the Territory and inside and outside the Field, with the right to grant sublicenses (subject to Section 5.3.4), under the Zogenix IP and Zogenix's interest in the Joint IP, to Develop, Manufacture, Commercialize, make, have made, use, offer for sale, sell and import Tevard Products subject to the restrictions in Article 7. For the avoidance of doubt, Tevard shall not be granted any rights to Prosecute and Maintain or enforce the licensed Joint IP to the extent not allocated to Tevard under Article 8. The royalty obligations set forth in Section 6.6 shall apply with respect to Tevard Products and any other Products from terminated Development Programs Developed, Manufactured or Commercialized by Tevard, alone or with any Third Party or through any Affiliate, Licensee or Sublicensee, as Tevard Products.

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5.3.4 Tevard's Sublicensing Rights. Tevard shall have the right to grant sublicenses under the rights granted to it under Sections 5.3.3 to any of its Affiliates and Third Parties. If Tevard grants a sublicense, the terms and conditions of this Agreement that are applicable to Sublicensees shall apply to such Sublicensee to the same extent as they apply to Tevard. Tevard assumes full responsibility, and shall remain liable, for causing the performance of all obligations of each Tevard Affiliate and Sublicensee to which it grants a sublicense, and will itself pay and account to Zogenix for all payments due under this Agreement by reason of operation of any such sublicense.

ARTICLE 6

PAYMENTS

Section 6.1 Initial Fee. In partial consideration for the rights, licenses, and Options granted to Zogenix hereunder, Zogenix shall pay Tevard a one-time, non-refundable, initial payment (the "Initial Payment") within five business days following the Effective Date. The Initial Payment amount shall be the difference of the Aggregate Option Agreement Payments subtracted from the amount of Ten Million Dollars ($10,000,000). In accordance with Section 2.1.5, ninety percent (90%) of the Initial Payment shall be allocated for Development Costs related to research and development and manufacturing activities for Licensed Products (including process development and contract manufacturing).

Section 6.2 Investment. In partial consideration for the rights, licenses, and Options granted to Zogenix hereunder, Zogenix shall purchase a Convertible Promissory Note, in substantially the form of Exhibit F, from Tevard in the amount of Five Million Dollars ($5,000,000) on the Effective Date.

Section 6.3 Option Exercise Fees. In partial consideration for the rights, licenses, and Options granted to Zogenix hereunder, Zogenix shall pay Tevard the following non-refundable, non-creditable fees, on a Development Program-by-Development Program basis, as set forth below:

Type of Fee	Amount
Option Exercise Fee for the Dravet Syndrome Program and Second Program	No Option Exercise Fee required or due
Option Exercise Fee for each Development Program other than the Dravet Syndrome Program and Second Program	$2,000,000
Terminal Option Exercise Fee (applies in lieu of the initial Option Exercise Fee if Option is exercised at the end of the Research Term pursuant to Section 4.1.2(b)(ii) or Section 4.1.2(c) if a Development Program other than a Terminal Exercise Disqualification Program has not progressed to delivery of the Option Package which meets the Option Package Criteria)	$500,000

Section 6.4 Development and Commercial Milestone Fees.

6.4.1 Milestone Payments.

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(a) In partial consideration for the rights, licenses, and Options granted to Zogenix hereunder Zogenix shall make the following non-refundable, non-creditable milestone payments to Tevard, on a Zogenix Development Program-by-Zogenix Development Program basis, within forty-five (45) days after the first achievement by Tevard, Zogenix, or their respective Affiliates, Licensees, or Sublicensees of the milestone events set forth in the tables in Section 6.4.2 and Section 6.4.3 below (each, a "Milestone Event").

(b) In the event a Milestone Event occurs in a Zogenix Development Program, all prior Milestone Events with respect to such Zogenix Development Program that have not occurred shall be deemed to have occurred, and any payment(s) associated with such prior Milestone Events that have not previously been paid shall be due and payable with the payment associated with the Milestone Event that occurred.

(c) The total milestone payments due with respect to the Dravet Syndrome Program shall not exceed one hundred million dollars ($100,000,000), and the total milestone payments for each of the Second Program and each Subsequent Option Program shall not exceed seventy million dollars ($70,000,000).

(d) For the avoidance of doubt, with respect to each Zogenix Development Program, each milestone payment in the tables in Section 6.4.2 and Section 6.4.3 is due only once regardless of the number of Clinical Trials conducted under such Zogenix Development Program, the number of Licensed Products or Indications under a Zogenix Development Program, or the number of times that a particular Milestone Event is achieved.

6.4.2 Milestone Events for the Dravet Syndrome Program:

Milestone Event	Amount
[***]	[***]

Milestone Event	Amount
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
Total:	$100,000,000

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6.4.3 Milestone Events for Each of the Second Program and Each Subsequent Option Program(s):

Milestone Event	Amount
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
Total:	$70,000,000

Section 6.5 Royalty Payments for Licensed Products.

6.5.1 In General. In partial consideration for the rights and licenses granted to Zogenix hereunder Zogenix shall pay Tevard tiered royalties on Net Sales of Licensed Products at the royalty rates set forth in the table below, on a Licensed Product-by-Licensed Product basis. Payments due from Zogenix to Tevard under this Section 6.5.1 shall be paid within forty-five (45) days after the end of each Calendar Quarter.

Annual Net Sales of Licensed Products

Annual Net Sales of Licensed Products	Royalty Rate Applicable to Net Sales of Licensed Products other than Optioned Dravet Product	Royalty Rate Applicable to Net Sales of Optioned Dravet Product
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

6.5.2 In License Payments. The Party that is a party to each In-License shall, subject to Section 6.5.3(b), be responsible for making any payments due to the applicable Inbound Licensor arising under or in connection with such In-License, provided that, if Tevard is the party to such In-License and fails to make such payment, then, in addition to any other rights or remedies available to Zogenix at law or in equity, Zogenix shall have the right to make such payment on Tevard's behalf and shall have the right, at its sole election to either (i) seek reimbursement of such payment from Tevard, and/or (ii) deduct the amounts paid by Zogenix under such Tevard In-License from any royalty or milestone payments otherwise due to Tevard under this Agreement.

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6.5.3 Royalty Term and Adjustments.

(a) Royalty Term. Zogenix's royalty obligations to Tevard under this Section 6.5 shall commence on a country-by-country and Licensed Product-by-Licensed Product basis on the date of the First Commercial Sale by Zogenix, its Affiliates, Licensees, or Sublicensees of the relevant Licensed Product in the relevant country and shall expire on a country-by-country basis and Licensed Product-by-Licensed Product basis on the latest of the following, as applicable: (a) the expiration of Patent-Based Exclusivity with respect to such Licensed Product in such country, (b) the expiration of Regulatory-Based Exclusivity with respect to such Licensed Product in such country, and (c) the tenth (10th) anniversary of the First Commercial Sale of such Licensed Product in such country by Zogenix, its Affiliates, Licensees, or Sublicensees, provided that there is Patent-Based Exclusivity for the Licensed Product in at least one country in the Territory at the time of such First Commercial Sale (the "Royalty Term"). The foregoing provisions of this Section 6.5 notwithstanding, the royalties payable with respect to Net Sales of Licensed Products shall be reduced, on a Licensed Product-by-Licensed Product and country-by-country basis, [***] of the amounts otherwise payable pursuant to Section 6.5.1 (with respect to Licensed Products [***]. Notwithstanding anything to the contrary herein, in no event shall the aggregate royalty payment, as adjusted by this Section 6.5.3, due from Zogenix to Tevard with respect to the Development, Commercialization and Manufacture of a Licensed Product be less than the aggregate amount that Tevard is required to pay to the Inbound Licensors of the Tevard In-License with respect to such Licensed Product. If any amount that Zogenix is entitled to deduct from the royalty payments due to Tevard under Section 6.5.1 with respect to a Licensed Product is not fully offset against such royalty amounts as a result of the preceding sentence, such amount may be carried forward and applied to future periods until fully exhausted.

(b) Future In-Licenses.

(i) Notwithstanding anything to the contrary herein, Zogenix shall have the right, without seeking the consent of the JDC, to independently negotiate a license to any additional technology or intellectual property (including any Patents) if necessary or useful to Develop, Commercialize or Manufacture a Product without infringing such intellectual property, including as part of settlement of any claim, litigation or administrative proceedings ("Additional Third Party IP"). For clarity, Tevard shall not, without Zogenix's prior written consent, enter into any license agreement for Additional Third Party IP applicable to any Licensed Development Program or Covering any Licensed Product. With respect to any such license agreement that Tevard is interested in entering into, Tevard shall provide Zogenix with a reasonable opportunity to review and comment on the proposed terms of such license that would be applicable to Zogenix as a sublicensee thereunder, and shall incorporate and advocate for such terms in negotiating such license.

(ii) On a Licensed Product-by-Licensed Product basis, if Zogenix directly obtains a license or other agreement to any Additional Third Party IP that is necessary or useful to Develop, Commercialize or Manufacture a Product, such license shall automatically be deemed an "In-License" and Zogenix shall have the right to deduct [***] of the amounts paid by Zogenix under any In-License from any royalty payments due to Tevard under Section 6.5.1 with respect to the applicable Licensed Product, provided that, in no event shall such royalty payments due to Tevard under Section 6.5.1 be reduced to [***] of the full amount set forth in Section 6.5.2 as the result of any such deduction under this Section 6.5.3(b)(ii). If any amount that Zogenix is entitled to deduct from the royalty payments due to Tevard under Section 6.5.1 with respect to a Licensed Product is not fully offset against such royalty amounts as a result of the preceding sentence, such amount may be carried forward and applied to future periods until fully exhausted.

(iii) If during the Term, Tevard believes that a license to Additional Third Party IP is necessary or useful to Develop, Commercialize or Manufacture a Product, Tevard shall promptly provide Zogenix, via the JDC, a written description of such Additional Third Party IP together with the proposed licensing terms

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therefor. If the Parties are in agreement that such Additional Third Party IP should be licensed, then the Parties shall discuss which Party shall lead such negotiations and thereafter, the designated Party shall use good faith efforts to license such Additional Third Party IP. The negotiating Party shall provide the other Party with a reasonable opportunity to review and comment on the proposed terms of such license that would be applicable to such other Party as a sublicensee thereunder, and shall reasonably consider and advocate for such comments when negotiating the terms of such license.

(iv) If Tevard obtains a license or other agreement to Additional Third Party IP pursuant to Section 6.5.3(b)(iii), Tevard shall promptly provide to Zogenix a written description of such Additional Third Party IP, together with a true and correct copy of such license or other agreement. If Zogenix notifies Tevard in writing after receipt thereof that Zogenix elects to receive a sublicense of rights granted under such Third Party license agreement, then such Third Party license agreement shall be an "In-License" under this Agreement. Zogenix shall, in addition to the other payments made by Zogenix to Tevard pursuant to this Article 6, pay to Tevard [***] of the amounts payable by Tevard pursuant to such In-License with respect to the Development, Commercialization and Manufacture of Licensed Products hereunder, and the Parties shall coordinate such payments by Zogenix so that Tevard receives such payments prior to the dates on which Tevard is required to pay the applicable Inbound Licensor. Tevard shall use Commercially Reasonable Efforts to ensure that (A) the royalty payments applicable to the Licensed Products shall be no higher than those royalty payments applicable to any other products licensed thereunder (including any products of Tevard's other licensees) and (B) the rights and obligations applicable to the Licensed Products shall be no more restrictive than those rights and obligations applicable to other products licensed thereunder (including any products of Tevard's other licensees).

(c) Generic Product Competition. If, on a Licensed Product-by-Licensed Product, country-by-country and Calendar Quarter-by-Calendar Quarter basis, Generic Product Competition is present with respect to such Licensed Product in such country during such Calendar Quarter, then the royalties payable with respect to such Licensed Product pursuant to Section 6.5.1 in such country during such Calendar Quarter shall be reduced to [***] of the amounts otherwise payable pursuant to Section 6.5.1.

(d) Additional Royalty if Zogenix Challenges the University Patents. Should Zogenix bring an action seeking to invalidate any University Patent, Zogenix will pay an additional royalty to Tevard during the pendency of such action that is equal to the increased royalty that Tevard pays to CWRU under the CWRU License. These additional royalties shall not be refundable. Moreover, should the outcome of such action determine that any claim of a University Patent challenged by Zogenix is both valid and infringed by a Licensed Product, Zogenix will pay an additional royalty that is equal to the increased royalty that Tevard pays to CWRU under the CWRU License during the remainder of the royalty term under the CWRU License. During the pendency of any action seeking to invalidate any University Patent, Zogenix shall not pay the additional royalties into any escrow or other similar account but shall pay such additional royalty to Tevard. This Section 6.5.3(d) shall not apply to situations where (i) Zogenix is required to participate in such patent challenge pursuant to a subpoena or court order or participates in a proceeding that is initiated by a patent office and not at the instigation of Zogenix or its Affiliates, (ii) any assertion by Zogenix or its Affiliates relating to validity, patentability, scope, priority, construction, non-infringement, inventorship, ownership or enforceability as a defense in any legal proceeding, administrative proceeding or arbitration brought by CWRU, WIBR or their licensees (including Tevard) or assignees asserting infringement against Zogenix or its Affiliates or (iii) any dispute or challenge brought by a Third Party which subsequently becomes an Affiliate of Zogenix provided the Zogenix causes such Third Party to initiate rescission of such dispute or challenge within sixty (60) days after such Third Party becomes an Affiliate of the Zogenix . For clarity, this Section 6.5.3(d) shall not apply to arguments made by Zogenix that distinguish the inventions claimed in patent applications owned or controlled by Zogenix from those claimed in the University Patents (a) in the ordinary course of ex parte prosecution of Zogenix's patent applications or (b) in inter partes

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proceedings before the United States Patent and Trademark Office or in any other agency or tribunal or court in any jurisdiction. For purposes of this Section 6.5.3(d), the term "University Patents" means those Patents licensed by Tevard pursuant to that certain License Agreement between Tevard and Case Western Reserve University, dated March 6, 2020 (the "CWRU License") and those Patents licensed by Tevard pursuant to that certain License Agreement between Tevard and The Wistar Institute of Anatomy and Biology and the University of Iowa Research Foundation, dated September 22, 2020 (the "Wistar License").

Section 6.6 Royalty Payments for Tevard Products.

6.6.1 Returned Development Programs. With respect to any Licensed Development Program that (i) becomes a Tevard Program subsequent to the filing of an IND with respect to such Development Program, if Tevard elects to Develop or Commercialize the Tevard Product(s) from such Tevard Program, Tevard shall pay Zogenix a royalty, on a Tevard Product-by-Tevard Product basis, on Net Sales of such Tevard Products by Tevard, its Affiliates, Licensees, or Sublicensees at the rate of [***], subject to the limitation in Section 6.6.2, or (ii) becomes a Tevard Program prior to the filing of an IND with respect to such Development Program, if Tevard elects to Develop or Commercialize Tevard Products, Tevard shall pay Zogenix a royalty, on a Tevard Product-by-Tevard Product basis, on Net Sales of such Tevard Products by Tevard, its Affiliates, Licensees, or Sublicensees at the rate of [***], subject to the limitation in Section 6.6.2. Payments due from Tevard to Zogenix under this Section 6.6.1 shall be paid on a Calendar Quarter basis within forty-five (45) days after the end of such Calendar Quarter.

6.6.2 Royalty Term for Tevard Products. Tevard's royalty obligations to Zogenix under this Section 6.6 shall commence on a country-by-country and Tevard Product-by-Tevard Product basis on the date of First Commercial Sale by Tevard, its Affiliates, Licensees, or Sublicensees of the relevant Tevard Product in the relevant country and shall expire on a country-by-country and Tevard Product-by-Tevard Product basis on the latest of the following, as applicable: (a) the expiration of Patent-Based Exclusivity with respect to such Tevard Product in such country, (b) the expiration of Regulatory-Based Exclusivity with respect to such Tevard Product in such country, and (c) the tenth (10th) anniversary of the First Commercial Sale of such Tevard Product in such country by Tevard, its Affiliates, Licensees, or Sublicensees, provided that with respect to clause (c) there is Patent-Based Exclusivity for the Tevard Product in at least one country in the Territory at the time of such First Commercial Sale.

(a) Generic Product Competition. If, on a Tevard Product-by-Tevard Product, country-by-country and Calendar Quarter-by-Calendar Quarter basis, Generic Product Competition is present with respect to such Tevard Product in such country during such Calendar Quarter, then the royalties payable with respect to such Tevard Product pursuant to Section 6.6.1 in such country during such Calendar Quarter shall be reduced to [***] of the amounts otherwise payable pursuant to Section 6.6.1.

Section 6.7 Reports; Development and Sales Milestones; Royalty Payments. Until the expiration of a Party's royalty and other payment obligations under this Article 6, such Party agrees to make written unaudited reports to the other Party within sixty (60) days after the end of each Calendar Quarter covering sales of Licensed Products or Tevard Products (as the case may be) on a product-by-product, country-by-country basis in the Territory by such Party, its Affiliates, Licensees, and Sublicensees during such Calendar Quarter. Each such written report shall provide (a) the Net Sales in Dollars and local currency for each Licensed Product in the Territory during the reporting period; and (b) the royalties payable, in Dollars, which shall have accrued hereunder with respect to such Net Sales. The information contained in each report under this Section 6.7 shall be considered Confidential Information of the Party providing the report. Concurrent with the delivery of each such report, the Party delivering such report shall make the royalty payment due the other Party under Article 6 for the Calendar Quarter covered by such report. In the case of

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transfers or sales of any Licensed Product or Tevard Product (as applicable) between the royalty-paying Party and an Affiliate, Licensee or Sublicensee of such Party, a royalty shall be payable only with respect to the sale of such Licensed Product or Tevard Product to an independent Third Party that is not an Affiliate, Licensee or Sublicensee of the seller.

Section 6.8 Methods of Payments. All payments due from one Party (the "Payor") to the other Party (the "Payee") under this Agreement shall be paid in Dollars by wire transfer to a bank in the United States designated in writing by the Payee.

Section 6.9 Accounting.

6.9.1 Payor agrees to keep, and to require its Affiliates, Licensees, and Sublicensees to keep, full, clear and accurate records for a minimum period of three (3) years after the conclusion of the Calendar Year in which the relevant payment is owed pursuant to this Agreement, setting forth the sales and other disposition of Licensed Products and Tevard Products sold or otherwise disposed of in sufficient detail to enable royalties and compensation payable to the Payee hereunder to be determined.

6.9.2 Payor further agrees, upon not less than ninety (90) days prior written notice, to permit, and to require its Affiliates, Licensees, and Sublicensees to permit, the Books and Records relating to such Licensed Product and Tevard Product to be examined by an independent accounting firm selected by Payee and reasonably acceptable to Payor for the purpose of verifying reports provided by Payor under this Article 6. Such audit shall not be performed more frequently than once in any twelve (12)-month period or once with respect to any reporting period, and shall be conducted under appropriate confidentiality provisions, for the sole purpose of verifying the accuracy and completeness of all financial, accounting and numerical information and calculations provided under this Agreement. The independent accounting firm shall have reasonable access, on reasonable notice and during Payor's normal business hours to individuals, records and responses to questions from auditors in a timely manner and have the right to make copies of relevant portions of Payor's Books and Records; provided that, any such copies shall be the Confidential Information of Payor, shall be protected by appropriate confidentiality obligations and shall not be shared with Payee or any other Person.

6.9.3 Such examination is to be made at the expense of Payee, except if the results of the audit reveal an underpayment of royalties, milestones, or other payments to Payee under this Agreement of ten percent (10%) or more in any Calendar Year, in which case reasonable audit fees for such examination shall be paid by Payor.

Section 6.10 Currency. All amounts payable and calculations hereunder shall be in Dollars. When conversion of payments from any foreign currency is required to be undertaken by the Payor, the USD equivalent shall be calculated using Payor's then-current standard exchange rate methodology as applied in its external reporting.

Section 6.11 Taxes and Withholding. Each Party shall be responsible for its own taxes, duties, levies, imposts, assessments, deductions, fees, withholdings or similar charges imposed on or measured by net income or overall gross income (including branch profits), gross receipts, capital, ability or right to do business, property, and franchise or similar taxes pursuant to Applicable Law. If the Payor is required to deduct or withhold from any payment due hereunder any taxes, duties, levies, imposts, assessments, deductions, fees, and other similar charges by Applicable Law or any Governmental Authority ("Withholding Taxes"), then the Payor shall pay such Withholding Taxes to the applicable Governmental Authority and make the payment to the Payee of the net amount due after deduction or withholding of such taxes, and such Withholding Taxes shall be treated for all purposes of this Agreement as having been paid to the Payee hereunder. The Payor shall submit to the Payee proof of payment of any Withholding Taxes

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within a reasonable period of time after such Withholding Taxes are remitted to the Governmental Authority or, if sooner, within the period prescribed by Applicable Law. The Parties shall reasonably cooperate to eliminate or minimize any Withholding Taxes. To the extent commercially reasonable, the Payor shall provide to the Payee reasonable prior notice of its intention to withhold in order to allow the Payee reasonable opportunity to provide sufficient information or documentation to eliminate or minimize Withholding Taxes. The Payor shall timely provide reasonably sufficient documentation to enable the Payee to receive any credits available under applicable tax Laws. Payee shall indemnify and hold harmless Payor for any taxes, including Withholding Taxes, Payee owes to a Governmental Authority for which Payor is held responsible and for which prior withholding has not been made, and Payor shall hold Payee harmless for any fees, penalties and interest that are imposed on Payee arising out of Payor's failure to withhold and remit Withholding Taxes to Governmental Authorities in accordance with this Section 6.11 and Applicable Laws, unless such failure arises from the acts or omissions of Payee (for example, the provision of incorrect beneficial owner information or invalid forms).

Section 6.12 Value Added Tax. Notwithstanding anything contained in Section 6.11, this Section 6.12 shall apply with respect to any value added tax, ad valorem, goods and services or similar tax chargeable on the supply or deemed supply of goods or services, sales and use taxes, transaction taxes, consumption taxes and other similar taxes required by Applicable Law including any interest, penalties or other additions to tax thereon, required under Applicable Law ("VAT"). All payments required under this Agreement are inclusive of VAT. If any VAT is required in respect of any such payment under Applicable Law, the Payor shall pay VAT at the applicable rate in respect of such payment as follows: (a) where the liability to collect, account for, or remit such VAT is a liability of the Payee, following the receipt of a valid VAT invoice in the appropriate form issued by the Payee in respect of such payment, such VAT to be payable on the later of the due date of the payment to which such VAT relates and forty-five (45) days after the receipt by the Payor of the applicable valid invoice relating to that VAT payment (provided, however, that the Payee shall return such VAT within a reasonable period of time to the extent that Payee actually receives under Applicable Law a refund or recovery of such VAT) or (b) where the liability to collect, account for, or remit such VAT is a liability of the Payor, timely account and pay for all applicable VAT to the proper tax authority. If the liability to collect, account for, or remit such VAT is a liability of Payee, the Payor shall not be responsible for any penalties, interest, and other additions thereon resulting from the failure by the Payee to collect (if not included on a valid VAT invoice) or remit any such VAT.

Section 6.13 Late Payments. Any undisputed amount owed by Payor to Payee under this Agreement that is not paid on or before the date such payment is due shall bear interest at a rate per annum equal to the lesser of the prime or equivalent rate per annum quoted by The Wall Street Journal on the first Business Day after such payment is due, plus two percent (2%), or the highest rate permitted by Applicable Law, calculated on the number of days such payments are paid after such payments are due and compounded monthly. Interest shall not accrue on undisputed amounts that were paid after the due date as a result of mistaken Payee actions (e.g., if a payment is late as a result of Payee providing an incorrect account for receipt of payment). In addition, the Payor shall reimburse the Payee for all costs, including attorneys' fees and legal expenses, incurred in the collection of late payments; provided that, the foregoing shall not apply to payments disputed in good faith by the Payor unless the Payee is successful in such dispute or the Payor ceases to dispute such payments.

ARTICLE 7

EXCLUSIVITY

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Section 7.1 During the Research Term. Except pursuant to Tevard's Development responsibilities under this Agreement, during the Research Term, neither Tevard nor any of its Affiliates shall, except as otherwise permitted in Section 7.3, (a) either alone or with or for any Third Party, Develop, Manufacture or Commercialize any Corrective Therapeutic Agent for the diagnosis, amelioration, mitigation, prevention, treatment and/or cure of Epilepsy, or (b) grant a license or sublicense to Develop, Manufacture or Commercialize any Corrective Therapeutic Agent for the diagnosis, amelioration, mitigation, prevention, treatment and/or cure of Epilepsy.

Section 7.2 During the Term. Except pursuant to Tevard's Development responsibilities under or otherwise pursuant to this Agreement, during the Term, neither Tevard nor any of its respective Affiliates shall, except as otherwise permitted in Section 7.3.1, (a) either alone or with or for any Third Party, Develop, Manufacture or Commercialize any Corrective Therapeutic Agent

(i) directed to Dravet Syndrome,

(ii) directed to any Indication to which any Licensed Product or Licensed Development Program is directed,

(iii) that is the same Corrective Therapeutic Agent contained in a Licensed Product,

(iv) that is directed to at least the same combination of Target(s) being developed or evaluated under a Development Program that becomes or may become a Licensed Development Program, or for which a Licensed Product is being Developed or Commercialized or a Licensed Program is directed, and/or

(v) that is a Protected Therapeutic Agent; or

(b) grant a license or sublicense or otherwise permit any Third Party to Develop, Manufacture or Commercialize any Corrective Therapeutic Agent as described in any of the foregoing (i) - (iv).

Section 7.3 Exceptions.

7.3.1 Subject to Section 2.4, the restrictions set forth in Section 7.1 and Section 7.2 shall not restrict either Party or its Affiliates from using Third Party contractors to perform Development, Manufacturing or Commercialization activities that such Party is permitted to perform directly under this Agreement.

7.3.2 The restrictions in Section 7.1 shall not prevent Tevard from Developing, Manufacturing or Commercializing any Corrective Therapeutic Agent inside the Field that is a Tevard Product, provided that such Developing, Manufacturing or Commercializing is not otherwise prohibited by Section 7.2.

Section 7.4 Protected Therapeutic Agents. On a [***] basis, Zogenix shall be permitted to nominate for discussion and mutual agreement by the JDC [***], certain Corrective Therapeutic Agents that, notwithstanding anything to the contrary herein, neither Tevard nor any of its respective Affiliates shall (a) [***] or (b) [***] (each a "Protected Therapeutic Agent"). For clarity, the restrictions in Section 7.2(v) and this Section 7.4 are in addition to the restrictions in Section 7.1 and Section 7.2(i) through (iv).

7.4.1 For each Licensed Development Program, Zogenix shall be permitted through the JDC to nominate for discussion and mutual agreement by the JDC up to [***] Protected Therapeutic Agents at any time for a period lasting until the occurrence of Product Transfer for such Licensed Development Program (each a "First Restricted List"). In addition, any time prior to Product Transfer for a Licensed Development Program Zogenix shall have the right through the JDC to nominate for discussion and mutual agreement by the JDC, the addition to such First Restricted List of one or more Corrective Therapeutic Agents or replacement of one or more Protected Therapeutic Agents on such First Restricted List with any other Corrective Therapeutic Agent, provided that (a) the number of Protected Therapeutic Agents for a particular

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Licensed Development Program does not [***] and (b) that such nominated Corrective Therapeutic Agent is not already being actively Developed by Tevard outside of the Field, or subject to a written, final term sheet or other written, final agreement between Tevard and a Third Party pertaining to the Development of such Corrective Therapeutic Agent outside of the Field; in each case as demonstrated by written documentation (which upon request by Zogenix shall be confidentially disclosed by Tevard to Zogenix in a manner that protects Tevard's sensitive business information).

7.4.2 Following the occurrence of Product Transfer for a Licensed Development Program, and for a period lasting until the Initiation of the first Pivotal Registration Trial for a Licensed Product from such Licensed Development Program, Zogenix shall be permitted through the JDC to nominate for discussion and mutual agreement by the JDC up to [***] Protected Therapeutic Agents from the First Restricted List for inclusion in a subsequent restricted list (each a "Second Restricted List") for such Licensed Development Program. In addition, at any time prior to Initiation of the first Pivotal Registration Trial for a Licensed Product from such Licensed Development Program, Zogenix shall have the right through the JDC to nominate for discussion and mutual agreement by the JDC the addition to such Second Restricted List of one or more Corrective Therapeutic Agents or replacement of one or more Protected Therapeutic Agents on such Second Restricted List with any other Corrective Therapeutic Agent, provided that (a) the number of Protected Therapeutic Agents for a particular Licensed Development Program does not [***] and (b) that such nominated Corrective Therapeutic Agent is not already being actively Developed by Tevard outside of the Field, or subject to a written, final term sheet or other written, final agreement between Tevard and a Third Party pertaining to the Development of such Corrective Therapeutic Agent outside of the Field; in each case as demonstrated by written documentation (which upon request by Zogenix shall be confidentially disclosed by Tevard to Zogenix in a manner that protects Tevard's sensitive business information). In addition, at Zogenix's request, the Parties shall discuss in good faith the addition of further Corrective Therapeutic Agents to the Second Restricted List for a particular Licensed Development Program, thus increasing the number of Protected Therapeutic Agents for such Licensed Development Program above [***], but in no event more than [***].

7.4.3 Following the Initiation of the first Pivotal Registration Trial for a Licensed Product from a Licensed Development Program, and for a period lasting [***], Zogenix shall be permitted through the JDC to nominate for discussion and mutual agreement by the JDC, up to [***] Protected Therapeutic Agents from the Second Restricted List for inclusion in a subsequent restricted list (each a "Third Restricted List") for such Licensed Development Program. In addition, at any time during the [***] period [***], Zogenix shall have the right through the JDC to nominate for discussion and mutual agreement by the JDC, the addition to such Third Restricted List of one or more Corrective Therapeutic Agents or replacement of one or more Protected Therapeutic Agents on such Third Restricted List with any other Corrective Therapeutic Agent, provided that (a) the number of Protected Therapeutic Agents for a particular Licensed Development Program [***] and (b) that such nominated Corrective Therapeutic Agent is not already being actively Developed by Tevard outside of the Field, or subject to a written, final term sheet or other written, final agreement between Tevard and a Third Party pertaining to the Development of such Corrective Therapeutic Agent outside of the Field; in each case as demonstrated by written documentation (which upon request by Zogenix shall be confidentially disclosed by Tevard to Zogenix in a manner that protects Tevard's sensitive business information). In addition, at Zogenix's request, the Parties shall discuss in good faith the addition of a further Corrective Therapeutic Agent to the Third Restricted List for a particular Licensed Development Program, thus increasing the number of Protected Therapeutic Agents for such Licensed Development Program above [***], but in no event more than [***].

7.4.4 Prior to the expiration of the period lasting until [***], Zogenix shall be permitted through the JDC to nominate for discussion and mutual agreement by the JDC, [***] from the Third Restricted List for inclusion in a subsequent restricted list (each a "Fourth Restricted List") for such Licensed Development

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Program, which restricted list shall last for the Term of such Licensed Development Program. For clarity, the Corrective Therapeutic Agents restricted under this Section 7.4.3 shall be in addition to those Corrective Therapeutic Agents restricted under Section 7.2(i) through (iv).

7.4.5 For clarity, each subsequent restricted list renders null and void any preceding restricted lists, and Tevard will not be prevented from Developing, Manufacturing or Commercializing, in accordance with any and all other restrictions under this Agreement, any Corrective Therapeutic Agent that was included in a prior restricted list but not included in a subsequent restricted list. Nothing in this Section 7.4 shall prevent Zogenix from nominating the same Corrective Therapeutic Agent for inclusion in a restricted list for more than one Licensed Development Program.

Section 7.5 Clarification. For clarity, this Article 7 shall not prevent Tevard from Developing, Manufacturing or Commercializing any vector (e.g., the AAV9 vector) for any other purpose solely due to Tevard's use of such vector in a Licensed Product or Licensed Development Program.

As used in this Article 7, "Corrective Therapeutic Agents" means [***].

As used in this Article 7, a Corrective Therapeutic Agent shall be deemed the "same" as a reference Corrective Therapeutic Agent if the first Corrective Therapeutic Agent has [***].

[***].

As used in this Article 7, the term "tRNA anticodon sequence" means the three bases of the tRNA molecule that pair with the mRNA codon.

ARTICLE 8

OWNERSHIP OF INTELLECTUAL PROPERTY RIGHTS

Section 8.1 Ownership of Inventions; Disclosure.

8.1.1 Ownership. Title to all Inventions and other intellectual property made solely by employees or agents of Tevard in the course of activities conducted pursuant to any Development Program shall be owned by Tevard; title to all Inventions and other intellectual property made solely by employees or agents of Zogenix in the course of activities conducted pursuant to any Development Program shall be owned by Zogenix; title to all Inventions and other intellectual property made jointly by employees or agents of Zogenix and Tevard in the course of activities conducted pursuant to any Development Program shall be owned jointly by Zogenix and Tevard. Inventorship of Inventions and other intellectual property made pursuant to this Agreement shall be determined in accordance with the patent laws and other applicable laws (including without limitation U.S. federal and state trade secret laws) of the United States. Except as expressly provided in this Agreement, neither Party shall have any obligation to account to the other for profits, or to obtain any approval of the other Party to license or exploit jointly-owned subject matter, by reason of joint ownership thereof, and each Party hereby waives any right it may have under the laws of any jurisdiction to require any such consent or accounting. For the avoidance of doubt, any jointly-owned Inventions and other intellectual property shall be deemed to be covered by the license granted under Section 4.2.1 and subject to the terms of this Agreement, including Article 7.

8.1.2 Disclosure of Inventions. Subject to Article 9 Tevard shall promptly disclose to Zogenix any Inventions made in connection with any Development Program, including any Licensed Development Program.

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8.1.3 Background IP. Each Party shall retain ownership of intellectual property rights existing as of the Effective Date, or developed or acquired independently of any Development Program, and nothing in this Agreement shall assign any ownership to the other Party with respect to such intellectual property rights.

Section 8.2 Patent Prosecution.

8.2.1 Tevard Patents.

(a) As between the Parties, Tevard shall be responsible, at its expense, and shall have the exclusive right for preparing, filing, Prosecuting and Maintaining the Tevard Patents and for defending against any opposition, reexamination, nullity action, interference, or other administrative or judicial challenges to the validity, title or enforceability thereof (each, a "Defense Proceeding") relating thereto (except that in connection with any counterclaims brought in actions subject to Section 8.3.2(a), the Party with responsibility for such action pursuant to Section 8.3.2(a) shall have responsibility for such Defense Proceedings). Without limiting the foregoing, Tevard shall, to the extent practicable, Prosecute and Maintain the Tevard Patents and conduct the actions in the immediately preceding sentence throughout the Territory, including all countries in which Licensed Products will be Manufactured or Commercialized. Tevard shall keep Zogenix fully informed with respect to (a) the filing of all Patent applications that arise from Section 8.2.1(a); (b) the issuance of Patents filed by Tevard pursuant to this Section 8.2.1(a); and (c) the abandonment or disclaimer of any Patent or Patent application maintained by Tevard pursuant to this Section 8.2.1. Without limiting the foregoing, Tevard shall (i) provide Zogenix with copies of the text of the applications for Tevard Patents specifically relating to or arising from the Development Programs to which Zogenix retains Option rights or in Licensed Development Programs as soon as practicable but at least ten (10) days before filing, except for urgent filings in which case Tevard shall provide copies as soon as practicable before, simultaneously with or immediately after filing; (ii) provide Zogenix with a copy of each submission made to and material document received from a patent authority, court or other tribunal regarding such Tevard Patents reasonably promptly after making such filing or receiving such material document, including a copy of each application as filed together with notice of its filing date and application number; (iii) keep Zogenix advised of the status of all material communications, actual and prospective filings or submissions regarding such Tevard Patents, and shall give Zogenix copies of any such material communications, filings and submissions proposed to be sent to any patent authority or judicial body; and (iv) consider in good faith and reasonably incorporate Zogenix's comments on the material communications, filings and submissions for such Tevard Patents.

(b) Tevard shall notify Zogenix as to any decision to abandon, to cease Prosecution and Maintenance of, or to discontinue paying the expenses of Prosecution and Maintenance of, any such Tevard Patent or related Patent application in any country in which it was filed. Tevard will provide such notices at least thirty (30) days prior to any filing or payment due date, or any other due date that requires action, in connection with such Tevard Patent. Thereafter, Tevard shall, within 30 days or before a statutory dues date for responding to a patent authority or judicial body or due date for a paying a maintenance fee, whichever is sooner, assign to Zogenix such Tevard Patents or Tevard Patent applications for which Section 8.2.1(b) is applicable.

8.2.2 Zogenix Patents. Zogenix shall be responsible, at its expense, and shall have the exclusive right, but not the obligation, for preparing, filing, Prosecuting and Maintaining the Zogenix Patents and for conducting Defense Proceedings relating thereto.

8.2.3 Joint Patents.

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(a) Zogenix shall be responsible for preparing, filing, Prosecuting and Maintaining Joint Patents arising in Development Programs to which Zogenix retains Option rights or in Licensed Development Programs (the "Zogenix-Prosecuted Joint Patents") and for defending any administrative or judicial challenges to invalidity, title, or enforceability relating thereto. The Parties shall equally share all costs related to the Zogenix-Prosecuted Joint Patents. Zogenix shall keep Tevard fully informed with respect to (a) the filing of all Zogenix-Prosecuted Joint Patent applications; (b) the issuance of any Zogenix-Prosecuted Joint Patent and (b) the abandonment of any Zogenix-Prosecuted Joint Patent. Without limiting the foregoing, Zogenix shall (i) provide Tevard with copies of the text of the applications for such Zogenix-Prosecuted Joint Patents as soon as practical but at least ten (10) days before filing, except for urgent filings in which case Zogenix shall provide copies as soon as practical before, simultaneously with or immediately after filing; (ii) provide Tevard with a copy of each submission made to and material document received from a patent authority, court or other tribunal regarding any such Zogenix-Prosecuted Joint Patents reasonably promptly after making such filing or receiving such material document, including a copy of each application as filed together with notice of its filing date and application number; (iii) keep Tevard advised of the status of all material communications, actual and prospective filings or submissions regarding such Zogenix-Prosecuted Joint Patents, and shall give Tevard copies of any such material communications, filings and submissions proposed to be sent to any patent authority or judicial body; and (iv) consider in good faith Tevard's comments on the material communications, filings and submissions for such Zogenix-Prosecuted Joint Patents.

(b) Zogenix shall notify Tevard as to any decision to abandon, to cease Prosecution and Maintenance of, or not to continue to pay the expenses of Prosecution and Maintenance of, any Zogenix-Prosecuted Joint Patent in any country in which it was filed. Zogenix will provide such notices at least thirty (30) days prior to any filing or payment due date, or any other due date that requires action, in connection with such Zogenix-Prosecuted Joint Patent. Thereafter, Tevard may, upon written notice to Zogenix, in both Parties' names and at Tevard's sole cost, control the filing for, Prosecution and Maintenance of such Zogenix-Prosecuted Joint Patents thereafter. Tevard will keep Zogenix reasonably informed of the status of the Zogenix-Prosecuted Joint Patents.

(c) Tevard shall be responsible for preparing, filing, prosecuting and maintaining Joint Patents other than the Joint Patents for which Zogenix has such responsibility pursuant to Section 8.2.3(a) (the "Tevard-Prosecuted Joint Patents") and for conducting any Defense Proceedings relating thereto. For clarity, the Tevard-Prosecuted Joint Patents shall include any former Zogenix-Prosecuted Joint Patents for which Zogenix has terminated responsibility pursuant to Section 8.2.3(b) and Tevard has provided notice pursuant to Section 8.2.3(b). The Parties shall equally share all costs related to the Tevard-Prosecuted Joint Patents. Tevard shall keep Zogenix fully informed with respect to (a) the filing of any Tevard-Prosecuted Joint Patent applications; (b) the issuance of Tevard-Prosecuted Joint Patents and (b) the abandonment of any Tevard-Prosecuted Joint Patent. Without limiting the foregoing, Tevard shall (i) provide Zogenix with copies of the text of the applications for such Tevard-Prosecuted Joint Patents as soon as practical but at least ten (10) days before filing, except for urgent filings in which case Tevard shall provide copies as soon as practical before, simultaneously with or immediately after filing; (ii) provide Zogenix with a copy of each submission made to and material document received from a patent authority, court or other tribunal regarding any such Tevard-Prosecuted Joint Patents reasonably promptly after making such filing or receiving such material document, including a copy of each application as filed together with notice of its filing date and application number; (iii) keep Zogenix advised of the status of all material communications, actual and prospective filings or submissions regarding such Tevard-Prosecuted Joint Patents, and shall give Zogenix copies of any such material communications, filings and submissions proposed to be sent to any patent authority or judicial body; and (iv) consider in good faith Zogenix's comments on the material communications, filings and submissions for such Tevard-Prosecuted Joint Patents.

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(d) Tevard shall notify Zogenix as to any decision to abandon, to cease Prosecution and Maintenance of, or not to continue to pay the expenses of Prosecution and Maintenance of, any Tevard-Prosecuted Joint Patent in any country in which it was filed. Tevard will provide such notices at least thirty (30) days prior to any filing or payment due date, or any other due date that requires action, in connection with such Tevard-Prosecuted Joint Patents. Thereafter, Tevard shall, within 30 days or before a statutory dues date for responding to a patent authority or judicial body or due date for a paying a maintenance fee, whichever is sooner, assign to Zogenix such Tevard-Prosecuted Joint Patents or Tevard-Prosecuted Joint Patent applications for which Section 8.2.1(d) is applicable.

8.2.4 Cooperation. Each Party shall reasonably cooperate with and assist the other Party in connection with the activities of such Party under this Section 8.2 upon the reasonable request of the other Party, including by making researchers and research records reasonably available and the execution of all such documents and instruments and the performance of such acts as may be reasonably necessary in order to permit the other Party to continue any filing, prosecution, maintenance or extension of such patents and patent applications, as well as any defense of any challenges to the validity, ownership, and enforceability of such patents and patent applications.

8.2.5 Patent Term Extension. Zogenix shall have the sole right to make decisions regarding, and to apply for, patent term extensions in the Territory, including in the United States with respect to extensions pursuant to 35 U.S.C. § 156 et. seq. and in other jurisdictions pursuant to supplementary protection certificates, and in all jurisdictions with respect to any other extensions that are now or become available in the future, wherever applicable, for all Zogenix Patents, Tevard Patents and Joint Patents with respect to Licensed Products, in each case including whether or not to so apply; provided, that for the Tevard Patents and the Joint Patents, Zogenix shall notify Tevard of Zogenix's interest in obtaining extensions and consult with Tevard to determine the course of action with respect to such filings. Tevard shall provide prompt and reasonable assistance, as requested by Zogenix, including by taking such action as is required under any Applicable Law to obtain such extension or supplementary protection certificate. To the extent that Tevard has the right to make decisions regarding and applying for patent term extensions under an applicable In-License, Tevard shall exercise its rights to extend such Patents as directed by Zogenix. To the extent that Tevard does not have such right under an applicable In-License but can or is otherwise not prohibited from requesting patent term extensions under such In-License, Tevard shall request such patent term extension under such In-License and if the Inbound Licensor under such In-License consents, then Tevard shall exercise its rights to extend such Patents as directed by Zogenix.

Section 8.3 Enforcement and Defense.

8.3.1 Notice. Each Party shall promptly notify the other of any knowledge it acquires of any actual or suspected infringement or misappropriation of the Zogenix IP, Tevard IP, or Joint IP with respect to any Competitive Product, in each case by a Third Party.

8.3.2 Actions.

(a) If any Tevard IP or Joint IP relating to a Licensed Product or Licensed Development Program is infringed or misappropriated by a Third Party that is developing, manufacturing or commercializing a Competitive Product in any country in the Territory, then Zogenix shall have the first right, but not the obligation, to institute, prosecute, and control any action or proceeding with respect to such infringement or misappropriation, by counsel of its own choice. If in any such proceeding brought by Zogenix, Tevard (or an Inbound Licensor) is required to join for standing purposes or in order for Zogenix to commence or continue any such proceeding, then Tevard (or an Inbound Licensor) shall join such proceeding, at Zogenix's expense, and shall be represented in such proceeding by counsel of Tevard's (or an Inbound Licensor's) choice. The exercise by Zogenix of the right to bring an action shall be subject to and consistent

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with the terms of all applicable In-Licenses; provided that, if, under the terms of an applicable In-License, Tevard has an applicable enforcement right that it cannot delegate to Zogenix then, at Zogenix's request and expense, Tevard shall exercise such rights in such enforcement action as directed by Zogenix. If Zogenix does not take action in the prosecution, prevention, or termination of any infringement or misappropriation pursuant to this Section 8.3.2(a), and has not commenced negotiations with the suspected malfeasor for the discontinuance of said malfeasance, then, within ninety (90) days after receipt of notice of the existence of an infringement or misappropriation (or in cases where there is a relevant statutory period during which an enforcement action must be commenced that would expire prior to the expiration of such ninety (90) day period and of which Tevard has notified Zogenix promptly after it becomes aware, then no less than fifteen (15) days prior to the expiration of such relevant statutory period), Tevard and Zogenix shall meet and discuss Zogenix's reasons for not initiating a lawsuit or otherwise making or prosecuting a claim. If thereafter, Tevard (or an Inbound Licensor) desires to initiate a lawsuit or otherwise make or prosecute a claim regarding a Tevard Patent with respect to the Competitive Product, Tevard shall so notify Zogenix and Tevard (or an Inbound Licensor) may, so long as Zogenix has not objected in writing within ten (10) Business Days of receipt of Tevard's notification, institute, prosecute, and control such action; provided that Tevard (or an Inbound Licensor) shall not enter into any settlement, consent judgment or other final disposition of such action in any manner that diminishes the rights or interests of Zogenix, including, without limitation, (i) restricting the scope, or adversely affecting the enforceability of Zogenix's intellectual property rights, including any rights granted to Zogenix under this Agreement (ii) requiring Zogenix to make a payment, (iii) requiring Zogenix to make an admission of legal wrongdoing in any way, and (iv) effecting an amendment of this Agreement, without the prior written consent of Zogenix. If in any such proceeding Zogenix is required to join for standing purposes or in order for Tevard (or an Inbound Licensor) to commence or continue any such proceeding, then Zogenix shall join such proceeding, at Tevard's (or Inbound Licensor's, as applicable) request and expense, and shall be represented in such proceeding by counsel of Zogenix's choice.

(b) Any and all expenses, including reasonable attorneys' fees, incurred by each Party (or an Inbound Licensor, as applicable) with respect to the prosecution, adjudication and/or settlement of a lawsuit or enforcement action in accordance with this section, including any related appeals, shall be paid entirely by the Party (or an Inbound Licensor, as applicable) that incurred the expenses.

(c) The party initiating the suit shall have the sole and exclusive right to elect counsel for any suit initiated by it pursuant to Section 8.3.2(a); provided that such counsel is reasonably acceptable to the other Party. The other Party (and/or an Inbound Licensor) shall have the right to participate in and be represented by counsel of its own selection and at its own expense in any suit instituted under Section 8.3.2(a) by the other Party for infringement or misappropriation.

(d) Each Party agrees to cooperate fully in any action under this Section 8.3.2 that is controlled by the other Party, including executing legal papers and cooperating in the prosecution as may be reasonably requested by the Controlling Party.

(e) If any Joint IP or Tevard IP relating to a Tevard Product is infringed or misappropriated by a Third Party in any country in the Territory, then Tevard shall have the sole right, but not the obligation, to institute, prosecute, and control any action or proceeding with respect to such malfeasance, by counsel of its own choice. If in any such proceeding Zogenix is required to join for standing purposes or in order for Tevard to commence or continue any such proceeding, then Zogenix shall join such proceeding, at Tevard's expense, and shall be represented in such proceeding by counsel of Zogenix's choice.

(f) Unless otherwise agreed by the Parties in writing, the amount of any recovery from a proceeding brought under Section 8.3.2 shall first be applied to the Out-of-Pocket costs of such action by the Party prosecuting the applicable action, and (A) if the prosecuting Party is the Party (together with its

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Affiliates, Licensees, and Sublicensees) Commercializing the applicable Licensed Product or Tevard Product affected by the infringing Competitive Product, any remaining recovery amount shall be treated as Net Sales hereunder and the prosecuting Party shall pay royalties thereon in accordance with Section 6.5.1 or Section 6.6, as applicable, or (B) otherwise, any remaining recovery amount shall be allocated first, such percentage owed to the Inbound Licensor pursuant to the applicable Tevard In-License, and then, of the remaining amount, [***]. If in connection with a proceeding brought under Section 8.3.2, an In-License counterparty is entitled to a portion of any recovery that is greater than the portion of the recovery payable, after costs, to Tevard, the Parties will meet and agree in good faith on an alternative sharing of such recovery to that set forth in the immediately preceding sentence that takes into account the amounts payable to the applicable In-License counterparties and results in an equitable allocation of the amounts remaining to Zogenix and Tevard after payment of such amounts to the applicable In-License counterparties.

(g) For avoidance of doubt, in the event that the European Unified Patent Court ("UPC") comes into existence, the decision on whether to opt-in or opt-out of the UPC for any Tevard Patents, Zogenix Patents or Joint Patents shall be made by Zogenix in Zogenix's sole discretion; provided that, as to Tevard Patents or Joint Patents specifically relating to a Tevard Product, Tevard shall make such decision from and after the time the applicable product becomes a Tevard Product.

8.3.3 Biosimilar Applications. Notwithstanding the provisions of Section 8.3.2, if either Party receives a copy of a Biosimilar Application referencing a Licensed Product, whether or not such notice or copy is provided under any Applicable Laws (including under the BPCIA, the United States Patient Protection and Affordable Care Act, or its successor provisions), or otherwise becomes aware that such a Biosimilar Application has been submitted to a Regulatory Authority for marketing authorization (such as in an instance described in 42 U.S.C. §262(l)(2)), the remainder of this Section 8.3.3 shall apply. Such Party will promptly, but in any event within ten (10) Business Days, notify the other Party. The owner of the relevant Patents will then seek permission to view the Biosimilar Application, information regarding the process or processes used to manufacture the product that is the subject of the Biosimilar Application, and related confidential information from the filer of the Biosimilar Application if necessary under 42 U.S.C. §262(l)(1)(B)(iii). If either Party receives any equivalent or similar communication or notice in the United States or any other jurisdiction, the Party receiving such communication or notice will within five (5) business days notify the other Party of such communication or notice to the extent permitted by Applicable Laws. Regardless of the Party that is the "reference product sponsor," as defined in 42 U.S.C. §262(l)(1)(A), for purposes of such Biosimilar Application:

(a) Zogenix will designate, to the extent permitted by Applicable Law, or otherwise Tevard will designate in accordance with Zogenix's instructions, the outside counsel and in-house counsel who will receive confidential access to the Biosimilar Application, information regarding the process or processes used to manufacture the product that is the subject of the Biosimilar Application, and any related confidential information pursuant to 42 U.S.C. §262(l)(1)(B)(ii).

(b) In each case, after consulting with Tevard and considering Tevard's comments in good faith, Zogenix shall have the right to (a) list any patents, including those Patents within the Tevard Patents, as required pursuant to 42 U.S.C. §262(l)(3)(A) or 42 U.S.C. §262(l)(7), (b) respond to any communications with respect to such lists from the filer of the Biosimilar Application, (c) negotiate with the filer of the Biosimilar Application as to whether to utilize a different mechanism for information exchange other than that specified in 42 U.S.C. §262(l)(1), and (d) as to the Patents that will be subject to the litigation procedure as described in 42 U.S.C. §262(l)(4), decide which Patent or Patents will be selected for litigation under 42 U.S.C. §262(l)(5)(B)(i)(II), and commence such litigation under 42 U.S.C. §262(l)(6). If Tevard is required pursuant to Applicable Law to execute any of these tasks it will do so in accordance with Zogenix's instructions.

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(c) Tevard shall cooperate with Zogenix's reasonable requests in connection with the foregoing activities to the extent required or permitted by Applicable Laws. Zogenix shall consult with Tevard prior to identifying any Patents within the Tevard Patents to a Third Party as contemplated by this Section 8.3.3. Zogenix shall consider in good faith advice and suggestions with respect thereto received from Tevard, and notify Tevard of any such lists or communications promptly after they are made

(d) Each Party will within five (5) Business Days after receiving any notice of commercial marketing provided by the filer of a Biosimilar Application pursuant to 42 U.S.C. §262(l)(8)(A), notify the other Party. To the extent permitted by Applicable Law, Zogenix will have the first right, but not the obligation, to seek an injunction against such commercial marketing as permitted pursuant to 42 U.S.C. §262(l)(8)(B) and to file an action for infringement. If required pursuant to Applicable Law, upon Zogenix's request, Tevard will assist in seeking such injunction or filing such infringement action after consulting with Zogenix. Except as otherwise provided in this Section 8.3.3, any action contemplated by this section will be subject to the other terms and conditions of Section 8.3.2.

8.3.4 Defense. With respect to any defense or declaratory judgment actions relating to a Tevard Patent, a Zogenix Patent or a Joint Patent, including any Defense Proceeding, the Party with responsibility for the prosecution of such Patent shall have the first right, but not the obligation, to assume the defense thereof at its sole cost and expense. With respect to any Defense Proceeding relating to a Joint Patent, if the Party with responsibility for the prosecution of the Joint Patent declines to assume the defense of such Patent, then the other Party shall have the right, but not the obligation, to assume the defense thereof at its sole cost and expense. For the avoidance of doubt, with respect to any Defense Proceeding relating to Tevard Patents, Tevard shall have the sole right, but not the obligation to assume the defense thereof at its sole cost and expense; provided, that Zogenix has the right, at its sole cost and expense, to join any such defense with counsel of its choice. With respect to any Defense Proceeding relating to Zogenix Patents, Zogenix shall have the sole right, but not the obligation to assume the defense thereof at its sole cost and expense. Each Party agrees to render such reasonable assistance as the defending Party may request, at the defending Party's expense, with respect to actions brought pursuant to this Section 8.3.4.

Section 8.4 Infringement Claimed by Third Parties.

8.4.1 In the event a Third Party commences, or threatens to commence, any proceeding against a Party to this Agreement alleging infringement of a Third Party's intellectual property by the Development, Manufacture, Commercialization, use, sale, offer for sale, export and/or import by Zogenix, its Affiliates, Licensees, or Sublicensees of any Licensed Product, the Party against whom such proceeding is threatened or commenced shall give prompt notice to the other Party.

8.4.2 Unless the Party against whom such proceeding is filed seeks indemnification for a claim covered pursuant to Article 11, such Party shall control the defense and settlement of any such proceeding under this Section 8.4.2 at its own cost.

ARTICLE 9

CONFIDENTIALITY

Section 9.1 Confidentiality; Exceptions. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing, the Parties agree that the receiving Party (the "Receiving Party") shall keep confidential and shall not publish or otherwise disclose or use for any purpose other than as provided for in this Agreement any Know-How or other confidential and proprietary information and materials, patentable or otherwise, in any form (written, oral, photographic, electronic, magnetic, or

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otherwise) which is disclosed to it by the other Party (the "Disclosing Party") or otherwise received or accessed by a Receiving Party in the course of performing its obligations or exercising its rights under this Agreement, including trade secrets, Know-How, inventions or discoveries, proprietary information, formulae, processes, techniques and information relating to a Party's past, present and future marketing, financial, and Development activities of any product or potential product or useful technology of the Disclosing Party and the pricing thereof (collectively, "Confidential Information"), except to the extent that it can be established by the Receiving Party that such Confidential Information:

9.1.1 was in the lawful knowledge and possession of the Receiving Party prior to the time it was disclosed to, or learned by, the Receiving Party, or was otherwise developed independently by the Receiving Party, as evidenced by written records kept in the ordinary course of business, or other documentary proof of actual use by the Receiving Party;

9.1.2 was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party;

9.1.3 became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the Receiving Party in breach of this Agreement; or

9.1.4 was disclosed to the Receiving Party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the Disclosing Party not to disclose such information to others.

For the avoidance of doubt, any information disclosed by Tevard to Zogenix on or prior to the Effective Date pursuant to any non-disclosure agreements by and between Tevard and Zogenix, including that certain Option Agreement For Exclusive License, dated October 14, 2019, (the "Existing Confidentiality Agreements") shall be Confidential Information of Tevard and Tevard Know-How for all purposes under this Agreement, provided that all Joint Know-How and all Tevard Know-How and Confidential Information related to any Licensed Development Program, irrespective of which Party is the Disclosing Party, shall be deemed the Confidential Information of Zogenix.

Section 9.2 Authorized Disclosure. Except as expressly provided otherwise in this Agreement, a Receiving Party may use and disclose Confidential Information of the Disclosing Party as follows: (a) under appropriate confidentiality provisions similar to those in this Agreement, in connection with the performance of its obligations or exercise of rights granted or reserved in this Agreement (including the rights to Develop and Commercialize Licensed Products and to grant licenses and sublicenses hereunder); or (b) to the extent such disclosure is reasonably necessary in filing or prosecuting patent, copyright and trademark applications, prosecuting or defending litigation, complying with applicable governmental regulations, seeking and obtaining Regulatory Approval, conducting non-clinical activities or clinical trials, preparing and submitting INDs or other filings to Regulatory Authorities, responding to inquiries from a Governmental Authority, or is otherwise required by Law, the rules of a recognized stock exchange or automated quotation system applicable to such Party; provided, however, that if a Receiving Party desires to respond to an inquiry from a Governmental Authority or is required by Law to make any such disclosure of a Disclosing Party's Confidential Information it will, except where impracticable, give reasonable advance notice to the Disclosing Party of such disclosure requirement and, if requested by the Disclosing Party, cooperate with the Disclosing Party to secure confidential treatment of such Confidential Information required to be disclosed; or (c) in communication with existing or prospective investors, consultants, advisors, licensors, licensees, or collaborators or others on a need to know basis, in each case under appropriate confidentiality provisions substantially equivalent to those of this Agreement; or (d) to the extent mutually agreed to in writing by the Parties.

Section 9.3 Publicity.

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9.3.1 Use of Names; Press Releases. Neither Party shall use the name, symbol, trademark, trade name or logo of the other Party or its Affiliates in any press release, publication or other form of public disclosure without the prior written consent of the other Party. Each Party agrees not to issue any press release or other public statement, whether oral or written, disclosing the existence of this Agreement, the terms hereof or any information relating to this Agreement without the prior written consent of the other Party (which consent shall not be unreasonable withheld, delayed or conditioned).

9.3.2 Public Disclosures and Publications Related to Development Programs and/or Products. Any proposed public disclosure (whether written, electronic, oral or otherwise) by either Party relating to any Development Program or any Product shall require the prior written consent of the other Party (which consent shall not be unreasonable withheld, delayed or conditioned). The Party desiring disclosure shall first provide to the other Party written notice of its intent to disclose and a draft of such proposed disclosure and the other Party shall have thirty (30) days after receipt of the draft disclosure to provide consent or request in writing the removal of portions deemed by such Party to contain confidential or patentable material owned by such Party, or to request a delay pending such Party's application for patent protection. Notwithstanding the foregoing, this Section 9.3.2 shall not apply to information which is in the public domain, nor shall it apply to Zogenix with respect to Development Programs that have become either Licensed Development Programs or Zogenix Development Programs or Products that have become Licensed Products.

9.3.3 Disclosures Required by Law. Notwithstanding the provisions of Sections 9.3.1 and 9.3.2, each Party may make any disclosures required of it to comply with any duty of disclosure it may have pursuant to law or governmental regulation or pursuant to the rules of any recognized stock exchange ("Securities Laws"). In the event of a disclosure required by Securities Laws, the Parties shall coordinate with each other with respect to the timing, form and content of such required disclosure. If so requested by the other Party, the Party subject to such obligation shall reasonably cooperate with efforts undertaken by the requesting Party to obtain an order protecting to the maximum extent possible the confidentiality of such provisions (including financial terms) of this Agreement as reasonably requested by the other Party. If the Parties are unable to agree on the form or content of any required disclosure, such disclosure shall be limited to the minimum appropriate disclosure, as reasonably determined by the disclosing Party in consultation with its legal counsel. Without limiting the foregoing, each Party shall consult with the other Party on the provisions of this Agreement, together with exhibits or other attachments attached hereto, to be redacted in any filings made by Tevard or Zogenix with the Securities and Exchange Commission (or other regulatory body) or as otherwise required by law.

Section 9.4 Termination of Prior Agreement. This Agreement supersedes and replaces the Existing Confidentiality Agreements. All information exchanged between the Parties under the Existing Confidentiality Agreements on or prior to the Effective Date shall be deemed Confidential Information hereunder and shall be subject to the terms of this Article 9.

Section 9.5 Remedies. Each Party shall be entitled to seek, in addition to any other right or remedy it may have, at Law or in equity, a temporary injunction, without the posting of any bond or other security, enjoining or restraining the other Party from any violation or threatened violation of this Article 9.

ARTICLE 10

REPRESENTATIONS AND WARRANTIES

Section 10.1 Representations and Warranties of Both Parties. Each Party hereby represents and warrants to the other Party, as of the Effective Date, that:

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10.1.1 such Party is duly organized, validly existing and in good standing under the Laws of the jurisdiction of its incorporation and has full corporate power and authority to enter into this Agreement and to carry out such Party's obligations hereunder;

10.1.2 such Party has taken all necessary action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder;

10.1.3 this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, binding obligation, enforceable against it in accordance with the terms hereof, subject to applicable bankruptcy, insolvency, reorganization, moratorium or other laws affecting creditors' rights generally and subject to general principles of equity regardless of whether considered in a proceeding at law or in equity;

10.1.4 the execution, delivery and performance of this Agreement by such Party does not conflict with any agreement or any provision thereof, or any instrument or understanding, oral or written, to which it is a party or by which it is bound, nor violate any Applicable Law or regulation of any court, governmental body or administrative or other agency having jurisdiction over such Party;

10.1.5 to the knowledge of such Party, no government authorization, consent, approval, license, exemption of or filing or registration with any court or governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign, under any Applicable Laws, is or will be necessary for, or in connection with, the transaction contemplated by this Agreement or any other agreement or instrument executed in connection herewith, or for the performance by it of its obligations under this Agreement and such other agreements, to conduct Clinical Trials or to seek or obtain Regulatory Approvals; and

10.1.6 it has not (i) employed and has not used a contractor or consultant that has employed, any individual or entity debarred under Section 306 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 335a, (or subject to a similar sanction of EMA or another Governmental Authority), or (ii) employed any individual who or entity that is the subject of an FDA debarment investigation or proceeding (or similar proceeding of EMA or other Governmental Authority), in the conduct of any pre-clinical activities or clinical studies of Corrective Therapeutic Agent.

Section 10.2 Representations and Warranties of Tevard. Tevard hereby represents and warrants to Zogenix, as of the Effective Date and, to the extent pertinent to the Development Program for which an Option Package is delivered, as of the date of delivery of an Option Package (subject to any disclosures in such Option Package which disclosures shall be deemed to be exceptions to such representations and warranties) that:

10.2.1 Tevard is the sole and exclusive owner of, or otherwise Controls via an exclusive license to, the Tevard Patents listed in Exhibit E and, as of the Effective Date, Tevard has no contractual or payment obligation to any Person with respect to such Tevard Patents except for the Tevard In-Licenses;

10.2.2 Tevard has the right to grant all rights and licenses it purports to grant to Zogenix with respect to the Tevard IP and Tevard's interest in the Joint IP under this Agreement;

10.2.3 Tevard has not granted any right or license to any Third Party relating to any of the Tevard IP or Tevard's interest in the Joint IP that conflicts or interferes with any of the rights or licenses granted or to be granted to Zogenix hereunder pursuant to the exercise of any Option to any Development Program;

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10.2.4 No claim or litigation has been brought or asserted against Tevard or, to its knowledge, any Third Party by any Person alleging that the Tevard IP or Tevard's Corrective Therapeutic Agent technology is infringing or if practiced or commercialized will infringe the rights of any Third Party;

10.2.5 To its knowledge, the Tevard Patents are valid and enforceable and Tevard has complied in all material respects (and to its knowledge its Inbound Licensors have complied) with all Applicable Laws and duties of candor with respect to the filing, prosecution and maintenance of the Tevard Patents. Tevard has paid (and to its knowledge its Inbound Licensors have paid) all maintenance and annuity fees with respect to the Tevard Patents due as of the Effective Date. To Tevard's knowledge, no dispute regarding inventorship of a Tevard Patent has been alleged or threatened;

10.2.6 To its knowledge, as of the Effective Date with respect to the Dravet Syndrome Program and as of the date of exercise by Zogenix of its Option with respect to each other Development Program, the Commercialization of any Corrective Therapeutic Agent as Developed by Tevard hereunder during the Term is not reasonably expected to require a license from any Third Party under any Third Party Patent, other than the Patents licensed under the Tevard In-Licenses and other than the Third Party Patents identified on Exhibit D (as updated from time to time by Tevard) at the time Tevard delivers the Option Package for such other Development Programs; and

10.2.7 Tevard represents and warrants that it has, as of the Effective Date with respect to the Dravet Syndrome Program and as of the date of exercise by Zogenix of its Option with respect to each other Development Program, provided to Zogenix all material information in its possession regarding the safety and efficacy of the Corrective Therapies which may be the subject of a Development Program and will, as of the time of Tevard's delivery of an Option Package, use Commercially Reasonable Efforts to provide to Zogenix all material information in its possession regarding the safety and efficacy of the Corrective Therapies which are the subject of the applicable Development Program covered by such Option Package, except to the extent that any of the foregoing would not be reasonably expected to have a material adverse effect on the applicable Development Program.

Section 10.3 Mutual Covenants. Each Party hereby covenants to the other Party that on and after the Effective Date:

10.3.1 All employees, officers and consultants of a Party or its Affiliates who are or will be working under this Agreement or who otherwise have access to any Confidential Information of the other Party shall have executed and delivered to such Party an assignment or other written agreement, requiring such Person to protect the confidentiality of any such Confidential Information to which such Person may have access;

10.3.2 All employees, officers and consultants of a Party or its Affiliates who are or could reasonably be expected to develop inventions or discoveries during the conduct of any activities under this Agreement shall have executed and delivered to such Party an assignment or other written agreement requiring such Person to assign all right, title and interest in and to their inventions and discoveries, whether or not patentable, to such Party as the sole owner thereof, including any Tevard Patents, Zogenix Patents and Joint Patents (unless such an assignment is not required under Applicable Law);

10.3.3 Such Party will not (a) employ or use any contractor or consultant that employs, any individual or entity debarred under Section 306 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 335a (or subject to a similar sanction of EMA or other Governmental Authority) or, (b) employ any individual who or entity that is the subject of an FDA debarment investigation or proceeding (or similar proceeding of EMA or other Governmental Authority), in each of clauses (a) and (b) in the conduct of its activities under any Development Program. Each Party agrees to inform the other Party in writing promptly if it or any such Person who is performing services hereunder is debarred or is subject to an FDA debarment investigation or

proceeding (or similar proceeding of EMA) or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the best of its or its Affiliates' knowledge, is threatened, relating to the debarment or conviction of it or any such Person performing services hereunder; and

10.3.4 Such Party shall (a) perform its activities pursuant to this Agreement in compliance in all material respects with good laboratory practices and good clinical practices and cGMP, in each case as applicable under Applicable Laws; and (b) with respect to any biological samples obtained from humans, obtain the appropriate informed consents in advance for the use of all such human biological samples, and use such samples at all times within the scope of the relevant informed consents.

Section 10.4 Additional Tevard Covenants. Additionally, Tevard covenants to Zogenix that:

10.4.1 During the Term, Tevard will not grant any right or license to any Third Party relating to any of the Tevard IP or Tevard's interest in the Joint IP that conflicts or interferes with any of the rights or licenses granted or to be granted to Zogenix hereunder pursuant to the exercise of any Option to any Development Program;

10.4.2 As of the date Tevard delivers an Option Package to the JDC for a Development Program, such Option Package shall, to Tevard's knowledge at the time of such delivery, have identified all intellectual property under which a license from a Third Party is or may be required for the Commercialization of the Licensed Products as Developed by Tevard thereunder, other than the In-Licenses existing as of such date; and

10.4.3 During the Term, Tevard shall not grant any right or license to any Third Party relating to any of the intellectual property rights it owns or Controls which would conflict with any of the rights or licenses granted or to be granted to Zogenix hereunder pursuant to the provisions of Article 4, Article 5 or Article 12.

Section 10.5 Additional Zogenix Covenants. Additionally, Zogenix covenants to Tevard that during the Term, Zogenix will not grant any right or license to any Third Party relating to any of the Zogenix IP or Zogenix's interest in the Joint IP that conflicts or interferes with any of the rights or licenses granted or to be granted to Tevard hereunder pursuant to the provisions of Section 5.3.

Section 10.6 Disclaimer. Except as otherwise expressly set forth in this Agreement, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY THAT ANY PATENTS ARE VALID OR ENFORCEABLE, AND EXPRESSLY DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. Without limiting the generality of the foregoing, except as otherwise expressly set forth in this Agreement, each Party disclaims any warranties with regards to: (a) the success of any study or test commenced under this Agreement, (b) the safety or usefulness for any purpose of the technology or materials it provides or discovers under this Agreement; or (c) the validity, enforceability, or non-infringement of any intellectual property rights or technology it provides or licenses to the other Party under this Agreement.

ARTICLE 11

INDEMNIFICATION; INSURANCE

Section 11.1 Indemnification by Zogenix. Zogenix shall indemnify, defend and hold harmless Tevard and its Affiliates, and their respective directors, officers, employees and agents, (each, an "Tevard Indemnitee") from and against any and all liabilities, damages, losses, costs and expenses, including the reasonable fees of attorneys and other professional Third Parties (collectively, "Losses") to the extent

arising out of or resulting from any and all Third Party suits, claims, actions, proceedings or demands ("Claims") based upon:

11.1.1 the negligence, recklessness or wrongful intentional acts or omissions of Zogenix or its Affiliates and its or their respective directors, officers, employees and agents, in connection with Zogenix's performance of its obligations or exercise of its rights under this Agreement;

11.1.2 any breach of any representation or warranty or express covenant made by Zogenix under Article 10 or any other provision under this Agreement;

11.1.3 failure by Zogenix to comply with any Applicable Law; or

11.1.4 the Development that is actually conducted by or on behalf of Zogenix (excluding any Development carried out by or on behalf of Tevard hereunder), the handling and storage by or on behalf of Zogenix of any chemical agents or other compounds for the purpose of conducting Development by or on behalf of Zogenix, and the Manufacture, marketing, Commercialization and sale by Zogenix and its Affiliates, Licensees, or Sublicensees (excluding Tevard) of any Licensed Product, including any product liability, personal injury, property damage or other damage, but excluding infringement of any Patent of any Third Party that is filed with a patent office in any jurisdiction on or prior to the date Zogenix determines that the applicable Option Package satisfies the Option Package Criteria, in each case resulting from any of the foregoing activities described in this Section 11.1.4, except, in each case, to the extent any such Losses or Claims (i) result from the gross negligence or willful misconduct of a Tevard Indemnitee, (ii) arises from the breach of any representation or warranty or obligation under this Agreement by Tevard and/or (iii) are subject to indemnification by Tevard under Section 11.2;

Section 11.2 Indemnification by Tevard. Tevard shall indemnify, defend and hold harmless Zogenix and its Affiliates, and their respective directors, officers, employees and agents (each, an "Zogenix Indemnitee"), from and against any and all Losses to the extent arising out of or resulting from any and all Claims based upon:

11.2.1 the negligence, recklessness or wrongful intentional acts or omissions of Tevard or its Affiliates or its or their respective directors, officers, employees and agents, in connection with Tevard's performance of its obligations or exercise of its rights under this Agreement;

11.2.2 any breach of any representation or warranty or express covenant made by Tevard under Article 10 or any other provision under this Agreement;

11.2.3 failure by Tevard to comply with any Applicable Law; or

11.2.4 the Development that is actually conducted by or on behalf of Tevard (excluding any Development carried out by Third Parties on behalf of Zogenix), the handling and storage by or on behalf of Tevard of any chemical agents or other compounds for the purpose of conducting Development by or on behalf of Tevard, and the Manufacture, marketing, Commercialization and sale by Tevard, its Affiliates, Licensee or Sublicensee (excluding Zogenix) of any Corrective Therapeutic Agent (including any Tevard Product) including (a) any product liability, personal injury, property damage or other damage, and (b) infringement of any patent or other intellectual property rights of any Third Party, in each case resulting from any of the foregoing activities described in this Section 11.2.4, except, in each case, to the extent any such Losses or Claims (i) result from the gross negligence or willful misconduct of a Zogenix Indemnitee, (ii) arises from the breach of any representation or warranty or obligation under this Agreement by Zogenix and/or (iii) are subject to indemnification by Zogenix under Section 11.1.

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Section 11.3 Procedure. A Person entitled to indemnification under this Article 11 (an "Indemnified Party") shall give prompt written notification to the Person from whom indemnification is sought (the "Indemnifying Party") of the commencement of any action, suit or proceeding relating to a Third Party claim for which indemnification may be sought or, if earlier, upon the assertion of any such claim by a Third Party (it being understood and agreed, however, that the failure by an Indemnified Party to give notice of a Third-Party claim as provided in this Section 11.3 shall not relieve the Indemnifying Party of its indemnification obligation under this Agreement except and only to the extent that such Indemnifying Party is actually damaged as a result of such failure to give notice). Within twenty (20) days after delivery of such notification, the Indemnifying Party may, upon written notice thereof to the Indemnified Party, assume control of the defense of such action, suit, proceeding or claim with counsel reasonably satisfactory to the Indemnified Party. If the Indemnifying Party does not assume control of such defense, the Indemnified Party shall control such defense and, without limiting the Indemnifying Party's indemnification obligations, the Indemnifying Party shall reimburse the Indemnified Party for all costs and expenses, including attorney fees, incurred by the Indemnified Party in defending itself within forty-five (45) days after receipt of any invoice therefor from the Indemnified Party. The Party not controlling such defense may participate therein at its own expense; provided that, except with respect to an indemnification obligation for an infringement Claim under Section 11.1.1(d), if the Indemnifying Party assumes control of such defense and the Indemnified Party in good faith concludes, based on advice from counsel, that the Indemnifying Party and the Indemnified Party have conflicting interests with respect to such action, suit, proceeding or claim, the Indemnifying Party shall be responsible for the reasonable fees and expenses of one counsel to the Indemnified Party in connection therewith. The Party controlling such defense shall keep the other Party advised of the status of such action, suit, proceeding or claim and the defense thereof and shall consider recommendations made by the other Party with respect thereto. The Indemnified Party shall not agree to any settlement of such action, suit, proceeding or claim without the prior written consent of the Indemnifying Party, which shall not be unreasonably withheld, delayed or conditioned. The Indemnifying Party shall not agree to any settlement of such action, suit, proceeding or claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the Indemnified Party from all liability with respect thereto, that imposes any liability or obligation on the Indemnified Party or that acknowledges fault by the Indemnified Party without the prior written consent of the Indemnified Party.

Section 11.4 Insurance. Each Party shall procure and maintain general liability and product liability insurance as follows:

11.4.1 Beginning with the Effective Date and for one (1) year after the date of expiration or termination of this Agreement and the Wistar License (whichever is later), general liability insurance in amounts not less than one million dollars ($1,000,000) per incident and two million dollars ($2,000,000) in the aggregate.

11.4.2 Beginning with the commencement of human Clinical Trials and for three (3) years after the date of expiration or termination of this Agreement and the Wistar License (whichever is later), product liability insurance in amounts not less than five million dollars ($5,000,000) per incident and five million dollars ($5,000,000) in the aggregate.

11.4.3 Each insurance policy required by Sections 11.4.1 and 11.4.2 shall be issued by an insurance company rated A-rating (A-rating or above by A.M. Best) or better and naming The Wistar Institute of Anatomy and Biology and the University of Iowa Research Foundation as additional insureds.

11.4.4 It is understood that such insurance shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this ARTICLE 11 or otherwise. Each Party shall provide the other Party with written evidence of such insurance upon request. Each Party shall notify the other Party at least fifteen (15) days prior to cancellation of any such coverage.

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Section 11.5 Limitation of Liability. EXCEPT FOR A BREACH OF Article 7 OR Article 9 OR FOR CLAIMS OF A THIRD PARTY THAT ARE SUBJECT TO INDEMNIFICATION UNDER THIS Article 11, NEITHER TEVARD NOR ZOGENIX, NOR ANY OF THEIR RESPECTIVE AFFILIATES, LICENSEES, OR SUBLICENSEES, WILL BE LIABLE TO THE OTHER PARTY TO THIS AGREEMENT, ITS AFFILIATES OR ANY OF THEIR LICENSEES OR SUBLICENSEES FOR ANY INDIRECT, CONSEQUENTIAL, SPECIAL OR PUNITIVE DAMAGES OR LOST PROFITS OR ROYALTIES, LOST DATA OR COST OF PROCUREMENT OF SUBSTITUTE GOODS OR SERVICES, WHETHER LIABILITY IS ASSERTED IN CONTRACT, TORT (INCLUDING NEGLIGENCE AND STRICT PRODUCT LIABILITY) OR CONTRIBUTION, AND IRRESPECTIVE OF WHETHER THAT PARTY OR ANY REPRESENTATIVE OF THAT PARTY HAS BEEN ADVISED OF, OR OTHERWISE MIGHT HAVE ANTICIPATED THE POSSIBILITY OF, ANY SUCH LOSS OR DAMAGE. NEITHER PARTY'S LIABILITY TO THE OTHER PARTY FOR ANY AND ALL ACTIONS, SUITS, CLAIMS, DEMANDS, EXPENSES, COSTS OR OTHER FORMS OF LIABILITY OF ANY NATURE OR KIND THAT MAY ARISE OUT OF OR RELATED TO THIS AGREEMENT WILL EXCEED THE TOTAL AMOUNT OF PAYMENTS RECEIVED BY TEVARD HEREUNDER.

ARTICLE 12

TERM AND TERMINATION

Section 12.1 Term; Expiration.

12.1.1 This Agreement shall become effective on the Effective Date and, unless earlier terminated pursuant to this Article 12, shall expire as follows:

(a) On a Licensed Product-by-Licensed Product or Tevard Product-by-Tevard Product and country-by-country basis, on the date of the expiration of all payment obligations under this Agreement with respect to such Licensed Product or Tevard Product in such country; and

(b) In its entirety upon the expiration of all payment obligations under this Agreement with respect to the last Licensed Product or Tevard Product in all countries in the Territory.

12.1.2 The period from the Effective Date until the date of expiration of this Agreement in its entirety, or, as applicable to a given Licensed Product, Tevard Product, or Development Program (including Licensed Development Program and Zogenix Development Program) until the date of the expiration of this Agreement in part with respect to such Licensed Product, Tevard Product, or Development Program is referred to herein as the "Term."

Section 12.2 Zogenix Unilateral Termination Rights. Zogenix shall have the right, at its sole discretion, exercisable at any time during the Research Term, to terminate this Agreement on a Licensed Development Program-by-Licensed Development Program basis, upon one hundred eighty (180) days' prior written notice to Tevard and at any time following the expiration of the Research Term and during the Term, to terminate this Agreement on a Licensed Development Program-by-Licensed Development Program basis, upon ninety (90) days' prior written notice to Tevard.

Section 12.3 Termination for Cause.

12.3.1 Termination for Material Breach.

(a) Material Breach by Tevard. Zogenix may, without prejudice to any other remedies available to it under Applicable Law or in equity, terminate this Agreement in whole or on a Development Program-by-Development Program or Tevard Program-by-Tevard Program basis if Tevard shall have materially breached or defaulted in the performance of its obligations hereunder with respect to such Development

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Program or Tevard Program (as applicable), and such default shall have continued for ninety (90) days (or, in the case of a payment breach, fifteen (15) Business Days) after written notice thereof was provided to Tevard by Zogenix, such notice describing the alleged breach.

(b) Material Breach by Zogenix. Tevard may, without prejudice to any other remedies available to it under Applicable Law or in equity, terminate this Agreement on a Development Program-by-Development Program basis prior to First Commercial Sale of any Product arising under such Development Program if Zogenix shall have materially breached or defaulted in the performance of its obligations hereunder with respect to such Development Program, and such default shall have continued for ninety (90) days (or, in the case of a payment breach, fifteen (15) Business Days) after written notice thereof was provided to Zogenix by Tevard, such notice describing the alleged breach.

12.3.2 Subject to Section 12.3.3, any such termination of this Agreement under this Section 12.3 shall become effective at the end of such ninety (90) day or fifteen (15) Business Day (as applicable) cure period, unless the Party alleged to have breached this Agreement (the "Breaching Party") has cured such breach or default prior to the expiration of such cure period, or if such breach is not susceptible to cure within such cure period even with the use of Commercially Reasonable Efforts, the other Party's (the "Non-Breaching Party") right to termination shall be suspended only if and for so long as the Breaching Party has provided to the Non-Breaching Party a written plan that is reasonably calculated to effect a cure, such plan is acceptable to the Non-Breaching Party, and the Breaching Party commits to and does carry out such plan; provided that, in no event shall such suspension of the Non-Breaching Party's right to terminate extend beyond ninety (90) days after the original cure period. The right of either Party to terminate this Agreement, or a portion of this Agreement, as provided in this Section 12.3 shall not be affected in any way by such Party's waiver or failure to take action with respect to any previous default. Notwithstanding anything to the contrary herein and without limiting Zogenix's rights and remedies hereunder, if Tevard materially breaches this Agreement during the Research Term, the Research Term shall automatically be extended pro-rata for each day that Tevard remains in breach; provided that, no such extension shall extend the Research Term beyond the earlier of (a) the delivery by Tevard of Option Packages that are deemed to satisfy the applicable Option Package Criteria by Zogenix (pursuant to Section 2.2.2) for two (2) Development Programs or (b) the tenth (10th) anniversary of the Effective Date.

12.3.3 Disagreement. If the Parties reasonably and in good faith disagree as to whether there has been a material breach, the Party that seeks to dispute that there has been a material breach may contest the allegation in accordance with Section 13.1. The cure period for any allegation made in good faith as to a material breach under this Agreement will, subject to Sections 12.3.1, 12.3.2 and 13.3.3, run from the date that written notice was first provided to the Breaching Party by the Non-Breaching Party.

Section 12.4 Termination of Licensed Product due to Safety Concern. Zogenix may terminate this Agreement with respect to a Licensed Development Program or Licensed Product at any time after Zogenix's exercise of the Option with respect to such Licensed Development Program if a Safety Concern arises with respect to such Licensed Development Program or Licensed Product.

Section 12.5 Termination upon Insolvency. Either Party may terminate this Agreement if, at any time, the other Party: (a) files in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of that Party or of its assets; (b) proposes a written agreement of composition or extension of its debts; (c) is served with an involuntary petition against it, filed in any insolvency proceeding, and such petition will not be dismissed within forty-five (45) days after the filing thereof; (d) passes a resolution for its winding up or proposes to be or is a party to any dissolution or liquidation; or (e) if the other Party will make an assignment for the benefit of its creditors.

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Section 12.6 Effect of Expiration or Termination.

12.6.1 Expiration. After the expiration of the Term pursuant to Section 12.1, the following terms shall apply:

(a) After expiration of the Term with respect to any Licensed Product in a country pursuant to Section 12.1.1(a), Zogenix's rights and licenses with respect to such Licensed Product in such country shall survive as fully-paid up, non-royalty bearing, rights and licenses.

(b) After expiration of the Term with respect to any Tevard Product in a country pursuant to Section 12.1.1(a), Tevard's rights and licenses with respect to such Tevard Product in such country shall survive as fully-paid up, non-royalty bearing, rights and licenses.

12.6.2 Termination by Zogenix for Convenience or for Safety Concern; Termination by Tevard for Cause or for Zogenix's Insolvency. If (i) Tevard terminates a Development Program pursuant to Section 12.3.1(b) or the entire Agreement pursuant to Section 12.5; or (ii) Zogenix terminates a Licensed Development Program pursuant to Section 5.3.2, Section 12.2 or Section 12.4:

(a) All Options with respect to the terminated Development Program(s) (or in the case of termination of the entire Agreement, all Options) that are unexercised as of the effective date of termination shall terminate and be of no force or effect.

(b) All licenses granted to Zogenix pursuant to Sections 4.2.1 and 4.2.2 with respect to all Licensed Products in the terminated Licensed Development Programs(s) shall be terminated and of no further force or effect (except with respect to Zogenix's sell-off right below).

(c) Zogenix will have no further obligations to make any milestone, royalty or other payments to Tevard under Article 6 with respect to any terminated Development Program, except for any such obligations that accrued prior to the date such Development Program became a Tevard Program and with respect to payment obligations accruing from Zogenix's sell-off right.

(d) Solely in the case of a termination by Tevard for cause pursuant to Section 12.3.1(b), Zogenix, its Affiliates and its Sublicensees shall have the right for one hundred and eighty (180) days to sell off any Licensed Products that have been manufactured, are in the process of being manufactured or are subject to firm orders at the time of termination provided that, such sales are made in the normal course consistent with Zogenix's past practice and Zogenix continues to comply with all of its payment, reporting and audit obligations under Article 6 with respect to Licensed Products.

(e) With respect to any Licensed Product in a terminated Licensed Development Program, such Licensed Product shall become a Tevard Product (or in the case of termination of the entire Agreement, all Licensed Products shall become Tevard Products).

(f) Zogenix shall deliver to Tevard, copies of the Know-How in its possession and Control that is material to the Licensed Products in such terminated Licensed Development Program. In addition, upon the reasonable request of Tevard, Zogenix shall reasonably cooperate, at Tevard's cost and expense, with Tevard to transition the Manufacture of the applicable Tevard Products to a contract manufacturing organization designated by Tevard.

(g) Tevard shall have the right to retain any license granted in Section 5.3.3 with respect to the Tevard Products arising from each applicable Development Program terminated by Zogenix; provided that, Tevard continues to comply with all of its payment (subject to its rights under Section 13.2), reporting and audit obligations under Article 6 with respect to Tevard Products.

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12.6.3 Termination by Zogenix for Cause or for Tevard's Insolvency. If Zogenix terminates this Agreement with respect to one or more Development Programs for Tevard's material breach pursuant to Section 12.3.1(a), or for Tevard's insolvency pursuant to Section 12.5:

(a) All licenses granted to Tevard pursuant to Section 5.3.3 with respect to all Tevard Products in the terminated Development Programs(s) shall be terminated and of no further force or effect (except with respect to Tevard's sell-off right below).

(b) Zogenix shall have the right to retain any license granted in Section 4.2 with respect to the Licensed Products arising from each applicable terminated Licensed Development Program for which Zogenix had already exercised its Option; provided that, Zogenix continues to comply with all of its payment (subject to its rights under Section 13.2), reporting and audit obligations under Article 6 with respect to Licensed Products.

(c) Subject to the applicable terms of any In-License, Zogenix shall no longer have any obligations with respect to diligence or to use Commercially Reasonable Efforts with respect to any Licensed Products resulting from any Licensed Development Program that was terminated by Zogenix pursuant to Section 12.3.1(a).

(d) Solely in the case of a termination by Zogenix for cause pursuant to Section 12.3.1(a), Tevard, its Affiliates and its Sublicensees shall have the right for one hundred and eighty (180) days to sell off any Tevard Products that have been manufactured, are in the process of being manufactured or are subject to firm orders at the time of termination provided that, such sales are made in the normal course consistent with Tevard's past practice and Tevard continues to comply with all of its payment, reporting and audit obligations under Article 6 with respect to Tevard Products.

Section 12.7 Accrued Rights; Surviving Provisions of the Agreement.

12.7.1 Termination, relinquishment or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of any Party prior to such termination, relinquishment or expiration including the payment obligations under Article 6 hereof, and any and all damages or remedies arising from any breach hereunder. Such termination, relinquishment or expiration shall not relieve any Party from obligations which are expressly indicated to survive termination of this Agreement.

12.7.2 The provisions of Article 9, Article 11 and Article 13, and Section 4.2 (only to the extent that the applicable license is retained after termination pursuant to Section 12.6.3(b) or as necessary for Zogenix to exercise its sell-off right under Section 12.6.2(d)), Section 5.3.3 (only to the extent that the applicable license is retained after termination pursuant to Section 12.6.3(a) or as necessary for Tevard to exercise its sell-off right under Section 12.6.3(d)) Section 6.5 - Section 6.13 (for final accounting), Section 8.1.1, Section 8.1.3, Section 12.6 and Section 12.7 and any applicable definitions in Article 1, including any other provision surviving by operation of the foregoing surviving provisions, shall survive the termination of this Agreement in its entirety or expiration of this Agreement for any reason, in accordance with their respective terms and conditions, and for the duration stated, and where no duration is stated, shall survive indefinitely. Article 9 shall survive for a period of five (5) years after the effective date of termination of this Agreement.

ARTICLE 13

MISCELLANEOUS

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Section 13.1 Dispute Resolution. Except for the matters expressly provided in Section 3.1.5, if a dispute between the Parties arises under this Agreement, either Party shall have the right to refer such dispute in writing to the respective Executive Officers, and such Executive Officers shall attempt in good faith to resolve such dispute. If the Parties are unable to resolve a given dispute pursuant to this Section 13.1 within thirty (30) days after referring such dispute to the Executive Officers, either Party may have the given dispute settled by binding arbitration pursuant to Section 13.3.

Section 13.2 Right to Set-Off. Without limiting either Party's rights under law or in equity, and upon prior written notice to the other Party either Party may exercise a right of set-off against any and all amounts due to such Party as determined by a final judgment of a court or arbitrator of competent jurisdiction.

Section 13.3 Arbitration Request. If a Party intends to begin an arbitration to resolve a dispute arising under this Agreement, such Party shall provide written notice (the "Arbitration Request") to the other Party of such intention and a statement of the issues for resolution. From the date of the Arbitration Request and until such time as the dispute has become finally settled, the running of the time periods as to which Party must cure a breach of this Agreement becomes suspended as to any breach that is the subject matter of the dispute.

13.3.1 Additional Issues. Within thirty (30) days after the receipt of the Arbitration Request, the other Party may, by written notice, add additional issues for resolution in a statement of counter-issues.

13.3.2 No Arbitration of Patent Issues. Any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of any Patents Covering the Development, Manufacture, Commercialization, use, importation, offer for sale or sale of Licensed Products shall be submitted to a court of competent jurisdiction in the country in which such Patents were granted or arose.

13.3.3 Arbitration Procedure. Any arbitration pursuant to this Article 13 will be held in New York, New York, United States unless another location is mutually agreed by the Parties. The arbitration will be governed under the rules of the International Chamber of Commerce, to the exclusion of any inconsistent state Law. The Parties shall mutually agree on the rules to govern discovery and the rules of evidence for the arbitration within forty-five (45) days after the Arbitration Request. If the Parties fail to timely agree to such rules, the United States Federal Rules of Civil Procedure will govern discovery and the United States Federal Rules of Evidence will govern evidence for the arbitration. The arbitration will be conducted by three (3) arbitrators, of which each Party shall appoint one, and the arbitrators so appointed will select the third and final arbitrator. The arbitrators shall have experience of pharmaceutical licensing disputes. The arbitrators may proceed to an award, notwithstanding the failure of either Party to participate in the proceedings. The arbitrators shall, within thirty (30) days after the conclusion of the arbitration hearing, issue a written award and statement of decision describing the essential findings and conclusions on which the award is based, including the calculation of any damages awarded. The arbitrators shall be limited in the scope of their authority to resolving only the specific matter which the Parties have referred to arbitration for resolution and shall not have authority to render any decision or award on any other issues. Subject to Section 11.5, the arbitrators shall be authorized to award compensatory damages, but shall not be authorized to award punitive, special, consequential, or any other similar form of damages, or to reform, modify, or materially change this Agreement. The arbitrator also shall be authorized to grant any temporary, preliminary or permanent equitable remedy or relief the arbitrator deems just and equitable and within the scope of this Agreement, including an injunction or order for specific performance. The award of the arbitrators shall be the sole and exclusive remedy of the Parties, except for those remedies that are set forth in this Agreement or which apply to a Party by operation of the applicable provisions of this Agreement, and the Parties hereby expressly agree to waive the right to appeal from the decisions of the arbitrators, and there shall be no appeal to any court or other authority (government or private) from the decision of the arbitrators. Judgment on the award rendered by the arbitrators may be enforced in any court having

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competent jurisdiction thereof, subject only to revocation of the award on grounds set forth in the United Nations Convention on the Recognition and Enforcement of Foreign Arbitral Awards.

13.3.4 Costs. Each Party shall bear its own attorneys' fees, costs, and disbursements arising out of the arbitration, and shall pay an equal share of the fees and costs of the arbitrators; provided, however, that the arbitrators, in their award, shall be authorized to determine whether a Party is the prevailing Party, and if so, to award to that prevailing Party reimbursement for its reasonable attorneys' fees, costs and disbursements (including, for example, expert witness fees and expenses, transcripts, photocopy charges and travel expenses).

13.3.5 Preliminary Injunctions. Notwithstanding anything in this Agreement to the contrary, a Party may seek a temporary restraining order or a preliminary injunction from any court of competent jurisdiction in order to prevent immediate and irreparable injury, loss, or damage on a provisional basis, pending the award of the arbitrator on the ultimate merits of any dispute.

13.3.6 Confidentiality. All proceedings and decisions of the arbitrators shall be deemed Confidential Information of each of the Parties, and shall be subject to Article 9.

Section 13.4 Governing Law. This Agreement and any dispute arising from the performance or breach hereof shall be governed by and construed and enforced in accordance with the Laws of the State of New York without reference to conflicts of laws principles; provided that, with respect to matters involving the enforcement of intellectual property rights, the Laws of the applicable country shall apply. The provisions of the United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Agreement or any subject matter hereof.

Section 13.5 Assignment. Neither Party may assign this Agreement without the consent of the other Party, except as otherwise provided in this Section 13.5. Either Party may assign this Agreement in whole or in part, including on a Development Program-by-Development Program basis, to any Affiliate of such Party without the consent of the other Party; provided that such assigning Party provides the other Party with written notice of such assignment and the assignee agrees in writing to assume performance of all assigned obligations. Further, each Party may assign this Agreement, and all of its rights and obligations, without the consent of the other Party to its successor in interest by way of merger, acquisition, or sale of all or substantially all of its business or assets to which this Agreement relates; provided that, such assigning Party provides the other Party with written notice of such assignment within thirty (30) days after such assignment, merger, acquisition or sale and the assignee agrees in writing to assume performance of all assigned obligations. Notwithstanding anything to the contrary herein, Tevard shall not assign this Agreement unless such assignee also assumes Tevard's rights and obligations under all In-Licenses and is assigned all of Tevard's rights under the Tevard IP and Joint IP. Similarly, Tevard shall not assign its rights under the Tevard IP and Joint IP to an Affiliate or Third Party without also assigning its rights under this Agreement to such Affiliate or Third Party. In addition, Zogenix shall not assign its rights under the Zogenix IP and Joint IP to Third Party without also assigning its rights under this Agreement to such Third Party, provided that in no event shall Zogenix be prevented from assigning its rights under the Zogenix IP and/or Joint IP to an Affiliate without assigning its rights under this Agreement to such Affiliate. The terms of this Agreement shall be binding upon and shall inure to the benefit of the successors, heirs, administrators and permitted assigns of the Parties. Any purported assignment in violation of this Section 13.5 shall be null and void. If a Party assigns this Agreement in whole or in part to an Affiliate or Third Party as permitted by this Section 13.5, (x) the assigning Party shall thereafter remain primarily liable for causing such assignee to perform all of the assigning Party's obligations hereunder and the other Party may enforce such obligation against the assigning Party to cause the performance by such assignee of such obligations without first seeking to obtain performance from the assignee or exercising any other remedy or right that the enforcing Party may have and (y) if the Party other than the assigning Party decides to proceed first to

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exercise any other remedy or right, or to proceed against another Person, the assigning Party shall nonetheless remain primarily liable for the performance of such assignee of all of the assigning Party's financial obligations hereunder with respect to this Agreement and for causing such assignee to perform all of the assigning Party's non-financial obligations hereunder with respect to this Agreement.

Section 13.6 Performance Warranty. Each Party hereby acknowledges and agrees that it shall be responsible for the full and timely performance as and when due under, and observance of all the covenants, terms, conditions and agreements set forth in this, Agreement by its Affiliate(s), Licensees, and Sublicensees.

Section 13.7 Force Majeure. No Party shall be held liable or responsible to the other Party nor be deemed to be in default under, or in breach of any provision of, this Agreement for failure or delay in fulfilling or performing any obligation (other than a payment obligation) of this Agreement when such failure or delay is due to force majeure, and without the fault or negligence of the Party so failing or delaying. For purposes of this Agreement, force majeure is defined as causes beyond the control of the Party, including acts of God; material changes in Law; actions or failures in action by relevant Governmental Authorities; war; civil commotion; destruction of production facilities or materials by fire, flood, earthquake, explosion or storm; shortages of supply; labor disturbances; epidemic; and failure of public utilities or common carriers. In such event Tevard or Zogenix, as the case may be, shall immediately notify the other Party of such inability and of the period for which such inability is expected to continue. The Party giving such notice shall thereupon be excused from such of its obligations under this Agreement as it is thereby disabled from performing for so long as it is so disabled for up to a maximum of ninety (90) days, after which time Tevard and Zogenix shall promptly meet to discuss in good faith how to best proceed in a manner that maintains and abides by the Agreement. Without limiting the foregoing, if claims excuse for any failure to perform during the Research Term, the Research Term shall automatically be extended pro-rata for each day that Tevard claims such excuse. To the extent possible, each Party shall use reasonable efforts to minimize the duration of any force majeure.

Section 13.8 Notices. Any notice or request required or permitted to be given under or in connection with this Agreement shall be deemed to have been sufficiently given if in writing and personally delivered or sent by certified mail (return receipt requested), facsimile transmission (receipt verified), or overnight express courier service (signature required), prepaid, to the Party for which such notice is intended, at the address set forth for such Party below:

If to Tevard, addressed to:	Tevard Biosciences, Inc. 700 Main Street Cambridge, MA 02139 Attn: Daniel Fischer, CEO E-mail: Telephone: Facsimile:
with a copy to: (which shall not constitute notice)	Arent Fox LLP 1717 K Street NW Washington, DC 20006

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	Attention: Richard J. Berman E-mail: Telephone: Facsimile:
If to Zogenix, addressed to:	Zogenix, Inc. 5959 Horton Street Suite 500 Emeryville, California 94608 Attn: Chief Financial Officer E-mail: Telephone: Facsimile:
with a copy to: (which shall not constitute notice)	Latham & Watkins LLP 12670 High Bluff Drive San Diego, CA 92130 Attention: Steven T. Chinowsky E-mail: Telephone: Facsimile:

or to such other address for such Party as it shall have specified by like notice to the other Parties, provided that, notices of a change of address shall be effective only upon receipt thereof. If delivered personally or by facsimile transmission, the date of delivery shall be deemed to be the date on which such notice or request was given. If sent by overnight express courier service, the date of delivery shall be deemed to be the next Business Day after such notice or request was deposited with such service. If sent by certified mail, the date of delivery shall be deemed to be the third (3rd) Business Day after such notice or request was deposited with the U.S. Postal Service.

Section 13.9 Export Control. Each Party acknowledges that the Laws of the United States restrict the export and re-export of commodities and technical data of United States origin. Each Party agrees that it will not export or re-export restricted commodities or the technical data of the other party in any form without the appropriate United States and foreign government licenses.

Section 13.10 Waiver. Neither Party may waive or release any of its rights or interests in this Agreement except in writing. The failure of either Party to assert a right hereunder or to insist upon compliance with any term of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition. No waiver by either Party of any condition or term in any one or more instances shall be construed as a continuing waiver of such condition or term or of another condition or term.

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Section 13.11 Severability. If any provision hereof should be held invalid, illegal or unenforceable in any jurisdiction, the Parties shall negotiate in good faith a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the Parties and all other provisions hereof shall remain in full force and effect in such jurisdiction and shall be liberally construed in order to carry out the intentions of the Parties hereto as nearly as may be possible. Such invalidity, illegality or unenforceability shall not affect the validity, legality or enforceability of such provision in any other jurisdiction.

Section 13.12 Entire Agreement. This Agreement, together with the Schedules and Exhibits hereto, set forth all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto and supersede and terminate all prior agreements and understanding between the Parties. In particular, and without limitation, this Agreement supersedes and replaces the Existing Confidentiality Agreements and any and all term sheets relating to the transactions contemplated by this Agreement and exchanged between the Parties prior to the Effective Date. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties hereto unless reduced to writing and signed by the respective authorized officers of the Parties.

Section 13.13 Independent Contractors. Nothing herein shall be construed to create any relationship of employer and employee, agent and principal, partnership or joint venture between the Parties. Each Party is an independent contractor. Neither Party shall assume, either directly or indirectly, any liability of or for the other Party. Neither Party shall have the authority to bind or obligate the other Party and neither Party shall represent that it has such authority.

Section 13.14 Headings; Construction; Interpretation. Headings used herein are for convenience only and shall not in any way affect the construction of or be taken into consideration in interpreting this Agreement. The terms of this Agreement represent the results of negotiations between the Parties and their representatives, each of which has been represented by counsel of its own choosing, and neither of which has acted under duress or compulsion, whether legal, economic or otherwise. Accordingly, the terms of this Agreement shall be interpreted and construed in accordance with their usual and customary meanings, and each of the Parties hereto hereby waives the application in connection with the interpretation and construction of this Agreement of any rule of Law to the effect that ambiguous or conflicting terms or provisions contained in this Agreement shall be interpreted or construed against the Party whose attorney prepared the executed draft or any earlier draft of this Agreement. Any reference in this Agreement to an Article, Section, subsection, paragraph, clause, Schedule or Exhibit shall be deemed to be a reference to any Article, Section, subsection, paragraph, clause, Schedule or Exhibit, of or to, as the case may be, this Agreement. Except where the context otherwise requires, (a) any definition of or reference to any agreement, instrument or other document refers to such agreement, instrument other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (b) any reference to any Law refers to such Law as from time to time enacted, repealed or amended, (c) the words “herein,” “hereof” and “hereunder,” and words of similar import, refer to this Agreement in its entirety and not to any particular provision hereof, (d) the words “include,” “includes,” “including,” “exclude,” “excludes,” and “excluding,” shall be deemed to be followed by the phrase “but not limited to,” “without limitation” or words of similar import, and (e) the word “or” is used in the inclusive sense (and/or).

Section 13.15 Financial Books and Records. Any financial Books and Records to be maintained under this Agreement by a Party or its Affiliates, Licensees, or Sublicensees and subject to an audit right hereunder shall be maintained in accordance with GAAP.

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Section 13.16 Further Actions. Each Party shall execute, acknowledge and deliver such further instruments, and do all such other acts, as may be necessary or appropriate in order to carry out the expressly stated purposes and the clear intent of this Agreement.

Section 13.17 Parties in Interest. All of the terms and provisions of this Agreement shall be binding upon, and shall inure to the benefit of and be enforceable by the Parties hereto and their respective successors, heirs, administrators and permitted assigns.

Section 13.18 Performance by Affiliates. Tevard acknowledges and agrees that Zogenix may perform some or all of its obligations under this Agreement through its Affiliates; provided, however, that Zogenix shall remain responsible for the performance by its Affiliates and will cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. To the extent that this Agreement imposes obligations on Affiliates of a Party, such Party agrees to cause its Affiliates to perform such obligations.

Section 13.19 Counterparts. This Agreement may be signed in counterparts, each and every one of which shall be deemed an original, notwithstanding variations in format or file designation which may result from the electronic transmission, storage and printing of copies from separate computers or printers. Facsimile signatures and signatures transmitted via PDF shall be treated as original signatures.

[Signature page follows]

IN WITNESS WHEREOF, and intending to be legally bound hereby, the Parties have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

TEVARD BIOSCIENCES, INC.
By: /s/ Daniel Fischer
Name: Daniel Fischer
Title: Chief Executive Officer

ZOGENIX, INC.
By: /s/ Stephen Farr
Name: Stephen Farr
Title: Chief Executive Officer

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Exhibits

Exhibit A – Targets

Exhibit B – Core Option Package Criteria

Exhibit C – Tevard In-Licenses

Exhibit D – Third Party Patents

Exhibit E – Tevard Patents

Exhibit F – Form of Secured Promissory Note

Exhibit G – Product Transfer Criteria

Exhibit H – Initial Development Plan for Dravet Syndrome Program

Exhibit I – Initial Development Plan for Second Program

Exhibit J – Initial Development Plan for Subsequent Option Programs

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Exhibit A

Targets

[***]

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Exhibit B

Core Option Package Criteria

[***]

Exhibit C

Tevard In-Licenses

1. License Agreement between Case Western Reserve University and Tevard Biosciences, Inc., dated March 6, 2020.

2. License Agreement between The Wistar Institute of Anatomy and Biology, University of Iowa Research Foundation and Tevard Biosciences, Inc., dated September 22, 2020.

Exhibit D

Third Party Patents

[***]

Exhibit E

Tevard Patents

[***]

Exhibt F

Form of Secured Promissory Note

THIS NOTE AND THE SECURITIES ISSUABLE UPON CONVERSION OF THIS NOTE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "ACT") OR UNDER THE SECURITIES LAWS OF CERTAIN STATES, AND MAY NOT BE SOLD, OFFERED FOR SALE, PLEDGED, HYPOTHECATED OR OTHERWISE TRANSFERRED EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT FILED UNDER THE ACT AND APPLICABLE STATE SECURITIES LAWS OR PURSUANT TO AN OPINION OF COUNSEL SATISFACTORY TO THE COMPANY THAT REGISTRATION IS NOT REQUIRED UNDER THE ACT OR THE APPLICABLE STATE SECURITIES LAWS OR UNLESS SOLD IN ACCORDANCE WITH RULE 144 UNDER THE ACT.

TEVARD BIOSCIENCES, INC.
CONVERTIBLE PROMISSORY NOTE

Note No. 1

$5,000,000

Issue Date
December 3, 2020

FOR VALUE RECEIVED, Tevard Biosciences, Inc., a Delaware corporation (the "Company"), hereby promises to pay Zogenix, Inc. ("Lender"), the principal balance equal to $5,000,000, together with simple interest on the unpaid principal balance of this Note from time to time outstanding at the rate of 3.5% per year; provided that in no event shall the interest rate be less than the minimum rate of interest required in order to avoid the imputation of interest for federal income tax purposes. Interest shall commence with the date hereof and shall continue on the outstanding unpaid principal until paid in full or converted. Interest on this Note shall be computed on the basis of a year of 365 days for the actual number of days elapsed.

1. Maturity. Unless earlier converted pursuant to the conversion provisions set forth herein, all outstanding principal and accrued interest under this Note (the "Outstanding Amount") shall be due and payable by the Company December 3, 2022 (the "Maturity Date").

2. Conversion of the Note. Effective upon the closing of a Qualified Financing (as defined below), the Outstanding Amount shall automatically be converted into shares of the same class and series of capital stock of the Company issued to other investors in the Qualified Financing (the "Conversion Shares") at a conversion price equal to the price paid per share for the Equity Securities (as defined below) by the other investors in the Qualified Financing (the "Conversion Price"), with any resulting fraction of a share rounded down to the nearest whole share. No payment will be made to Lender in lieu of any fractional shares to which Lender would otherwise have been entitled, and such amounts shall be extinguished without any further payment on the part of the Company. The number of Conversion Shares to be issued upon such conversion shall be equal to the quotient obtained by dividing the Outstanding Amount on this Note, on the date of conversion, by the Conversion Price. "Qualified Financing" means the first issuance or series of related issuances by the Company of Equity Securities following the date of this Note from which the Company receives immediately available gross proceeds of at least $10 million (excluding proceeds from this Note and any other indebtedness of the Company that

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convert into equity in such financing). The Company shall notify Lender in writing of the anticipated occurrence of a Qualified Financing at least five days prior to the closing date of the Qualified Financing, notifying Lender of the conversion to be effected and the terms under which the Equity Securities of the Company are anticipated to be sold in such Qualified Financing. The issuance of Conversion Shares pursuant to the conversion of this Note shall be upon and subject to the same terms and conditions applicable to the Equity Securities sold in the Qualified Financing. Lender hereby agrees to execute and become party to all customary agreements that the Company reasonably requests in connection with such Qualified Financing. As promptly as practicable after the conversion of this Note, the Company at its expense shall issue and deliver to the holder of this Note, upon surrender of this Note by Lender to the Company, a certificate or certificates for the number of full Conversion Shares issuable upon such conversion. Upon the conversion of this Note, Lender shall have no further rights under such Note, whether or not such Note is surrendered. “Equity Securities” means a series of the Company’s common stock or preferred stock issued by the Company for bona fide equity financing purposes.

3. Payment Upon Change of Control. If there is a Change of Control (as defined below) of the Company prior to the conversion of this Note for any reason, the Company shall pay to Lender, upon the closing of the Change of Control and in full satisfaction of this Note, the Change of Control Multiple (as defined below). The “Change of Control Multiple” means two times (2x) the outstanding principal balance of this Note. A “Change of Control” means (i) a merger or consolidation in which (x) the Company is a constituent party or (y) a subsidiary of the Company is a constituent party and the Company issues shares of its capital stock pursuant to such merger or consolidation, except any such merger or consolidation involving the Company or a subsidiary in which the shares of capital stock of the Company outstanding immediately prior to such merger or consolidation continue to represent, or are converted into or exchanged for shares of capital stock that represent, immediately following such merger or consolidation, a majority, by voting power, of the capital stock of (1) the surviving or resulting corporation or (2) if the surviving or resulting corporation is a wholly-owned subsidiary of another corporation immediately following such merger or consolidation, the parent corporation of such surviving or resulting corporation, (ii) the sale by the stockholders of the Company, in a single transaction or series of related transactions, of capital stock representing at least 50% of the outstanding voting power of the Company, or (iii) the sale, lease, transfer, exclusive license (but for clarity excluding any exclusive license in a specific field of use entered into in the ordinary course of business) or other disposition, in a single transaction or series of related transactions, by the Company or any subsidiary of the Company of all or substantially all the assets of the Company and its subsidiaries taken as a whole, or the sale or disposition (whether by merger, consolidation or otherwise) of one or more subsidiaries of the Company if substantially all of the assets of the Company and its subsidiaries taken as a whole are held by such subsidiary or subsidiaries, except where such sale, lease, transfer, exclusive license or other disposition is to a wholly owned subsidiary of the Company; provided that a Change of Control shall not include any transaction or series of related transactions principally for bona fide equity financing purposes (including, but not limited to, the Qualified Financing) in which cash is received by the Company or any successor or indebtedness of the Company is cancelled or converted or a combination thereof occurs. The Company shall notify Lender in writing of the anticipated occurrence of a Change of Control at least five days prior to the closing date of the Change of Control.

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4. Defaults and Remedies.

4.1 Events of Default. Upon the occurrence of an Event of Default (as defined below), at the option and upon the declaration of the Lender and upon written notice to the Company, the entire unpaid principal and accrued interest on the Note shall be immediately due and payable, without presentment, demand, protest or notice of any kind, all of which are hereby expressly waived, but subject to the conversion rights set forth herein. The following events shall be considered events of default with respect to the Note (individually, an "Event of Default" and collectively, "Events of Default"):

(a) if the Company fails to pay any of the principal, interest or any other amounts payable under this Note when due and payable;

(b) if the Company files any petition or action for relief under any bankruptcy, reorganization, insolvency or moratorium law or any other law for the relief of, or relating to, debtors, now or hereafter in effect, or seeks the appointment of a custodian, receiver, trustee (or other similar official) of the Company or all or any substantial portion of the Company's assets, or makes any assignment for the benefit of creditors or takes any action in furtherance of any of the foregoing, or fails to generally pay its debts as they become due; or

(c) if an involuntary petition is filed, or any proceeding or case is commenced, against the Company (unless such proceeding or case is dismissed or discharged within 60 days of the filing or commencement thereof) under any bankruptcy, reorganization, arrangement, insolvency, adjustment of debt, liquidation or moratorium statute now or hereafter in effect, or a custodian, receiver, trustee, assignee for the benefit of creditors (or other similar official) is applied or appointed for the Company or to take possession, custody or control of any property of the Company, or an order for relief is entered against the Company in any of the foregoing.

4.2 Remedies. Upon the occurrence of an Event of Default, Lender shall have then, or at any time thereafter, all of the rights and remedies afforded creditors generally by the applicable federal laws or the laws of the State of Delaware at law, in equity or otherwise.

5. Prepayment. This Note may not be prepaid, in whole or in part, prior to the Maturity Date without the prior written consent of the Lender. If prepayment is consented to by the Lender (a) it will be without any prepayment penalties and (b) interest will no longer continue to accrue on any prepaid principal amounts after such prepayments. The Company hereby waives demand, notice, presentment, protest and notice of dishonor.

6. Payment. All payments by the Company under this Note shall be in immediately available funds at the principal office of the Company, or at such other place as Lender may from time to time designate in writing to the Company. All payments by the Company under this Note shall be made without set-off or counterclaim and be free and clear and without any deduction or withholding for any taxes or fees of any nature whatever, unless the obligation to make such deduction or withholding is imposed by law. All payments by the Company under this Note shall be applied first to the accrued interest due and payable hereunder and the remainder, if any, applied to the outstanding principal.

7. Directors, Officers and Stockholders Not Liable. Lender agrees that no stockholder, director or officer of the Company shall have any personal liability for any amounts due and payable pursuant to this Note.

8. Interest Cutoff. If a Change of Control or Qualified Financing is consummated, all interest on this Note shall be deemed to have stopped accruing as of a date selected by the Company that is up to five (5) days prior to the consummation of the Change of Control or Qualified Financing.

9. Representations, Warranties and Covenants of the Company. The Company hereby represents and warrants to the Lender as of the Issue Date that:

9.1 Organization, Good Standing, Corporate Power and Qualification. The Company is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware and has all requisite corporate power and authority to carry on its business as now conducted and as presently proposed to be conducted. The Company is duly qualified to transact business and is in good standing in Massachusetts and in each other jurisdiction in which the failure to so qualify would have a material adverse effect on the business, assets (including intangible assets), liabilities, financial condition, property or results of operations of the Company.

9.2 Authorization. All corporate action required to be taken by the Company's board of directors (the "Board") and stockholders in order to authorize the Company to enter into this Note, and to issue the Conversion Shares has been taken. All action on the part of the officers of the Company necessary for the execution and delivery of this Note, the performance of all obligations of the Company under this Note, and the issuance and delivery of the Conversion Shares has been taken. This Note, when executed and delivered by the Company, shall constitute valid and legally binding obligations of the Company, enforceable against the Company in accordance with its respective terms except (i) as limited by applicable bankruptcy, insolvency, reorganization, moratorium, fraudulent conveyance, or other laws of general application relating to or affecting the enforcement of creditors' rights generally, or (ii) as limited by laws relating to the availability of specific performance, injunctive relief, or other equitable remedies.

9.3 Board Composition. The Company agrees to use best efforts to cause the Board to include, as of the Issue Date and for so long as this Note is outstanding, one (1) person designated by the Lender, who shall initially be Stephen Farr, Chief Executive Officer of the Lender. After giving effect to the preceding sentence, the Board shall be comprised of: Stephen Farr, Warren Lammert (Chairman), Jeffrey Walsh, Orrin Devinsky, Harvey Lodish, Michael Jasulavic and Daniel Fischer.

For avoidance of doubt, this Section 9.3 shall terminate and be of no further force or effect upon (i) the entry into a customary investor rights agreement, voting agreement or similar agreement by and among the Company, the Lender and the other parties thereto in connection with a Qualified Financing or (ii) any other conversion or termination of this Note.

10. Miscellaneous.

10.1 Accredited Investor Representation. By accepting this Note and countersigning below, Lender represents and warrants to the Company that such Lender is an “accredited investor” as defined in Rule 501(a) under the Act.

10.2 No “Bad Actor” Disqualification. Lender hereby represents that no “bad actor” disqualifying event described in Rule 506(d)(1)(i)-(viii) of the Act (a “Disqualification Event”) is applicable to Lender or any of its Rule 506(d) Related Parties (as defined below), except, if applicable, for a Disqualification Event as to which Rule 506(d)(2)(ii) or (iii) or (d)(3) is applicable. For purposes of this Note, “Rule 506(d) Related Party” means any individual, corporation, partnership, trust, limited liability company, association or other entity that is a beneficial owner of Lender’s securities for purposes of Rule 506(d) of the Act.

10.3 Governing Law; Jurisdiction and Venue; Waiver of Jury Trial. This Note shall be governed by and construed in accordance with the General Corporation Law of the State of Delaware as to matters within the scope thereof, and as to all other matters shall be governed by and construed in accordance with the internal laws of the State of Delaware, without regard to conflict of law principles that would result in the application of any law other than the law of the State of Delaware. Each of the parties irrevocably consents to the exclusive jurisdiction of, and venue in, the state courts in the State of Delaware (or in the event of exclusive federal jurisdiction, the courts of the State of Delaware), in connection with any matter based upon or arising out of this Note or the matters contemplated herein, and agrees that process may be served upon them in any manner authorized by the laws of the State of Delaware for such persons. Each of the parties hereto irrevocably waives, to the fullest extent permitted by law, any and all right to trial by jury in any legal proceeding (whether in contract, tort or otherwise) arising out of or related to this Note.

10.4 Successors and Assigns. This Note shall inure to the benefit of and be binding upon the respective successors and assigns of the parties. Nothing in this Note is intended to confer upon any party other than the parties hereto or their respective successors and assigns any rights, remedies, obligations or liabilities under or by reason of this Note, except as expressly provided in this Note. Notwithstanding the forgoing, any transfer of this Note may be effected only in accordance with the provisions of this Note and with the prior written consent of the Company. Lender and any subsequent holder of this Note receives this Note subject to the foregoing terms and conditions, as well as all other terms and conditions contained in this Note, and agrees to comply with all such terms and conditions for the benefit of the Company and any other Lenders.

10.5 Titles and Subtitles. The titles and subtitles used in this Note are used for convenience only and are not to be considered in construing or interpreting this Note.

10.6 Entire Agreement; Amendments and Waivers. This Note constitutes the full and entire understanding and agreement between the parties with regard to the subjects hereof. The terms and provisions of this Note may be modified or amended and the observance of any term of this Note may be waived (either generally or in a particular instance and either retroactively or prospectively) only with the written consent of the Company and the Lender.

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10.7 Delay or Omission; Waiver of Presentment. No delay or omission on the part of Lender in exercising any right under this Note shall operate as a waiver of such right or of any other right of Lender, nor shall any delay, omission or waiver on any one occasion be deemed a bar to or waiver of the same or any other right on any future occasion. The Company and every endorser or guarantor of this Note, regardless of the time, order or place of signing, hereby waives presentment, demand, protest and notices of every kind and assents to any permitted extension of the time of payment and to the addition or release of any other party primarily or secondarily liable hereunder.

10.8 No Rights as Stockholder. Until the conversion of this Note, Lender shall not have or exercise any rights by virtue hereof as a stockholder of the Company.

10.9 Severability. If any provision of this Note is held to be unenforceable under applicable law, such provision shall be excluded from this Note and the balance of this Note shall be interpreted as if such provision were so excluded and shall be enforceable in accordance with its terms.

10.10 Expenses. The Company and Lender shall bear their own legal and other expenses with respect to this Note.

10.11 Counterparts. This Note may be executed in two or more counterparts, each of which shall be deemed an original and all of which together shall constitute one instrument.

10.12 Electronic and Facsimile Signatures. Any signature page delivered electronically or by facsimile (including, without limitation, transmission by .pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, e.g., www.docusign.com) shall be binding to the same extent as an original signature page.

10.13 Notice. All notices required or permitted hereunder shall be in writing and shall be deemed effectively given: (a) upon personal delivery to the party to be notified; (b) when sent by confirmed electronic mail or confirmed facsimile if sent during normal business hours of the recipient, if not, then on the next business day; (c) five (5) business days after having been sent by registered or certified mail, return receipt requested, postage prepaid; or (d) one business day after deposit with a nationally recognized overnight courier, specifying next day delivery, with written verification of receipt. All communications to the Company shall be sent to the address or other contact information as set forth beneath its signature. All communications to Lender shall be sent to Lender’s address or such other contact information as set forth beneath its signature. Or at such other address or contact information as the relevant recipient may designate pursuant to the provisions of this Section 10.13.

[Signature Page Follows]

IN WITNESS WHEREOF, the parties have executed this Convertible Promissory Note as of the date set forth above.

TEVARD BIOSCIENCES, INC.
By:_____

Name: Daniel Fischer
Title: Chief Executive Officer
Address:
c/o Lab Central
700 Main Street
Cambridge MA 02139
Email:

With a copy (which shall not constitute notice) to:

Arent Fox LLP
Attn: Ricardo Fischer
1717 K Street, NW
Washington, DC 20006-5344

LENDER:
ZOGENIX, INC.

By:_____

Name: Stephen Farr
Title: Chief Executive Officer
Address:
5959 Horton Street
Emeryville, CA 94608

With a copy (which shall not constitute notice) to:

Latham & Watkins LLP
Attn: Cheston J. Larson
12670 High Bluff Drive
San Diego, CA 92130

Exhibit G

Product Transfer Criteria

[***]

Second Program

[To be prepared and attached by the JDC following the Effective Date]

Subsequent Option Program

[To be prepared and attached by the JDC following the Effective Date]

Exhibit H

Initial Development Plan
for
Dravet Syndrome Program

[***]

Exhibit I

Initial Development Plan
for
Second Program
[To be prepared and attached by the JDC following the Effective Date]

Exhibit J

Initial Development Plan
for
Subsequent Option Programs
[To be prepared and attached by the JDC following the Effective Date]

Exhibit 21.1

SUBSIDIARIES OF ZOGENIX, INC.

All subsidiaries are wholly-owned, directly or indirectly, by Zogenix, Inc.

Name of Subsidiary	Jurisdiction of Formation
Modis Therapeutics, Inc.	Delaware

Name of Non-U.S. Subsidiary	Jurisdiction of Formation
Zogenix Europe Limited	United Kingdom
Zogenix GmbH	Germany
Zogenix International Limited	United Kingdom
Zogenix K.K.	Japan
Zogenix ROI Limited	Ireland
Zogenix SAS	France
Zogenix S.r.l.	Italy

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statements:

(1) Registration Statement (Form S-3 No. 333-239158) and in the related Prospectus of Zogenix, Inc.,

(2) Registration Statement (Form S-8 No. 333-170875) pertaining to the 2006 Equity Incentive Plan, the 2010 Equity Incentive Award Plan and the 2010 Employee Stock Purchase Plan of Zogenix, Inc.,

(3) Registration Statement (Form S-8 No. 333-181543) pertaining to the 2010 Equity Incentive Award Plan of Zogenix, Inc.,

(4) Registration Statement (Form S-8 No. 333-197998) pertaining to the Employment Inducement Equity Incentive Award Plan, as amended of Zogenix Inc.,

(5) Registration Statement (Form S-8 No. 333-224797) pertaining to the Employment Inducement Equity Incentive Award Plan and the 2010 Employee Stock Purchase Plan of Zogenix, Inc.,

(6) Registration Statement (Form S-8 No. 333-233062) pertaining to the 2010 Equity Incentive Award Plan, as amended of Zogenix Inc., and

(7) Registration statement (Form S-8 No. 333-238840) pertaining to the Employee Stock Purchase Plan of Zogenix, Inc.

of our reports dated March 1, 2021, 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, 2020.

/s/ Ernst & Young LLP

Redwood City, California
March 1, 2021

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, 2020;
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: March 1, 2021

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, 2020;
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: March 1, 2021

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, 2020, 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: March 1, 2021

/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, 2020, 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: March 1, 2021

/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.