ZOGENIX, INC. Form 424B5 December 22, 2017 Table of Contents

> Filed Pursuant to Rule 424(b)(5) Registration No. 333-220759

CALCULATION OF REGISTRATION FEE

Proposed

Maximum

Title of Each Class of Aggregate Amount of

Securities to be Registered Offering Price Registration Fee(1)

Common Stock, par value \$0.001 per share \$75,000,000 \$9,337.50

(1) Calculated pursuant to Rule 457(o) and in accordance with Rule 457(r) under the Securities Act of 1933, as amended, or the Securities Act. Payment of the registration fee at the time of filing of the registrant s registration statement on Form S-3, filed with the Securities and Exchange Commission on October 2, 2017 (File No. 333-220759), was deferred pursuant to Rules 456(b) and 457(r) under the Securities Act, and is paid herewith. Pursuant to Rule 457(p) under the Securities Act, filing fees of \$8,546.47 previously paid with respect to \$79,873,561.48 in aggregate offering price of unsold securities that were registered pursuant to a registration statement on Form S-3 (File No. 333-211265) filed by the registrant on May 10, 2016, by means of a prospectus dated May 24, 2016, are being carried forward, of which the entire amount is offset against the \$9,337.50 registration fees due for this offering. The balance of the registration fee, \$791.03, is being paid herewith.

PROSPECTUS SUPPLEMENT

(To Prospectus Dated October 2, 2017)

Up to \$75,000,000

Common Stock

We have previously entered into a Controlled Equity OfferingSM sales agreement, dated May 10, 2016, with Cantor Fitzgerald & Co., or Cantor, relating to the offer and sale of shares of our common stock offered by this prospectus supplement. In accordance with the terms of the sales agreement, under this prospectus supplement we may offer and sell shares of our common stock, \$0.001 par value per share, having an aggregate offering price of up to \$75.0 million from time to time through Cantor, acting as agent.

Our common stock is listed on The Nasdaq Global Market under the symbol ZGNX. On December 20, 2017, the last reported sale price of our common stock on The Nasdaq Global Market was \$38.45 per share.

Sales of our common stock, if any, under this prospectus supplement will be made by any method permitted that is deemed an at the market offering as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended, or the Securities Act, including sales made directly on or through the Nasdaq Global Market or any other existing trading market for our common stock. Cantor is not required to sell any specific amount, but will act as our sales agent using commercially reasonable efforts consistent with its normal trading and sales practices. There is no arrangement for funds to be received in any escrow, trust or similar arrangement.

Cantor will be entitled to compensation at a commission rate up to 3.0% of the gross sales price per share sold. In connection with the sale of the common stock on our behalf, Cantor will be deemed to be an underwriter within the meaning of the Securities Act and the compensation of Cantor will be deemed to be underwriting commissions or discounts.

Investing in our securities involves risks. See the <u>Risk Factors</u> on page S-7 of this prospectus supplement concerning factors you should consider before investing in our securities.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus supplement or the accompanying prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus supplement is December 22, 2017.

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ABOUT THIS PROSPECTUS SUPPLEMENT

This prospectus supplement relates to the offering of our common stock. Before buying any of the common stock that we are offering, we urge you to carefully read this prospectus supplement, together with the accompanying prospectus and information incorporated by reference as described under the heading Where You Can Find More Information; Incorporation by Reference. These documents contain important information that you should consider when making your investment decision.

We provide information to you about this offering of our common stock in two separate documents that are bound together: (1) this prospectus supplement, which describes the specific details regarding this offering; and (2) the accompanying base prospectus, which provides general information, some of which may not apply to this offering. Generally, when we refer to this prospectus, we are referring to both documents combined. If information in this prospectus supplement is inconsistent with the accompanying base prospectus, you should rely on this prospectus supplement. To the extent there is a conflict between the information contained in this prospectus supplement, on the one hand, and the information contained in any document incorporated by reference in this prospectus supplement, on the other hand, you should rely on the information in this prospectus supplement. If any statement in one of these documents is inconsistent with a statement in another document having a later date for example, a document incorporated by reference into this prospectus supplement the statement in the document having the later date modifies or supersedes the earlier statement. You should read this prospectus supplement and the accompanying prospectus, including the information incorporated by reference and any free writing prospectus that we have authorized for use in connection with this offering, in their entirety before making an investment decision.

You should rely only on the information contained or incorporated by reference in this prospectus supplement and the accompanying prospectus, along with the information contained in any free writing prospectus that we have authorized for use in connection with this offering. We have not, and Cantor Fitzgerald & Co. has not, authorized anyone to provide you with information that is different. We are offering to sell and seeking offers to buy shares of our common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus supplement, the accompanying prospectus, the documents and information incorporated by reference in this prospectus supplement and the accompanying prospectus, and any free writing prospectus that we have authorized for use in connection with this offering are accurate only as of their respective dates, regardless of the time of delivery of this prospectus supplement or of any sale of our common stock.

When we refer to Zogenix, we, our, us and the Company in this prospectus supplement, we mean Zogenix, Inc. including its consolidated subsidiary, unless otherwise specified. When we refer to you, we mean the holders of the applicable series of securities.

We use our registered trademarks, DosePro® and Zogenix , in this prospectus supplement. All other trademarks, trade names and service marks appearing in this prospectus supplement or the documents incorporated by reference herein 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. Solely for convenience, trademarks and tradenames referred to in this prospectus supplement appear without the ® and symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or that the applicable owner will not assert its rights, to these trademarks and tradenames.

WHERE YOU CAN FIND MORE INFORMATION; INCORPORATION BY REFERENCE

Available Information

We file reports, proxy statements and other information with the SEC. Information filed with the SEC by us can be inspected and copied at the Public Reference Room maintained by the SEC at 100 F Street, N.E., Washington, D.C. 20549. You may also obtain copies of this information by mail from the Public Reference facilities of the SEC at prescribed rates. Further information on the operation of the SEC s Public Reference Room in Washington, D.C. can be obtained by calling the SEC at 1-800-SEC-0330. The SEC also maintains a web site that contains reports, proxy and information statements and other information about issuers, such as us, who file electronically with the SEC. The address of that website is http://www.sec.gov.

Our web site address is www.zogenix.com. The information on our web site, however, is not, and should not be deemed to be, a part of this prospectus supplement.

This prospectus supplement and the accompany prospectus are part of a registration statement that we filed with the SEC and does not contain all of the information in the registration statement. The full registration statement may be obtained from the SEC or us, as provided below. Forms of the indenture and other documents establishing the terms of the offered securities are or may be filed as exhibits to the registration statement. Statements in this prospectus supplement about these documents are summaries and each statement is qualified in all respects by reference to the document to which it refers. You should refer to the actual documents for a more complete description of the relevant matters. You may inspect a copy of the registration statement at the SEC s Public Reference Room in Washington, D.C. or through the SEC s website, as provided above.

Incorporation by Reference

The SEC s rules allow us to incorporate by reference information into this prospectus supplement, which means that we can disclose important information to you by referring you to another document filed separately with the SEC. The information incorporated by reference is deemed to be part of this prospectus supplement, and subsequent information that we file with the SEC will automatically update and supersede that information. Any statement contained in a previously filed document incorporated by reference will be deemed to be modified or superseded for purposes of this prospectus supplement to the extent that a statement contained in this prospectus supplement modifies or replaces that statement.

We incorporate by reference our documents listed below and any future filings made by us with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended, which we refer to as the Exchange Act in this prospectus supplement, between the date of this prospectus supplement and the termination of the offering of the securities described in this prospectus supplement. We are not, however, incorporating by reference any documents or portions thereof, whether specifically listed below or filed in the future, that are not deemed filed with the SEC, including our Compensation Committee report and performance graph or any information furnished pursuant to Items 2.02 or 7.01 of Form 8-K or related exhibits furnished pursuant to Item 9.01 of Form 8-K.

This prospectus supplement and the accompanying prospectus incorporate by reference the documents set forth below that have previously been filed with the SEC:

our Annual Report on Form 10-K for the year ended December 31, 2016, filed with the SEC on March 10, 2017;

our Quarterly Reports on Form 10-Q for the quarter ended March 31, 2017, June 30, 2017, September 30, 2017, filed with the SEC on May 4, 2017, August 8, 2017 and November 7, 2017, respectively;

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our Current Reports on Form 8-K filed with the SEC on January 30, 2017, March 1, 2017, April 28, 2017, May 23, 2017, June 22, 2017, August 3, 2017, September 22, 2017, September 29, 2017, October 2, 2017, October 3, 2017, November 22, 2017, November 29, 2017, December 4, 2017 and December 22, 2017;

our Definitive Proxy Statement on Schedule 14A (other than information furnished rather than filed), filed with the SEC on April 12, 2017; and

the description of our Common Stock contained in our registration statement on Form 8-A, filed with the SEC on November 12, 2010, and any amendment or report filed with the SEC for the purpose of updating the description.

All reports and other documents we subsequently file pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act prior to the termination of this offering, including all such documents we may file with the SEC after the date of the initial registration statement and prior to the effectiveness of the registration statement, but excluding any information furnished to, rather than filed with, the SEC, will also be incorporated by reference into this prospectus supplement and deemed to be part of this prospectus supplement from the date of the filing of such reports and documents.

You may request a free copy of any of the documents incorporated by reference in this prospectus supplement (other than exhibits, unless they are specifically incorporated by reference in the documents) by writing or telephoning us at the following address:

Zogenix, Inc.

Attn: Corporate Secretary

5858 Horton Street, #455

Emeryville, CA 94608

(510) 550-8300

Exhibits to the filings will not be sent, however, unless those exhibits have specifically been incorporated by reference in this prospectus supplement and the accompanying prospectus.

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PROSPECTUS SUPPLEMENT SUMMARY

The items in the following summary are described in more detail later in this prospectus supplement and in the accompanying prospectus. This summary provides an overview of selected information and does not contain all the information you should consider before investing in our common stock. Therefore, you should read the entire prospectus supplement, the accompanying prospectus and any free writing prospectus that we have authorized for use in connection with this offering carefully, including the Risk Factors section, and other documents or information included or incorporated by reference in this prospectus supplement and the accompanying prospectus before making any investment decision.

Zogenix, Inc.

Company Overview

We are a pharmaceutical company committed to developing and commercializing central nervous system, or CNS, therapies that address specific clinical needs for people living with orphan and other CNS disorders who need innovative treatment alternatives to help them improve their daily functioning. Our current primary area of focus is orphan or rare childhood-onset epilepsy disorders.

We currently own and control worldwide development and commercialization rights to ZX008, our lead product candidate. ZX008 is low-dose fenfluramine for the treatment of seizures associated with Dravet syndrome and Lennox-Gastaut syndrome, or LGS.

Dravet syndrome is a rare and catastrophic form of pediatric-onset epilepsy with life threatening consequences for patients and for which current treatment options are very limited. ZX008 has received orphan drug designation in the United States and European Union, or the EU, for the treatment of Dravet syndrome. In January 2016, we received notification of Fast Track designation from the U.S. Food and Drug Administration, or the FDA, for ZX008 for the treatment of Dravet syndrome. We initiated our Phase 3 clinical trials in North America (Study 1501) in January 2016 and in Europe and Australia in June 2016 (Study 1502). Study 1501 and Study 1502 are each identical randomized, double-blind, placebo-controlled studies of ZX008 as adjunctive therapy for patients with uncontrolled seizures who have Dravet syndrome. In January 2017, we announced our plan to report top-line results from Study 1501 and Study 1502 via a prospective merged study analysis approach whereby top-line results from the first 119 subjects randomized into either Study 1501 or 1502 would be reported initially as Study 1. In April 2017, we completed enrollment of Study 1 and, in September 2017, we announced positive top-line results for Study 1. The trial met its primary objective of demonstrating that ZX008, at a dose of 0.8 mg/kg/day, 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). ZX008 0.8 mg/kg/day also demonstrated statistically significant improvements versus placebo in all key secondary measures, including the proportion of patients with clinically meaningful reductions in seizure frequency and longest seizure-free interval. The same analyses comparing a 0.2 mg/kg/day ZX008 dose versus placebo also demonstrated statistically significant improvement compared with placebo.

In September 2016, we initiated the pharmacokinetic and safety profile portion of Study 1504, a two-part, double blind, randomized, two arm pivotal Phase 3 clinical trial of ZX008 in Dravet syndrome patients who are taking stiripentol, valproate and clobazam as part of their baseline standard care. In February 2017, we initiated the safety and efficacy portion of Study 1504, a two-arm study that compares ZX008 versus placebo across the titration and 12-week maintenance periods at multiple sites, which currently includes sites in France, the Netherlands, United States, Canada, Germany, the United Kingdom and Spain. Study 1504 will enroll approximately 40 patients per

treatment group. We expect to report top-line results from Study 1504 in the first half of 2018. We believe we are on track to submit applications for regulatory approvals for ZX008 in the United States and Europe in the second half of 2018.

LGS is another rare and catastrophic form of pediatric-onset epilepsy with life threatening consequences for patients and for which current treatment options are very limited. Beginning in first quarter of 2016, we funded an open-label dose-finding twenty-patient investigator initiated study in patients with LGS. In December 2016, we presented initial data from an interim analysis of the first 13 patients to have completed at least 12 weeks of this Phase 2 open-label, dose-finding clinical trial at the American Epilepsy Society Meeting. These data demonstrated that ZX008 provided clinically meaningful improvement in major motor seizure frequency in patients with severe refractory LGS, with seven out of 13 patients (54%) achieving at least a 50% reduction in the number of major motor seizures, at doses below the 0.8 mg/kg/day maximum. In addition, ZX008 was generally well tolerated without any observed signs or symptoms of valvulopathy or pulmonary hypertension, as expected based on our epilepsy program to date. We believe these data indicate that ZX008 has the potential to be a safe and effective adjunctive treatment for LGS. Based on the strength of the LGS data generated, in the first quarter of 2017, we submitted an investigational new drug, or IND, application to the FDA to initiate a Phase 3 program of ZX008 in LGS, which became effective in April 2017. In the first half of 2017, ZX008 received orphan drug designation for the treatment of LGS from the FDA in the United States and the European Medicines Agency in the EU. In November 2017, we announced that we had initiated our Phase 3 clinical trial for LGS.

Corporate Information

We were formed as a Delaware corporation on May 11, 2006 as SJ2 Therapeutics, Inc. We commenced our operations on August 25, 2006 and changed our name to Zogenix, Inc. on August 28, 2006. Our principal executive offices are located at 5858 Horton Street, Suite 455, Emeryville, California 94608, and our telephone number is 1-866-ZOGENIX (1-866-964-3649). We formed a wholly-owned subsidiary, Zogenix Europe Limited, in June 2010, a company organized under the laws of England and Wales and which is located in the United Kingdom, and whose principal operations were to support the manufacture of the DosePro technology. Zogenix International Limited is a wholly-owned subsidiary of Zogenix Europe Limited which was acquired in October 2014.

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THE OFFERING

Common stock offered by us pursuant to this Shares of our common stock having an aggregate offering price of up to prospectus supplement \$75.0 million.

Plan of Distribution At the market offering that may be made from time to time on The

Nasdaq Global Market or other market for our common stock in the United States through our agent, Cantor Fitzgerald & Co. See the section entitled Plan of Distribution on page S-11 of this prospectus supplement.

entitied <u>Than of Distribution</u> on page 5-11 of this prospectus supplemen

Use of Proceeds We intend to use the net proceeds from this offering to fund clinical

research and development of ZX008, including the completion of our ongoing clinical trials and regulatory submissions for Dravet syndrome and to fund Phase 3 clinical development for Lennox-Gastaut syndrome, commercial infrastructure for ZX008 for Dravet syndrome and working

capital and general corporate purposes.

Risk Factors You should read the Risk Factors section of this prospectus supplement

and in the documents incorporated by reference in this prospectus supplement for a discussion of factors to consider before deciding to

invest in our common stock.

Nasdaq Global Market symbol ZGNX

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RISK FACTORS

Investment in any securities offered pursuant to this prospectus supplement involves risks. You should carefully consider the risk factors described below and the risk factors incorporated by reference to our most recent Annual Report on Form 10-K and any subsequent Quarterly Reports on Form 10-Q or Current Reports on Form 8-K we file after the date of this prospectus supplement, and all other information contained or incorporated by reference into this prospectus supplement, as updated by our subsequent filings under the Exchange Act, before acquiring any of such securities. The occurrence of any of these risks might cause you to lose all or part of your investment in the offered securities.

Risks Relating to this Offering

If you purchase shares of our common stock sold in this offering, you will experience immediate and substantial dilution in the net tangible book value of your shares. In addition, we may issue additional equity or convertible debt securities in the future, which may result in additional dilution to investors.

The price per share of our common stock being offered may be higher than the net tangible book value per share of our outstanding common stock prior to this offering. Assuming that an aggregate of 1,950,585 shares of our common stock are sold at a price of \$38.45 per share, the last reported sale price of our common stock on The Nasdaq Global Market on December 20, 2017, for aggregate gross proceeds of approximately \$75.0 million, and after deducting commissions and estimated offering expenses payable by us, new investors in this offering will incur immediate dilution of \$37.61 per share. For a more detailed discussion of the foregoing, see the section entitled Dilution below. To the extent outstanding stock options or warrants are exercised, there will be further dilution to new investors. In addition, to the extent we need to raise additional capital in the future and we issue additional shares of common stock or securities convertible or exchangeable for our common stock, our then existing stockholders may experience dilution and the new securities may have rights senior to those of our common stock offered in this offering.

We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from this offering, including for any of the purposes described in the section entitled. Use of Proceeds, and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. Our management might not apply our net proceeds in ways that ultimately increase the value of your investment. We expect to use the net proceeds from this offering to fund clinical research and development of ZX008, including the completion of our ongoing clinical trials and regulatory submissions for Dravet syndrome and to fund Phase 3 clinical development for Lennox-Gastaut syndrome, commercial infrastructure for ZX008 for Dravet syndrome and working capital and general corporate purposes. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest the net proceeds from this offering in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders. If we do not invest or apply the net proceeds from this offering in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus supplement, the accompanying prospectus and the documents incorporated by reference herein contain forward-looking statements. All statements other than statements of historical facts contained in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference herein are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. This prospectus supplement, the accompanying prospectus and the documents incorporated by reference herein also contain estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

In some cases, you can identify forward-looking statements by terms such as may, will. should, expect, plan, anticipate, intend, project, contemplates, believes, estimates, predicts, potential or could, target, negative of these terms or other similar expressions. The forward-looking statements in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference herein are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this prospectus supplement and are subject to a number of risks, uncertainties and assumptions, including those under Risk Factors and elsewhere in this prospectus supplement. The events and circumstances reflected in our forward-looking statemen