ZOGENIX, INC.
Form 424B3
February 14, 2013
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Filed Pursuant to Rule 424(b)(3)
Registration No. 333-185900

PROSPECTUS

Common Stock

15,784,200 Shares

This prospectus relates to the offering by us of 15,784,200 shares of our common stock that may be issued upon the exercise of warrants that we sold in connection with the public offering completed on July 27, 2012. See Warrants.

Our common stock is traded on the Nasdaq Global Market under the symbol ZGNX. On February 13, 2013, the closing price of our common stock was $1.44.

Investing in our securities involves risks. See Risk Factors on page 3.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is February 14, 2013

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ABOUT ZOGENIX

We are a pharmaceutical company commercializing and developing products for the treatment of central nervous system disorders and pain. Our first commercial product, Sumavel® DosePro® (sumatriptan injection) Needle-free Delivery System, was launched in January 2010. Sumavel DosePro offers fast-acting, easy-to-use, needle-free subcutaneous administration of sumatriptan for the acute treatment of migraine and cluster headache in a pre-filled, single-use delivery system. Sumavel DosePro is the first drug product approved by the U.S. Food and Drug Administration, or FDA, that allows for the needle-free, subcutaneous delivery of medication. In June 2012, we entered into a co-promotion agreement with Mallinckrodt LLC pursuant to which we granted to Mallinckrodt a co-exclusive right to promote Sumavel DosePro to a mutually agreed prescriber audience in the United States, beginning no later than August 2012. Our lead product candidate, Zohydro ER (hydrocodone bitartrate, formerly ZX002) is a 12-hour extended-release formulation of hydrocodone without acetaminophen for the treatment of moderate to severe chronic pain requiring around-the-clock opioid therapy. We completed Phase 3 development of Zohydro ER in 2011, and we submitted the New Drug Application, or NDA, for Zohydro ER to the FDA in May 2012. In July 2012, the FDA accepted our NDA as being sufficiently complete for a full review and assigned a Prescription Drug User Fee Act, or PDUFA, target action date of March 1, 2013. In December 2012, an advisory committee convened by the FDA voted 2-11 (with 1 abstention) against the approval of Zohydro ER. The advisory committee provides the FDA with independent expert advice and recommendations; however, the final decision regarding approval is made by the FDA. Sumavel DosePro and Zohydro ER each has the potential to address significant unmet medical needs and become important and widely-used additions to the treatment options available to patients and physicians in the United States multi-billion dollar migraine and chronic pain markets, respectively.

We are also developing Relday , a proprietary, long-acting injectable formulation of risperidone using Durect Corporation s SABER controlled-release formulation technology through a July 2011 development and license agreement with Durect. Risperidone is used to treat the symptoms of schizophrenia and bipolar disorder in adults and teenagers 13 years of age and older. If successfully developed and approved, we believe Relday may be the first subcutaneous antipsychotic product that allows for once-monthly dosing. The existing long-acting injectable risperidone product achieved global net sales of $1.58 billion in 2011 with 72% of net sales outside of the United States, according to industry reports, and requires twice monthly, 2 mL intramuscular injections with a 21 gauge or larger needle. We believe Durect s SABER controlled-release technology will allow Relday to be delivered subcutaneously on a once-monthly basis with a simplified dosing regimen, improved pharmacokinetic profile and significant reduction in injection volume versus currently marketed long-acting injectable antipsychotics. Based upon these characteristics, Relday may provide an important alternative to currently marketed long-acting injectable antipsychotics as well as a new long-acting treatment option for patients that currently use daily oral antipsychotic products. In May 2012, we filed an investigational new drug, or IND, application with the FDA. In July 2012, we initiated our first IND clinical trial for Relday. This Phase 1 clinical trial was a single-center, open-label, safety and pharmacokinetic trial of 30 patients with chronic, stable schizophrenia or schizoaffective disorder. We announced positive single-dose pharmacokinetic results from the Phase 1 clinical trial on January 3, 2013. Adverse events in the Phase 1 trial in patients diagnosed with schizophrenia were generally mild to moderate and consistent with other risperidone products. Based on the favorable safety and pharmacokinetic profile demonstrated with the 25 mg and 50 mg once-monthly doses tested in the Phase 1 trial, we extended the study to include an additional cohort of 10 patients at a 100 mg dose of the same formulation. The addition of this 100 mg dose to the study will enable evaluation of dose proportionality across the full dose range that would be anticipated to be used in clinical practice. Positive results from this study extension would better position us to begin a multi-dose clinical trial, which would provide the required steady-state pharmacokinetic and safety data prior to initiating Phase 3 development studies. We expect to complete the extension of the Phase 1 clinical trial during the second quarter of 2013. The development of Relday will first focus on its delivery by conventional needle and syringe in order to allow the administration of different volumes of the same formulation of Relday by a healthcare professional. We anticipate that the introduction of our DosePro needle-free technology for administration of Relday can occur later in development or as part of life cycle management after further work involving formulation development, technology enhancements, and applicable regulatory approvals.

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Our DosePro technology is a novel, patent-protected, needle-free drug delivery system designed for self-administration of a pre-filled, single dose of liquid drug. We believe the FDA s approval of Sumavel DosePro represents an important validation of the technology. Results from our pre-clinical and clinical studies demonstrate that DosePro can be used successfully with small molecules and biological products, including protein therapeutics and monoclonal antibodies. We are building our internal product pipeline by investigating proven drugs that can be paired with DosePro to enhance their benefits and commercial attractiveness. We are evaluating the market potential, formulation requirements and clinical development pathway of an additional central nervous system compound that could be paired with DosePro to enhance its commercial attractiveness. We are also seeking to capitalize on our DosePro technology by out-licensing it to potential partners enabling them to enhance, differentiate or extend the life cycle of their proprietary injectable products. In March 2012, we entered into a Co-Marketing and Option Agreement with Battelle Memorial Institute, or Battelle, pursuant to which we granted to Battelle the exclusive right to co-market our DosePro drug delivery technology to a specified list of Battelle s pharmaceutical clients. We acquired the DosePro technology and related intellectual property from Aradigm Corporation in August 2006.

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 12400 High Bluff Drive, Suite 650, San Diego, CA 92130, 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 are to support the manufacture of the DosePro technology. Our website address is www.zogenix.com. The information on, or accessible through, our website is not part of this prospectus. Unless the context requires otherwise, references in this prospectus to Zogenix, we, us and our refer to Zogenix, Inc., including, as of June 7, 2010, its consolidated subsidiary.

DosePro®, Intraject®, Relday , Sumavel®, Zogenix and Zohydro ER are our trademarks. All other trademarks, trade names and service marks appearing in this prospectus 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.

RISK FACTORS

You should carefully consider the specific risks set forth under Risk Factors in the applicable prospectus supplement, under Risk Factors under Item 1A of Part I of our most recent annual report on Form 10-K, and under Risk Factors under Item 1A of Part II of our subsequent quarterly reports on Form 10-Q, as updated by our subsequent filings under the Securities Exchange Act of 1934, as amended, or the Exchange Act, each of which is incorporated by reference in this prospectus, before making an investment decision. For more information, see Information Incorporated by Reference.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference herein contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Exchange Act that involve substantial risks and uncertainties. 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 terminology, although not all forward-looking statements contain

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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. These forward-looking statements include, but are not limited to, statements about:

- our ability to maintain and increase market demand for, and sales of, Sumavel DosePro;
- our ability to successfully execute our sales and marketing strategy for the commercialization of Sumavel DosePro;
- the progress and timing of clinical trials for our product candidates, including the initiation of a multi-dose clinical trial and Phase 3 development studies for Relday, the timing of completion of the extension of the Phase 1 trial for Relday and the introduction of DosePro technology with Relday and the timing thereof;
- the potential for the FDA to approve the NDA for Zohydro ER despite the advisory committee s recommendation against approval;
- the timing of submissions to, and decisions made by, the FDA and other regulatory agencies, including foreign regulatory agencies, and demonstrating the safety and efficacy of Zohydro ER or any other product candidates to the satisfaction of the FDA and such other agencies;
- adverse side effects or inadequate therapeutic efficacy of Sumavel DosePro that could result in product recalls, market withdrawals or product liability claims;
- the safety and efficacy of Zohydro ER and our other product candidate;
- the market potential for migraine treatments, and our ability to compete within that market;
- the goals of our development activities and estimates of the potential markets for our product candidates, and our ability to compete within those markets;
- estimates of the capacity of manufacturing and other facilities to support our product and product candidates;
- our ability to ensure adequate and continued supply of Sumavel DosePro to successfully meet anticipated market demand;
- our and our licensors ability to obtain, maintain and successfully enforce adequate patent and other intellectual property protection of our products and product candidates and the ability to operate our business without infringing the intellectual property rights of others;
- our ability to obtain and maintain adequate levels of coverage and reimbursement from third-party payors for Sumavel DosePro or any of our other 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 legislation; and

projected cash needs and our expected future revenues, operations and expenditures.

You should read this prospectus and the documents incorporated by reference herein completely and with the understanding that our actual results may differ materially from what we expect as expressed or implied by our forward-looking statements. In light of the significant risks and uncertainties to which our forward-looking statements are subject, you should not place undue reliance on or regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified timeframe, or at all. These forward-looking statements represent our estimates and assumptions only as of the date of this prospectus regardless of the time of delivery of this prospectus or any sale of our common stock and, except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements,

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whether as a result of new information, future events or otherwise after the date of this prospectus. 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.

WARRANTS

In connection with our public offering completed on July 27, 2012, we entered into an Underwriting Agreement dated July 24, 2012 with Stifel, Nicolaus & Company, Incorporated, Wells Fargo Securities, LLC, Leerink Swann LLC, Oppenheimer & Co. Inc. and William Blair & Company, L.L.C., pursuant to which we sold 35,058,300 shares of our common stock and warrants to purchase 15,784,200 shares of our common stock, or the Warrants. This prospectus relates to the offering of the shares issuable upon exercise of the Warrants. The Warrants, which are exercisable on or after the one-year anniversary of their original issuance and on or before the date that is five years after their original issuance, entitle the holders thereof to purchase shares of our common stock at an exercise price of $2.50 per share of common stock.

USE OF PROCEEDS

We would receive proceeds of up to approximately $39,460,500 if all of the Warrants were exercised for cash. We anticipate that the net proceeds, if any, would be used to fund the ongoing commercialization of Sumavel DosePro, clinical development of our product candidates, and, if approved by the FDA, the commercialization of Zohydro, and for working capital and other general corporate purposes. Pending the uses described above, we plan to invest any proceeds in short- and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government. We anticipate that the Warrants will be exercised from time to time based upon the decisions of the individual warrant holders. To the extent that the Warrants are not exercised, our net proceeds will be reduced. There is no assurance that any or all the Warrants will be exercised or that we will receive the net proceeds that would be available if all the Warrants had been exercised.

PLAN OF DISTRIBUTION

The shares issuable upon exercise of the Warrants are offered solely by us, and no underwriters are participating in this offering. We anticipate that the shares offered will be previously authorized but unissued. The Warrants may be exercised by giving written notice and paying the exercise price in accordance with their terms.

LEGAL MATTERS

Latham & Watkins LLP, San Diego, California, will issue an opinion about certain legal matters with respect to the securities.

EXPERTS

Ernst & Young LLP, independent registered public accounting firm, has audited our consolidated financial statements and schedule included in our Annual Report on Form 10-K for the year ended December 31, 2011 (which contains an explanatory paragraph describing conditions that raise substantial doubt about our ability to continue as a going concern as described in Note 1 to our consolidated financial statements), as set forth in their report, which is incorporated by reference in this prospectus and elsewhere in the registration statement. Our financial statements and schedule are incorporated by reference in reliance on Ernst & Young LLP s report, given on their authority as experts in accounting and auditing.

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WHERE YOU CAN FIND MORE INFORMATION

We have filed with the Commission a registration statement on Form S-3 under the Securities Act, of which this prospectus forms a part. The rules and regulations of the Commission allow us to omit from this prospectus certain information included in the registration statement. For further information about us and our securities, you should refer to the registration statement and the exhibits and schedules filed with the registration statement. With respect to the statements contained in this prospectus regarding the contents of any agreement or any other document, in each instance, the statement is qualified in all respects by the complete text of the agreement or document, a copy of which has been filed as an exhibit to the registration statement.

We file reports, proxy statements and other information with the Commission under the Exchange Act. You may read and copy this information from the Public Reference Room of the Commission, 100 F Street, N.E., Room 1580, Washington, D.C. 20549, at prescribed rates. You may obtain information on the operation of the Public Reference Room by calling the Commission at 1-800-SEC-0330. The Commission also maintains an Internet website that contains reports, proxy statements and other information about issuers, like us, that file electronically with the Commission. The address of that website is *www.sec.gov*.

INFORMATION INCORPORATED BY REFERENCE

The Commission allows us to incorporate by reference the information we file with it which means that we can disclose important information to you by referring you to those documents instead of having to repeat the information in this prospectus. The information incorporated by reference is considered to be part of this prospectus, and later information that we file with the Commission will automatically update and supersede this information. We incorporate by reference the documents listed below and any future information filed (rather than furnished) with the Commission under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act between the date of this prospectus and the termination of the offering and also between the date of the initial registration statement and prior to effectiveness of the registration statement, provided, however, that we are not incorporating any information furnished under Item 2.02 or Item 7.01 of any current report on Form 8-K:

- our annual report on Form 10-K for the year ended December 31, 2011, which was filed on March 12, 2012;
- our quarterly report on Form 10-Q for the quarter ended March 31, 2012, which was filed on May 15, 2012, the quarter ended June 30, 2012, which was filed on August 9, 2012, and the quarter ended September 30, 2012, which was filed on November 8, 2012;
- our definitive proxy statement on Schedule 14A (other than information furnished rather than filed), which was filed on April 30, 2012;
- our current reports on Form 8-K, which were filed on March 30, 2012, April 17, 2012, May 2, 2012, May 30, 2012, June 6, 2012, June 7, 2012, July 12, 2012, July 16, 2012, July 24, 2012, August 1, 2012, November 2, 2012, November 26, 2012, December 10, 2012, January 3, 2013 and February 7, 2013;
- our current report on Form 8-K/A, which was filed on July 25, 2012; and
- the description of our common stock contained in our registration statement on Form 8-A, which was filed on November 12, 2010, including any amendments or reports filed for the purpose of updating the description.

These documents may also be accessed on our website at *www.zogenix.com*. Except as otherwise specifically incorporated by reference in this prospectus, information contained in, or accessible through, our website is not a part of this prospectus.

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We will furnish without charge to you, upon written or oral request, a copy of any or all of the documents incorporated by reference, including exhibits to these documents by writing or telephoning us at the following address:

Zogenix, Inc.

12400 High Bluff Drive, Suite 650

San Diego, CA 92130

Attention: Corporate Secretary

(858) 259-1165