ZOGENIX, INC.
Form S-1
August 24, 2011
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As filed with the Securities and Exchange Commission on August 24, 2011

Registration No. 333-

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-1

REGISTRATION STATEMENT

Under

The Securities Act of 1933

ZOGENIX, INC.

(Exact name of registrant as specified in its charter)

Delaware	**2834**	**20-5300780**

(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

12671 High Bluff Drive, Suite 200

San Diego, CA 92130

(858) 259-1165

(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

Roger L. Hawley

Chief Executive Officer

Zogenix, Inc.

12671 High Bluff Drive, Suite 200

San Diego, CA 92130

(858) 259-1165

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ¨

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

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

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer x (Do not check if a smaller reporting company)	Smaller reporting company ¨

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered(1)	Proposed Maximum Aggregate Offering Price per Share(2)	Proposed Maximum Aggregate Offering Price(2)	Amount of Registration Fee
Common Stock, $0.001 par value	13,800,000	$3.44	$47,472,000	$5,512

(1) Includes 1,800,000 additional shares that the underwriters have the option to purchase.
(2) Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule 457(c) under the Securities Act of 1933, as amended, based on the average of the high and low sales price of the common stock as reported on the Nasdaq Global Market on August 22, 2011.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities or the solicitation of an offer to buy these securities in any state in which such offer, solicitation or sale is not permitted.

SUBJECT TO COMPLETION DATED AUGUST 24, 2011

PROSPECTUS

12,000,000 Shares of Common Stock

We are selling 12,000,000 shares of our common stock.

Our common stock is listed on the Nasdaq Global Market under the symbol ZGNX. On August 22, 2011, the last reported sale price of our common stock on the Nasdaq Global Market was $3.40 per share.

Investing in our common stock involves a high degree of risk. Before buying any shares you should read the discussion of material risks of investing in our common stock in Risk Factors beginning on page 10.

	Per Share	Total
Public Offering Price	$	$
Underwriting Discounts and Commissions	$	$
Proceeds to us, before expenses	$	$

We have granted a 30-day option to the underwriters to purchase up to 1,800,000 additional shares of our common stock (15% of the shares sold).

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 underwriters expect to deliver the shares on or about , 2011 through the book-entry facilities of the Depository Trust Company.

Joint Book-Running Managers

Leerink Swann **Wells Fargo Securities**

Stifel Nicolaus Weisel **William Blair & Company** **Oppenheimer & Co.**

The date of this prospectus is , 2011.

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We launched our first product, Sumavel® DosePro®, using our proprietary DosePro technology in January 2010.

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission. This prospectus does not contain all of the information included in the registration statement. For a more complete understanding of our business and the securities we are offering, you should carefully read the registration statement, including its exhibits and this prospectus before making an investment decision.

You should rely only on the information contained in this prospectus and in any free writing prospectus that we may provide to you in connection with this offering. Neither we nor any of the underwriters has authorized anyone to provide you with information different from, or in addition to, that contained in this prospectus or any such free writing prospectus. If anyone provides you with different or inconsistent information, you should not rely on it. Neither we nor any of the underwriters is making an offer to sell or seeking offers to buy these securities in any jurisdiction where or to any person to whom the offer or sale is not permitted. The information in this prospectus is accurate only as of the date on the front cover of this prospectus and the information in any free writing prospectus that we may provide you in connection with this offering is accurate only as of the date of that free writing prospectus. Our business, financial condition, results of operations and prospects may have changed since those dates.

For investors outside the United States: Neither we nor any of the underwriters has done anything that would permit this offering or possession or distribution of this prospectus or any free writing prospectus we may provide to you in connection with this offering in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus and any such free writing prospectus outside of the United States.

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PROSPECTUS SUMMARY

This summary does not contain all of the information you should consider before buying shares of our common stock. You should read the entire prospectus carefully, especially the Risk Factors section and our financial statements and the related notes appearing at the end of this prospectus, before deciding to invest in shares of our common stock. Unless the context requires otherwise, references in this prospectus to Zogenix, we, us and our refer to Zogenix, Inc., including its consolidated subsidiary, Zogenix Europe Limited.

Overview

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. Our lead product candidate, Zohydro, is a novel, oral, single-entity extended-release formulation of *hydrocodone* currently in Phase 3 development for the treatment of moderate to severe chronic pain in patients requiring around-the-clock opioid therapy. We reported positive top-line results from our pivotal Phase 3 efficacy trial for Zohydro in August 2011 and expect to submit a New Drug Application, or NDA, with the FDA by early 2012. Sumavel DosePro and Zohydro 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.

Sumavel DosePro may serve as a treatment alternative to oral and nasal triptans and may offer simple, convenient administration when compared to traditional, needle-based *sumatriptan* injection. According to its Prescribing Information, Sumavel DosePro can provide onset of migraine pain relief in as little as ten minutes for some patients. As a result, we believe that Sumavel DosePro has the potential to be prescribed by a broad physician audience, especially for difficult to treat migraine episodes.

Migraine is a syndrome that affects approximately 30 million people in the United States, according to a 2010 National Headache Foundation press release. Triptans are the class of drugs most often prescribed for treating migraines. In the United States in the 12 months ended December 2010, triptans generated sales of approximately $3.5 billion and *sumatriptan*, including branded and generic forms, represented the largest market share of the seven approved triptans, with sales of approximately $2.1 billion, according to Wolters Kluwer Pharma Solutions (Source® PHAST Institution/Retail).

We launched the commercial sale of Sumavel DosePro in the United States in January 2010 with our co-promotion partner, Astellas Pharma US, Inc., or Astellas. Our sales and marketing organization is comprised of approximately 100 professionals. Our field sales force of approximately 80 representatives promotes Sumavel DosePro primarily to neurologists and other prescribers of migraine medications, including headache clinics and headache specialists. To build upon our success in growing Sumavel DosePro prescriptions, we have initiated activities to expand our field sales force in the United States to approximately 95 sales representatives by the end of the third quarter of 2011. Our promotional efforts are complemented by our collaboration with Astellas and approximately 400 of its sales representatives, who are promoting Sumavel DosePro primarily to primary care physicians, OB/GYNs, emergency medicine physicians and urologists in the United States. We also have entered into a partnership for Sumavel DosePro with Desitin Arzneimittel GmbH to accelerate development and regulatory approvals in Europe and further enhance the global commercial potential of Sumavel DosePro.

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Sumavel DosePro has demonstrated significant quarterly growth in total prescriptions since its launch in January 2010. For the six months ended June 30, 2011, we recognized $16.2 million in net product revenue from sales of Sumavel DosePro, represented by more than 32,000 aggregate dispensed prescriptions (Source® PHAST Retail, January 2011 June 2011). Sumavel DosePro continues to add new and repeat prescribers in both the neurology and primary care settings. The product is also gaining use from a range of patient segments, including new triptan users, patients being converted to the product from other migraine drugs and patients who have been prescribed Sumavel DosePro and also have other triptan prescriptions. This experience is consistent with our belief that many patients will selectively use Sumavel DosePro for their more challenging migraine episodes, while continuing to use oral triptans to treat their less severe migraine episodes. Through our ongoing efforts with the largest commercial health plans, Sumavel DosePro is achieving broad coverage in the United States, with a reimbursement claims approval rate of approximately 80% since launch through June 2011 (Source® Dynamic Claims January 2010 June 2011).

Our lead product candidate, Zohydro, is a novel, oral, single-entity extended-release formulation of *hydrocodone* currently in Phase 3 development for the treatment of moderate to severe chronic pain in patients requiring around-the-clock opioid therapy. Zohydro utilizes Elan Pharma International Limited s, or Elan s, proprietary Spheroidal Oral Drug Absorption System, or SODAS® Technology, which serves to enhance the release profile of *hydrocodone* to provide consistent 12-hour pain relief relative to existing immediate-release combination formulations. Most marketed *hydrocodone* products contain the analgesic combination ingredient *acetaminophen,* which if taken in high quantities over time can cause liver toxicity. In June 2009, the FDA organized a joint advisory committee meeting that highlighted the public health problem of liver injury related to the use of *acetaminophen* in both over-the-counter and prescription products. Zohydro, if approved, may represent the first available extended-release version of *hydrocodone* and also the first *hydrocodone* product that is not combined with another analgesic. As a result, we believe Zohydro could generate sales from both patients who are using immediate-release opioid products on a chronic basis and patients already using extended-release opioids. We initiated the Phase 3 clinical development program for Zohydro in March 2010 and reported positive top-line results from our pivotal Phase 3 efficacy trial in August 2011. The trial successfully met its primary efficacy endpoint in demonstrating a significant difference (p=0.008) between the mean changes in daily pain intensity Numeric Rating Scale (NRS) scores between Zohydro and placebo groups. We expect to submit an NDA with the FDA by early 2012. We in-licensed exclusive U.S. rights to Zohydro from Elan in 2007.