ZOGENIX, INC.
Form 8-K
October 27, 2014

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d)

of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): October 24, 2014

ZOGENIX, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-34962**	**20-5300780**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

12400 High Bluff Drive, Suite 650, San Diego, CA 92130
(Address of Principal Executive Offices) (Zip Code)
Registrant s telephone number, including area code: (858) 259-1165

(Former Name or Former Address, if Changed Since Last Report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

¨ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

¨ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

¨ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

¨ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 1.01. Entry into a Material Definitive Agreement.

On October 24, 2014, Zogenix Europe Limited (Zogenix Europe), a wholly-owned subsidiary of Zogenix, Inc. (the Company or Zogenix) located in the United Kingdom, acquired Brabant Pharma Limited, a privately-held company organized under the laws of England and Wales (Brabant), pursuant to the terms of a Sale and Purchase Agreement (the Sale and Purchase Agreement), dated October 24, 2014, by and among Zogenix Europe, Zogenix, Brabant and Anthony Clarke, Richard Stewart, Ann Soenen-Darcis, Jennifer Watson, Reyker Nominees Limited and Aquarius Life Science Limited (collectively, the Sellers). In connection with the consummation of the transactions on October 24, 2014 (the closing) contemplated by the Sale and Purchase Agreement, Zogenix Europe purchased the issued share capital of Brabant from the Sellers (the Acquisition) and the Company agreed to guarantee the obligations, commitments, undertakings and warranties of Zogenix Europe. Brabant owns worldwide development and commercialization rights to Brabafen™, low-dose fenfluramine, for the treatment of Dravet syndrome (also known as Severe Myoclonic Epilepsy of Infancy). Dravet syndrome is a rare and catastrophic form of pediatric epilepsy with life threatening consequences for patients and current treatment options are very limited. Brabafen has recently received orphan drug designation in Europe and the United States for the treatment of Dravet syndrome.

Under the terms of the Sale and Purchase Agreement, at the closing Zogenix Europe paid to the Sellers consideration of (i) $20.0 million in cash (plus the $8.4 million which represents the net cash position of Brabant at the closing), of which $2.0 million (the escrow amount) will be deposited into escrow to fund potential indemnification claims for a period of 6 months, and (ii) 11,995,202 shares (the Shares) of the Company s common stock, par value $0.001 per share (the Common Stock). Zogenix Europe also committed to paying up to an aggregate amount of $50.0 million upon the achievement of specified regulatory milestones and $45.0 million upon the achievement of specified sales milestones. The Company has agreed to use commercially reasonable efforts (as defined in the Sale and Purchase Agreement) to develop and commercialize Brabafen and to achieve the milestones.

The safety and effectiveness of Brabafen has been evaluated in a continuing, long-term, open-label, study in 15 Dravet syndrome patients (the study). The average duration of treatment in the study is currently more than 12 years, with the longest duration of treatment at more than 26 years. More than two-thirds (67%) of patients were seizure free for at least a year after the latest assessment with an average seizure free period of 5.5 years. The majority (87%) of patients had a greater than 75% reduction in seizure frequency. Brabafen was shown to be well tolerated in the study, and treatment side effects were mild and transient for the entire study treatment period. There were no reports of pulmonary hypertension and there were no deaths. Two patients showed sub-clinical evidence of cardiac valve thickening that was judged to be clinically insignificant following detailed investigation by independent cardiologists. Similar findings spontaneously resolved in a third patient. Based upon feedback from the U.S. Food and Drug Administration and the European Medicines Agency, the Company expects to initiate two Phase 3 studies (of 40 to 60 Dravet syndrome patients per study) during the second quarter of 2015 in the United States and Europe, with top-line results potentially available in the first half of 2016.

In September 2012, Brabant entered into a collaboration and license agreement (the License Agreement) with the Universities of Antwerp and Leuven in Belgium (the Universities). Under the terms of the License Agreement, the Universities granted Brabant an exclusive worldwide license to use the data obtained from the study, as well as certain intellectual property related to fenfluramine for the treatment of Dravet syndrome. Brabant is required to pay a mid single-digit percentage royalty on net sales of fenfluramine or, in the case of a sublicense of fenfluramine, a percentage in the mid-twenties of the sub-licensing revenues. The License Agreement terminates in September 2020; however, upon the commencement of Phase 3 clinical trials of fenfluramine or marketing approval by a regulatory authority, the License Agreement will be extended until September 2045. The License Agreement may be terminated by the Universities if Brabant: (a) does not use commercially reasonable efforts to (i) develop and commercialize fenfluramine for the treatment of Dravet syndrome or related conditions stemming from infantile epilepsy, or (ii) seek approval of fenfluramine for the treatment of Dravet syndrome in the United States; or (b) if Brabant becomes insolvent, shall make an assignment for the benefit of creditors, or shall have a petition in bankruptcy filed for or against it or for any similar relief has been filed against it. The Company can terminate the License Agreement upon

specified prior written notice to the Universities.

Both Zogenix Europe and the Sellers agreed to customary warranties and covenants in the Sale and Purchase Agreement. The Sellers agreed to indemnify Zogenix Europe for certain matters, including breaches of warranties and covenants included in the Sale and Purchase Agreement, up to the escrow amount, subject to limited exceptions.

Pursuant to the Sale and Purchase Agreement, the Company has agreed to prepare and file a registration statement on Form S-3 covering the resale of the Shares issued to the Sellers within 90 days of the closing and to use

commercially reasonable efforts to cause such registration statement to be declared effective as promptly as practicable following the filing.

The foregoing descriptions of the terms of the Sale and Purchase Agreement and the License Agreement are qualified in their entirety by reference to the provisions of such agreement. A copy of the Sale and Purchase Agreement is attached hereto as Exhibit 10.1 and is incorporated herein by reference. The Company expects to file the License Agreement with the Company s Annual Report on Form 10-K.

Item 2.01. Completion of Acquisition or Disposition of Assets

On October 24, 2014, Zogenix Europe completed its acquisition of Brabant as described in Item 1.01, which description is incorporated herein by reference.

Item 3.02. Unregistered Sales of Equity Securities

As partial consideration for the acquisition of Brabant described above, on October 24, 2014, Zogenix issued an aggregate of 11,995,202 shares of Common Stock to the Sellers in connection with the closing of the Acquisition.

The Shares have not been registered under the Securities Act or any state securities laws. Zogenix is relying on the exemption from the registration requirements of the Securities Act by virtue of Section 4(2) thereof.

As described in Item 1.01 of this Current Report on Form 8-K, which is incorporated by reference into this item 3.02, Zogenix has agreed to file a registration statement for the resale of the Shares. The Shares may not be offered or sold in the United States absent registration or exemption from registration under the Securities Act and any applicable state securities laws. Neither this Current Report on Form 8-K nor any of the exhibits attached hereto is an offer to sell or the solicitation of an offer to buy shares of Common Stock or other securities of Zogenix.

Reference is made to the descriptions of the Sale and Purchase Agreement in Item 1.01 of this Current Report.

* * *

Zogenix cautions you that statements included in this Current Report on Form 8-K that are not a description of historical facts are forward-looking statements. Words such as believes, anticipates, plans, expects, indicates, w intends, potential, suggests, assuming, designed and similar expressions are intended to identify forward-looking statements. These statements are based on the company s current beliefs and expectations. These forward-looking statements include statements regarding the timing of the commencement of Phase 3 clinical trials for Brabafen and the receipt of top-line results from these clinical trials. The inclusion of forward-looking statements should not be regarded as a representation by Zogenix that any of its plans will be achieved. Actual results may differ from those set forth in this report due to the risk and uncertainties inherent in Zogenix s business, including, without limitation: risks associated with the acquisition of Brabant and integration of Brabant s operations into Zogenix s business, including an increase in near and long-term expenditures, exposure to unknown liabilities and diversion of Zogenix s management s time and attention; the inherent risks of clinical development of Brabafen; the potential that earlier clinical trials may not be predictive of future results; and other risks detailed in Zogenix s public periodic filings with the U.S. Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and Zogenix undertakes no obligation to revise or update this report to reflect events or circumstances after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement. This caution is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995.

Item 9.01. Financial Statements and Exhibits.

(a) Financial Statements of the Business Acquired

The financial statements required by Item 9.01(a) of Form 8-K will be filed by amendment within 71 calendar days after the date this report on Form 8-K must be filed.

(b) Pro Forma Financial Information

The pro forma financial statements required by Item 9.01(b) of Form 8-K will be filed by amendment within 71 calendar days after the date this report on Form 8-K must be filed.

(d) Exhibits

Exhibit No.	Description
10.1*	Sale and Purchase Agreement, dated October 24, 2014, by and among Zogenix Europe Limited, Zogenix, Inc., Brabant Pharma Limited and Anthony Clarke, Richard Stewart, Ann Soenen-Darcis, Jennifer Watson, Rekyer Securities plc and Aquarius Life Science Limited, as sellers.

* Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ZOGENIX, INC.

Date: October 27, 2014

By: /s/ Ann D. Rhoads
Name: Ann D. Rhoads
Title: Executive Vice President, Chief Financial Officer, Treasurer and Secretary

EXHIBIT INDEX

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