

SECURITIES AND EXCHANGE COMMISSION

FORM 8-K

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FILER

**Furiex Pharmaceuticals, Inc.**

CIK: **1484478** | IRS No.: **271197863** | State of Incorpor.: **DE** | Fiscal Year End: **1231**  
Type: **8-K** | Act: **34** | File No.: **001-34641** | Film No.: **13550765**  
SIC: **2834** Pharmaceutical preparations

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919-456-7800

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

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**FORM 8-K**

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**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of  
the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported) January 25, 2013**

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**FURIEX PHARMACEUTICALS, INC.**

**(Exact name of registrant as specified in its charter)**

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**Delaware**

**(State or other jurisdiction  
of incorporation)**

**001-34641  
(Commission  
File Number)**

**27-1197863  
(IRS Employer  
ID Number)**

**3900 Paramount Parkway, Suite 150,  
Morrisville, North Carolina 27560  
(Address of principal executive offices) (Zip Code)**

**Registrant's telephone number, including area code (919) 456-7800**

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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:

- 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))
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**Item 8.01. Other Events.**

On January 25, 2013, Furiex Pharmaceuticals, Inc. issued a press release confirming Takeda's announcement of the FDA's decision regarding the NDAs for Nesina, Oseni and Kazano. A copy of this press release is attached as Exhibit 99.1.

**Item 9.01. Financial Statements and Exhibits.****(d) Exhibits**

Exhibit

<u>No.</u>	<u>Description</u>
99.1	Press release issued January 25, 2013.

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SIGNATURE

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 thereunto duly authorized.

FURIEX PHARMACEUTICALS, INC.

Date: January 28, 2013

/s/ Marshall H. Woodworth

Marshall H. Woodworth

Chief Financial Officer



## Contact

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## **Furiex Confirms Takeda's Receipt of FDA Approval of NESINA (alogliptin) and Fixed-Dose Combinations OSENI (alogliptin and pioglitazone) and KAZANO (alogliptin and metformin HC1) for the Treatment of Type 2 Diabetes**

**MORRISVILLE, N.C. (January 25, 2013)** - Furiex Pharmaceuticals, Inc. (NASDAQ: FURX) today confirmed that Takeda Pharmaceutical Company Limited has received approval from the U.S. Food and Drug Administration of three new type 2 diabetes therapies, NESINA (alogliptin) and the fixed-dose combination therapies, OSENI (alogliptin and pioglitazone) and KAZANO (alogliptin and metformin HC1), for the treatment of type 2 diabetes in adults as adjuncts to diet and exercise.

Under its agreement with Takeda, Furiex is entitled to receive a \$25 million milestone payment as a result of this approval, as well as royalties on sales in the United States and potential sales-based milestones. Furiex has already been receiving royalty payments from Takeda for the sale of NESINA and LIOVEL in Japan.

"Receiving regulatory approvals for NESINA, OSENI and KAZANO in the U.S. marks an important milestone for Furiex," said Fred Eshelman, Pharm.D., chairman of Furiex. "These approvals should enable Takeda to build on the success of NESINA in Japan and leverage its more than 20 years of clinical and patient experience in the type 2 diabetes therapeutic area."

"We are pleased to see these important therapies become available for patients with type 2 diabetes," said June Almenoff, M.D., Ph.D., president and chief medical officer of Furiex. "Type 2 diabetes is a complex disease, requiring careful long-term disease management. We believe these new treatments in the U.S. offer patients additional therapeutic options for managing the disease."

## **About Type 2 Diabetes**

Type 2 diabetes is the most common form of diabetes and has reached epidemic proportions globally. The global health care expenditures to treat and prevent diabetes and its complications were estimated at \$471 billion in 2012. By 2030, this number is projected to exceed \$595 billion. In addition to diet and exercise, patients often need to take multiple medications to help manage blood glucose. Because of the chronic nature of this disease, combination therapy is often required to maintain diabetic control over many years of therapy.

## **About NESINA, OSENI and KAZANO**

NESINA is a DPP-4 inhibitor for the treatment of type 2 diabetes as an adjunct to diet and exercise. DPP-4 inhibitors address insulin deficiency by slowing the inactivation of incretin hormones GLP-1 (glucagon-like peptide-1) and GIP (glucose-dependent insulinotropic peptide). As a result, an increased amount of active incretins enables the pancreas to secrete insulin in a glucose-dependent manner, thereby assisting

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in the management of blood glucose levels. A New Drug Application for alogliptin was approved in April 2010 by the Japanese Ministry of Health, Labour and Welfare for the treatment of type 2 diabetes, and Takeda currently sells the therapy under the brand name NESINA in this market.

OSENI is a fixed dose combination therapy that combines alogliptin and pioglitazone in a single tablet for the treatment of type 2 diabetes in adults as an adjunct to diet and exercise. Pioglitazone is a thiazolidinedione that directly targets insulin resistance, a condition in which the body does not efficiently use the insulin it produces to control blood glucose levels. It is currently approved for use in adults for the treatment of type 2 diabetes as an adjunct to diet and exercise. A New Drug Application for the alogliptin and pioglitazone fixed-dose combination was approved in July 2011 by the Japanese Ministry of Health, Labour and Welfare for the treatment of type 2 diabetes, and Takeda currently sells the therapy under the brand name LIOVEL in this market.

KAZANO is a fixed dose combination therapy for the treatment of type 2 diabetes that combines alogliptin and metformin in a single tablet. Metformin is a widely-used diabetes medication that acts primarily by reducing the amount of glucose produced by the liver. These medications work in combination to help patients with type 2 diabetes manage their blood glucose levels.

Please see accompanying Full Prescribing Information, including Medication Guide, for NESINA.

Please see accompanying Full Prescribing Information, including Medication Guide, for KAZANO.

Please see accompanying Full Prescribing Information, including Medication Guide, for OSENI.

#### **About Furiex**

Furiex Pharmaceuticals is a drug development collaboration company that uses innovative clinical development design to accelerate and increase value of drug development programs by advancing them through the drug discovery and development process in a cost-efficient manner. Our drug development programs are designed and driven by a core team with extensive drug development experience. The company collaborates with pharmaceutical and biotechnology companies and has a diversified product portfolio and pipeline with multiple therapeutic candidates, including one Phase III-ready asset, two compounds in Phase III development, one of which is with a partner, and three products on the market. The company's mission is to develop innovative medicines faster and at a lower cost, thereby improving profitability and accelerating time to market while providing life-improving therapies for patients. For more information, visit [www.furiex.com](http://www.furiex.com).

*Except for historical information, all of the statements, expectations and assumptions contained in this news release are forward-looking statements that involve a number of risks and uncertainties. Although Furiex attempts to be accurate in making these forward-looking statements, it is possible that future circumstances might differ from the assumptions on which such statements are based. In addition, other important factors which could cause actual results to differ materially include the following: reliance on our collaborators to market our products; the demand for our products; the risks and expense of continuing the research and development activities of our existing candidates; time required to gain regulatory approvals; our continuing losses and potential need for additional capital; and the other risk factors set forth from time to time in the SEC filings for Furiex, copies of which can be found on our website.*