PIPEX PHARMACEUTICALS, INC.

Form 8-K March 18, 2008

# **UNITED STATES**

## SECURITIES AND EXCHANGE COMMISSION

**WASHINGTON, D.C. 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): March 17, 2008

Pipex Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware 01-12584

13-3808303

(State or other jurisdiction of

(Commission

(IRS Employer

incorporation)

File Number)

Identification Number)

3930 Varsity Drive

Ann Arbor, MI 48108

(Address of principal executive offices) (Zip Code)

(734) 332-7800

#### (Registrant's telephone number, including area code)

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:

- O Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- O Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- O Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- O 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 March 17, 2008, a scientific collaborator of the Registrant informed the Registrant that pursuant to a teleconference between such collaborator and the FDA of the same date, such collaborator s physician sponsored investigational new drug application (IND) for oral tetrathiomolybdate for Wilson s disease had been placed on clinical hold pending the potential resolution, if any, of FDA concerns that the Registrant believes to be similar to those raised by the FDA and described by the Registrant in its Form 8-K and press release of February 29, 2008. The IND that is the subject of the clinical hold includes an active dose optimization comparator protocol of oral tetrathiomolybdate that to date has enrolled and treated approximately 40 neurologically presenting Wilson s disease patients the data from which the Registrant intends to collect, analyze and present to the FDA at a Type B meeting to be requested to discuss a potential revised New Drug Application submission. The Registrant cannot provide any assurance that its collaborator will be successful in lifting the clinical hold imposed by the FDA, that the Registrant will be successful in preparing and filing a revised NDA, that any such newly filed NDA will be accepted for filing or that upon review of any such NDA by the FDA, the Registrant will be successful in overcoming the concerns raised by the FDA and that oral tetrathiomolybdate for initially presenting neurologic Wilson's disease will be approved by the FDA.

### **SIGNATURE**

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

PIPEX PHARMACEUTICALS, INC.

Dated: March 17, 2008

By: /s/ Steve H. Kanzer
Steve H. Kanzer, CEO