

REPLIDYNE INC  
Form 8-K  
January 28, 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): January 28, 2008 (January 22, 2008)**

**REPLIDYNE, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**000-52082**

(Commission File Number)

**84-1568247**

(I.R.S. Employer  
Identification No.)

**1450 Infinite Drive,  
Louisville, Colorado**

(Address of principal executive offices)

**80027**

(Zip Code)

**303-996-5500**

(Registrant's telephone number, including area code)

**Not Applicable**

(Former name, former address and former fiscal year, 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:

- 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 22, 2008, Replidyne, Inc. (the Company ) received a Warning Letter (the Letter ) from the U.S. Food and Drug Administration (the FDA ) pursuant to the completion of the FDA 's review of clinical trials performed in connection with the December 2005 new drug application ( NDA ) filed by the Company in support of faropenem medoxomil 300 mg tablets twice per day dose, in respect of which the FDA issued a non-approvable letter in October 2006. The clinical trials that supported this NDA were conducted by Bayer Corporation as a previous licensee of faropenem medoxomil. The Company intends to respond timely to the issues raised by the FDA.

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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 hereunto duly authorized.

**REPLIDYNE, INC.**

Dated: January 28, 2008

By: /s/ Mark L. Smith  
Mark L. Smith  
Chief Financial Officer Principal Accounting  
Officer