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	**000-52082**	**84-1568247**
(State or other jurisdiction of incorporation or organization)	*(Commission File Number)*	*(I.R.S. Employer Identification No.)*

1450 Infinite Drive, Louisville, Colorado	**80027**
(Address of principal executive offices)	*(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:

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))

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.

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