

REPLIDYNE INC
Form 8-K
November 02, 2007

**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): November 2, 2007 (November 2, 2007)

REPLIDYNE, INC.

(Exact name of registrant as specified in its charter)

Delaware

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

**1450 Infinite Drive,
Louisville, Colorado**

*(Address of principal executive
offices)*

000-52082

(Commission File Number)

84-1568247

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

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 7.01 Regulation FD Disclosure.

Replidyne, Inc. announced today that it has negotiated a special clinical protocol assessment with the U.S. Food and Drug Administration for a prospective, randomized, double-blind clinical trial to evaluate the efficacy and safety of faropenem medoxomil 600mg tablets, dosed twice per day, versus placebo in the treatment of acute bacterial sinusitis. *Safe Harbor*

The statements included herein contain plans, intentions, objectives, estimates and expectations that constitute forward-looking statements about Replidyne, Inc. that involve significant risks and uncertainties. Actual results could differ materially from those discussed due to a number of factors including, the success and timing of pre-clinical studies and clinical trials; the Company's ability to obtain and maintain regulatory approval of product candidates and the labeling under any approval that may be obtained; plans to develop and commercialize product candidates; the loss of key scientific or management personnel; the size and growth of the potential markets for the Company's product candidates and the Company's ability to serve those markets; regulatory developments in the U.S. and foreign countries; the rate and degree of market acceptance of any future products; the accuracy of Company estimates regarding expenses, future revenues and capital requirements; the Company's ability to obtain and maintain intellectual property protection for our product candidates; the successful development of the Company's sales and marketing capabilities; the success of competing drugs that are or become available; and the performance of third party manufacturers. These and additional risks and uncertainties are described more fully in the Company's Form 10-K and most recent periodic report filed with the SEC under the Securities Exchange Act of 1934. Copies of filings made with the SEC are available through the SEC's electronic data gather analysis and retrieval system (EDGAR) at www.sec.gov. All forward-looking statements made herein are made as of the date hereof and the Company assumes no obligation to update such forward-looking statements.

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: November 2, 2007

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