

REPLIDYNE INC
Form 8-K
November 06, 2006

**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 3, 2006

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)*

80026

(Zip Code)

720-996-5500

(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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INFORMATION TO BE INCLUDED IN THE REPORT

Section 7 Regulation FD

Item 7.01 Regulation FD Disclosure.

Our chief financial officer and chief commercial officer intend to conduct meetings with investors, stockholders and analysts on or after November 7, 2006. We expect to use the presentation materials furnished as Exhibit 99.1 hereto, in whole or in part and possibly with immaterial modifications, in connection with such meetings and from time to time thereafter. The fact that these presentation materials are being furnished should not be deemed an admission as to the materiality of any information contained in the materials. We do not intend to file any update to these presentation materials. The information contained in the presentation materials is summary information that is intended to be considered in the context of our filings with the Securities and Exchange Commission and other public announcements that we may make, by press release or otherwise, from time to time.

We expect to make copies of the presentation materials, including such graphic images, available for viewing at the Investor Relations section of our website located at www.replidyne.com, although we reserve the right to discontinue that availability at any time.

Some of the matters discussed in the attached presentation materials contain forward-looking statements that involve significant risks and uncertainties, including statements relating to the completion and reporting of results from our clinical trials and the potential advantages of our product candidates. Actual results could differ materially from those projected and we caution investors not to place undue reliance on the forward-looking statements contained in, or made in connection with, the presentation materials.

Among other things, the projected commencement and completion of any of our clinical trials and the dissemination of the results of the clinical trials may be affected by difficulties or delays, including difficulties or delays caused by regulatory issues, timing of clinical trial initiations, patient enrollment, patient treatment, data collection or data analysis, the detailed design of future trials, and the loss of key scientific or management personnel. In addition, our results may be affected by our effectiveness at managing our financial resources, our ability to successfully develop and market our current product candidates, our ability to obtain and maintain regulatory approval of product candidates and the labeling under any approval that may be obtained, the size and growth of the potential markets for our product candidates and our ability to serve those markets, the rate and degree of market acceptance of any future products, the success of competing drugs that are or become available, our ability to obtain or enforce intellectual property protection for our product candidates, difficulties or delays in manufacturing our product candidates and the performance of third party manufacturers, regulatory developments involving current and future product candidates and the performance of our collaboration partners. Delays in clinical programs, whether caused by competition, adverse events, patient enrollment rates, regulatory issues or other factors, could adversely affect our financial position and prospects. Prior clinical trial program designs and results are not necessarily predictive of future clinical trial designs or results. Preliminary clinical trial results may not be confirmed upon full analysis of the detailed results of a trial. If our product candidates do not meet safety or efficacy endpoints in clinical evaluations, they will not receive regulatory approval and we will not be able to market them. Even if our product candidates meet safety and efficacy endpoints, regulatory authorities may not approve them or we may face post-approval problems that require the withdrawal of our product from the market. Operating expense and cash flow projections involve a high degree of uncertainty, including variances in future spending rates due to changes in corporate priorities, the timing of and outcomes of clinical trials, competitive developments and the impact on expenditures and available capital from licensing and strategic collaboration opportunities. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue one or more of our drug development or discovery research programs. We are at an early stage of development and may not ever have any products that generate significant revenue.

It is our policy to update or reconfirm our public guidance only by issuing a press release or filing a publicly accessible document with the SEC. We generally plan to provide guidance as part of our annual and quarterly earnings releases but reserve the right to provide guidance at different intervals or to revise our practice in future periods. Clinical guidance contained in the presentation materials is as of November 3, 2006 and financial guidance relating to our current cash, cash equivalents and investments contained in the presentation materials is as of

September 30, 2006. We undertake no duty or obligation to update any forward-looking statements as a result of new information, future events or changes in our expectations.

Section 9 Financial Statements and Exhibits

Item 9.01 Financial Statements and Exhibits.

(c) *Exhibits.*

99.1 Replidyne, Inc. Investor and Analyst Presentation Materials

In accordance with General Instruction B.2. of Form 8-K, the information presented in this filing and furnished in the exhibit attached hereto shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such a filing.

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 3, 2006

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Replidyne, Inc. Investor and Analyst Presentation Materials