CARDIOVASCULAR SYSTEMS INC

FORM 8-K
(Current report filing)

Filed 12/10/07 for the Period Ending 12/10/07

Address	651 CAMPUS DRIVE
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Telephone	651-259-1600
CIK	0001180145
Symbol	CSII
SIC Code	3841 - Surgical and Medical Instruments and Apparatus
Industry	Medical Equipment & Supplies
Sector	Healthcare
Fiscal Year	06/30

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): December 10, 2007 (December 10, 2007)

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:

☐ 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))

Item 7.01 Regulation FD Disclosure.

On December 10, 2007, Replidyne issued a press release regarding an operational restructuring to align resources with strategic priorities. A copy of the press release is furnished as Exhibit 99.1 to this Form 8-K.

In accordance with General Instruction B.2. of Form 8-K, the information presented under this Item 7.01 and attached as Exhibit 99.1 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.

Item 9.01 Financial Statements and Exhibits.

(c) *Exhibits.*

99.1	Press Release, dated December 10, 2007, Entitled "Replidyne Provides Strategic Update - Initiatives Include Restructuring and Pipeline Prioritization."

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: December 10, 2007

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release, dated December 10, 2007, Entitled “Replidyne Provides Strategic Update - Initiatives Include Restructuring and Pipeline Prioritization.”

EXHIBIT 99.1

Replidyne contact:
Sabrina B. Oei
Dir. Investor & Public Relations
T: (303) 996-5535

Replidyne Provides Strategic Update
- Initiatives include restructuring and pipeline prioritization -

Louisville, CO, December 10, 2007 — Replidyne, Inc. (Nasdaq: RDYN) today announced an operational restructuring to align critical resources with strategic priorities. These priorities include identifying a partner for Replidyne's late-stage antibiotic, faropenem medoxomil (faropenem), advancing and expanding its infectious disease pipeline, and exploring additional corporate development opportunities.

The key elements of the Company's operating strategy going forward are as follows:

- **Corporate restructuring.** To better align the organization with its strategic and operations priorities, Replidyne has reduced headcount by approximately 35 percent, primarily in the administrative, clinical, regulatory, and commercial functions.
- **Pipeline programs.** Replidyne will retain key research and development expertise to progress its most promising preclinical programs, including REP3123, its investigational antibacterial for the treatment of *C. difficile* -associated disease (CDAD), and its DNA replication inhibition program. As a result of prioritizing these preclinical programs, Replidyne has suspended the development of topical antibiotic REP8839 due to the additional investment required to optimize the formulation and the niche market opportunity.
- **Development strategy for faropenem.** Replidyne will continue its ongoing placebo-controlled Phase III trial for faropenem in acute exacerbation of chronic bronchitis (AECB). This clinical trial is approaching 50 percent enrollment and results are expected in 2008. Consistent with prior guidance, Replidyne will not initiate enrollment in clinical trials for faropenem in acute bacterial sinusitis (ABS) and community-acquired pneumonia (CAP) until a partner is identified.
- **Business development.** Replidyne will retain a strong business development capability that, in addition to seeking a partner for faropenem, will pursue opportunities to augment Replidyne's pipeline.

“We have re-sized Replidyne to align the organization with our near-term strategic interests and financial responsibilities,” stated Kenneth J. Collins, Replidyne’s President and CEO. “By retaining our key scientific assets and our experienced management team, we maintain our core value as an infectious disease company. While Replidyne continues to build on our most promising research and development programs, we will also focus on pursuing strategic alternatives that bring value to Replidyne shareholders.”

As of November 30, 2007, Replidyne had cash assets of approximately $93 million. Based on currently planned clinical trials and development activities, as well as the restructuring announced today, the Company believes it has internal cash resources to support operations for at least the next two fiscal years. In connection with the restructuring, Replidyne expects to include a restructuring expense of approximately $1.5 million primarily related to employee severance payments.

Conference Call Information

Replidyne will host a conference call and webcast today, December 10, 2007, at 4:45 P.M. ET to discuss these corporate developments. Callers may participate in the conference call by dialing 866-711-8198 (domestic) or 617-597-5327 (international). The passcode is 99126093. To access the live webcast, log on to the Company’s website at www.Replidyne.com and go to the Investor Relations section.

A replay of the conference call will be available approximately one hour after the completion of the call through Monday, December 17, 2007 at midnight. Callers may access the replay by dialing 888-286-8010 (U.S. participants) or 617-801-6888 (international participants). The passcode is 28540844. To access a replay of the webcast, visit the Investor Relations section of the Company’s website at www.Replidyne.com .

About Faropenem

Faropenem is a late-stage antibiotic product candidate intended to treat adult respiratory tract infections including acute bacterial sinusitis (ABS), community-acquired pneumonia (CAP) and acute exacerbation of chronic bronchitis (AECB). Faropenem is a member of the penem subclass within the beta-lactam class of antibiotics. Beta-lactams are generally characterized by their favorable safety and tolerability profiles, as well as their broad spectrum of activity, and as a result are often used as first line therapy in many respiratory and skin infections in adult and pediatric patients.

In March 2007, Replidyne announced a clinical development program, agreed to by the U.S. Food and Drug Administration (FDA), in which four Phase III clinical trials consisting of one placebo-controlled trial in each of ABS and AECB and two non-inferiority trials in CAP would be adequate to submit a new drug application for faropenem covering the three indications. In November 2007, the FDA accepted Replidyne’s special protocol assessment (SPA) for faropenem in ABS. The FDA’s guidance for

establishing non-inferiority margins in clinical trials, such as the comparator studies recommended for CAP, is still evolving. If approved, faropenem would be the first oral penem available to treat patients with community respiratory tract infections.

About *Clostridium difficile* and REP3123

C. difficile is a Gram-positive anaerobic bacterium that causes *C. difficile* -associated disease (CDAD). CDAD is on the rise worldwide, both in number of cases and severity of the disease. Most cases of CDAD occur in a hospital setting due to increased use of antibiotics and other chemotherapeutics that disrupt normal intestinal flora, an ageing population, and difficulty of eradicating *C. difficile* spores. However, more recently, CDAD has been acquired in the community setting where several outbreaks with increased mortality have occurred.

REP3123 is a new narrow spectrum antibacterial agent that *in vitro* prevents the growth of *C. difficile* by inhibiting an essential enzyme in the bacterial cell called methionyl tRNA synthetase that blocks the organism from synthesizing proteins. In preclinical studies, REP3123 has been shown to inhibit growth, toxin production and spore-forming in *C. difficile* bacteria while leaving normal gut flora unharmed. Replidyne intends to file an investigation new drug (IND) application for REP3123 in the second half of 2008.

About DNA Replication Inhibition

DNA replication is one of the essential steps in bacterial growth and remains an attractive target for therapeutic intervention with new antibacterial agents. Replidyne is advancing a lead series of novel DNA replication inhibitors identified from its proprietary compound collection. These inhibitors use a novel mechanism of action to block an essential step in the DNA replication process. Based on current preclinical data, the series exhibits oral bioavailability and bactericidal activity against all major classes of antibiotic-resistant Gram-positive bacteria, including clinically-relevant resistant phenotypes such as methicillin-resistant *S. aureus* (MRSA), vancomycin-resistant enterococci (VRE) and penicillin-resistant *S. pneumoniae* (PRSP).

About Replidyne, Inc.

Replidyne is a biopharmaceutical company focused on discovering, developing, in-licensing and commercializing innovative anti-infective products. Replidyne's lead product, faropenem medoxomil, is a novel oral community antibiotic, expected to be appropriate for use as a first-line antibiotic for treatment of respiratory and skin infections in adult and pediatric patients. Replidyne's investigational antibacterial agent REP3123 targets Gram-positive *C. difficile* bacteria and *C. difficile* -associated disease (CDAD). Replidyne is pursuing the development of other novel anti-infective programs based on its DNA replication inhibition technology and its in-house discovery research.

Safe Harbor

This press release contains 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 a new partner for faropenem on acceptable terms; 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 most recent Form 10-Q 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 in the press release are made as of the date hereof and the Company assumes no obligation to update the forward-looking statements in the document.

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