SECURITIES & EXCHANGE COMMISSION EDGAR FILING

CorMedix Inc.

Form: 8-K

Date Filed: 2016-11-10

Corporate Issuer CIK: 1410098

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 10, 2016

CORMEDIX INC.
(Exact Name of Registrant as Specified in Charter)

Delaware	001-34673	20-5894890
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

1430 U.S. Highway 206, Suite 200, Bedminster NJ	07921
(Address of Principal Executive Offices)	(Zip Code)

Registrant's Telephone Number, Including Area Code: (908) 517-9500

(Former Name or Former Address, 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 (*see* General Instruction A.2. below):

☐ 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 2.02. Results of Operations and Financial Condition.

On November 10, 2016, CorMedix, Inc. issued a press release announcing its operating results for the third quarter ended September 30, 2016. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein in its entirety by reference.

The information in this Item 2.02 (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated November 10, 2016.

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.

CORMEDIX INC.

Date: November 10, 2016

By: /s/ Khoso Baluch
Name: Khoso Baluch
Title: Chief Executive Officer

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CENTRAL INDEX KEY: 0001410098
STANDARD INDUSTRIAL CLASSIFICATION: PHARMACEUTICAL PREPARATIONS [2834]
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STATE OF INCORPORATION: DE
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CorMedix Inc. Reports Third Quarter 2016 Financial Results and Provides Business Updates

Conference Call Today at 4:30 p.m. Eastern Time

Bedminster, NJ – November 10, 2016 – CorMedix Inc. (NYSE MKT: CRMD), a biopharmaceutical company focused on developing and commercializing therapeutic products for the prevention and treatment of infectious and inflammatory diseases, today reported financial results for the third quarter ended September 30, 2016, and highlighted recent business updates. The Company will host a conference call today at 4:30 p.m. Eastern Time.

Key Business and Financial Updates:

Corporate:

- Appointed former Lilly and UCB executive Khoso Baluch as CEO, bringing >30 years of operational and product launch experience, both U.S. and internationally
- Entered into collaboration with Pediatric Oncology Experimental Therapeutics Investigators Consortium (POETIC) to develop taurolidine-based therapies for treating rare pediatric cancers

Neutrolin® Phase 3 Program:

- Recently completed a comprehensive assessment of LOCK-IT 100, involving principle investigators and other clinical staff from multiple clinical trial sites
- Continued to enroll hemodialysis patients and engage new clinical sites; currently expect to complete patient enrollment in LOCK-IT 100 in the fourth quarter of 2017
- Final LOCK-IT 200 Phase 3 study is planned to be conducted in oncology patients with chronic central venous catheters; timing of initiation will be based on the final trial protocol and funding

Financial:

- $26.7 million in cash and short-term investments as of September 30, 2016, vs $28.6 million at June 30, 2016
- Net change in cash during the third quarter was $1.9 million; net cash used in operation in the third quarter was $6.5 million
- Filed for a new $40 million at-the-market (ATM) program to replace, when available, the current ATM program that has $4.1 million remaining

“Neutrolin has the potential to alleviate the significant public health and pharmacoeconomic burden caused by catheter-related bloodstream infections, to the benefit of patients and healthcare systems worldwide,” said Khoso Baluch, CorMedix CEO. “In the face of antibiotic resistance and a vulnerable patient population, we expect Neutrolin to emerge as a powerful anti-infective with a broad spectrum mechanism of action against most types of bacterial and fungal infections, including MRSA, without any evidence of microbial resistance.”

“Completing the Phase 3 program for Neutrolin as expeditiously as possible remains our highest priority. Following a comprehensive assessment of LOCK-IT 100, which involved our principle investigators and other clinical staff from multiple clinical sites in the study, as well as a number of our Key Opinion Leaders, regulatory counsel and biostatisticians, we have developed a multi-pronged strategy to enhance our trial processes and accelerate patient enrollment. Based on current projections, we expect to complete enrollment by the fourth quarter of 2017. We are committed and energized to bring this much-needed product candidate to market, and to deliver long-term value to our shareholders through successful commercialization.”

Mr. Baluch continued, “Beyond Neutrolin, we are excited about the prospects of our taurolidine-based platform based upon the broad applicability of its anti-microbial and potentially therapeutic properties. To that end, we are evaluating the feasibility of new indications and formulations of taurolidine by establishing several early research collaborations. Our newest collaboration with POETIC to develop taurolidine as a therapy for rare, orphan indications like pediatric neuroblastoma and osteosarcoma is a prime example of how, if feasible, CorMedix may unlock significant future value and build a pipeline of product candidates based on the unique attributes of our taurolidine platform.”

Selected Financial Results for the Three Months and Nine Months Ended September 30, 2016

For the three months ended September 30, 2016, CorMedix reported a net loss of $9.1 million, or $0.23 per share, compared to a net loss of $4.7, or $0.14 per share for the same period last year, an increase of $4.4 million. For the nine months ended September 30, 2016, the Company reported an operating loss of $18.2 compared to an operating loss of $14.3 million for the same period last year, an increase of $3.9 million. The increase in operating loss from the previous quarter reflects the increased activity in the on-going Phase 3 LOCK-IT-100 trial, manufacturing and product development.

The Company had $26.7 million in cash and short-term investments as of September 30, 2016, compared to $28.6 million as of June 30, 2016, a net reduction of $1.9 million. For the third quarter 2016, the Company used $6.5 million to fund operations, primarily focused on conducting our Neutrolin Phase 3 program and related G&A activities. The cash used to fund operations was partially offset by cash from financing sources. CorMedix received approximately $438,800 from the exercise of stock options for 567,500 common shares and $4.2 million from the sale of 2,541,716 common shares under the ATM program. As of September 30, 2016, there was approximately $4.1 million remaining available under the current ATM program. CorMedix will have an additional $40 million available under a new ATM program, once it receives a waiver from Elliott Associates, L.P. of participation rights and the associated registration statement is declared effective by the SEC. Upon the new ATM becoming effective, the $4.1 million remaining under the current ATM will expire.

The Company had 40.4 million, 37.3 million, and 36.1 million shares of common stock outstanding as of September 30, 2016, June 30, 2016, and March 30, 2016, respectively.

Mr. Baluch concluded, “Our goal is to remain focused on clinical execution in our Phase 3 studies while operating the company as efficiently as possible, managing potential shareholder dilution against our ability to reach key value inflection points. We believe this strategy has the potential to deliver maximum value for our shareholders upon clinical success for Neutrolin.”

Readers are referred to, and encouraged to read in its entirety, the Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, filed with the Securities and Exchange Commission, which includes updates on the Neutrolin Phase 3 clinical program as well as the Company’s business plans and operations, financial condition and results of operations.

Conference Call Information:

The live conference call is scheduled to begin today at 4:30 p.m. Eastern Time. Please call five minutes before the conference call is scheduled to begin.

Dial-In (Toll Free)	877-407-9210
International Dial-In	201-689-8049

A replay of the teleconference will be available until November 17, 2016, 11:59 p.m. Eastern Time

Replay Number:	877-481-4010
Replay International:	919-882-2331
Conference ID:	10105

About CorMedix Inc.

CorMedix Inc. is a biopharmaceutical company focused on developing and commercializing therapeutic products for the prevention and treatment of infectious and inflammatory disease. The Company is focused on developing its lead product Neutrolin®, a novel, non-antibiotic antimicrobial solution designed to prevent costly and dangerous bloodstream infections associated with the use of central venous catheters. Such infections cost the U.S. healthcare system approximately $6 billion annually and contribute significantly to increased morbidity and mortality. Neutrolin is currently in a Phase 3 clinical study in patients undergoing chronic hemodialysis via a central venous catheter. The company is planning to conduct its second Phase 3 study in patients with cancer receiving IV parenteral nutrition, chemotherapy and hydration via a chronic central venous catheter, subject to sufficient resources. If successful, the two pivotal studies may be submitted to the FDA for potential approval for both patient populations. Neutrolin has FDA Fast Track status and is designated as a Qualified Infectious Disease Product, contributing to potentially FDA priority review and up to 10 years of market exclusivity upon potential U.S. approval. It is already a CE Marked product in Europe and other territories. CorMedix is also seeking to unlock additional value for its taurolidine-based technology by establishing collaborative partnerships in oncology and medical device applications. For more information visit: www.cormedix.com.

For Investors & Media:

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Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are subject to risks and uncertainties. All statements, other than statements of historical facts, regarding management's expectations, beliefs, goals, plans or CorMedix's prospects, future financial position, financing plans, future revenues and projected costs should be considered forward-looking. Readers are cautioned that actual results may differ materially from projections or estimates due to a variety of important factors, including: the cost, timing and results of the ongoing and planned Phase 3 trials for Neutrolin® in the U.S. and the resources needed to commence and complete those trials; obtaining additional financing to support CorMedix's research and development and clinical activities and operations; the risks and uncertainties associated with CorMedix's ability to manage its limited cash resources; obtaining regulatory approvals to conduct clinical trials and to commercialize CorMedix's product candidates, including marketing of Neutrolin in countries other than Europe; the risks associated with the launch of Neutrolin in new markets; CorMedix's ability to enter into, execute upon and maintain collaborations with third parties for its development and marketing programs; CorMedix's ability to maintain its listing on the NYSE MKT; the outcome of clinical trials of CorMedix's product candidates and whether they demonstrate these candidates' safety and effectiveness; CorMedix's dependence on its collaborations and its license relationships; achieving milestones under CorMedix's collaborations; CorMedix's dependence on preclinical and clinical investigators, preclinical and clinical research organizations, manufacturers, sales and marketing organizations, and consultants; and protecting the intellectual property developed by or licensed to CorMedix. These and other risks are described in greater detail in CorMedix's filings with the SEC, copies of which are available free of charge at the SEC's website at www.sec.gov or upon request from CorMedix. CorMedix may not actually achieve the goals or plans described in its forward-looking statements, and investors should not place undue reliance on these statements. CorMedix assumes no obligation and does not intend to update these forward-looking statements, except as required by law.

CORMEDIX INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenue	$ 44,451	$ 35,947	$ 102,390	$ 187,184
Cost of sales	(43,922)	(35,396)	(281,342)	(154,514)
Gross profit (loss)	529	551	(178,952)	32,670
Operating Expenses:				
Research and development	(6,840,413)	(1,764,468)	(11,702,965)	(4,796,571)
Selling, general and administrative	(2,318,091)	(2,948,643)	(6,449,608)	(7,996,922)
Total operating expenses	(9,158,504)	(4,713,111)	(18,152,573)	(12,793,493)
Loss from operations	(9,157,975)	(4,712,560)	(18,331,525)	(12,760,823)
Interest income	32,866	25,019	93,928	30,817
Foreign exchange transaction gain (loss)	(1,091)	674	(5,622)	(5,352)
Value of warrants issued in connection with backstop financing	-	-	-	(1,583,252)
Interest expense	-	(1,609)	(992)	(2,635)
Total Income (Expense)	31,775	24,084	87,314	(1,560,422)
Net loss	(9,126,200)	(4,688,476)	(18,244,211)	(14,321,245)
Other comprehensive income (loss)	(6,847)	7,082	21,168	814
Comprehensive loss	$ (9,133,047)	$ (4,681,394)	(18,223,043)	(14,320,431)
Net Loss Per Common Share – Basic and Diluted	$ 0.23	$ 0.14	$ 0.49	$ 0.48

CORMEDIX INC. AND SUBSIDIARY
CONDENSED BALANCE SHEET INFORMATION

	September 30, 2016 (Unaudited)	December 31, 2015*
Assets		
Cash, cash equivalents and short-term investments	$ 26,653,659	$ 35,385,804
Total Assets	$ 28,840,431	$ 37,101,729
Total Liabilities	$ 5,061,065	$ 3,090,241
Accumulated Deficit	$ (112,635,806)	$ (94,391,595)
Total Stockholders' Equity	$ 23,779,366	$ 34,011,488

*Condensed from audited financial statements.