CorMedix Inc.
Form 10-Q
August 13, 2012

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 30, 2012

.. TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number 001-34673

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

Delaware	20-5894890
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
745 Rt. 202-206, Suite 303, Bridgewater, NJ	08807
(Address of Principal Executive Offices)	(Zip Code)

(908) 517-9500

(Registrant's Telephone Number, Including Area Code)

_____

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

The number of shares outstanding of the issuer's common stock, as of August 12, 2012 was 11,408,274.

CORMEDIX INC.

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PART I
FINANCIAL INFORMATION

Item 1. Financial Statements.

CorMedix Inc.
(A Development Stage Company)

CONDENSED BALANCE SHEETS

	June 30, 2012 (Unaudited)	December 31, 2011 (Note 1)
ASSETS		
Current assets		
Cash and cash equivalents	$893,936	$ 1,985,334
Prepaid research and development expenses	700	19,888
Other receivable	-	493,855
Other prepaid expenses and current assets	105,177	31,897
Total current assets	999,813	2,530,974
Property and equipment, net	8,178	11,689
Deferred financing costs	15,000	-
Security deposit	13,342	13,342
TOTAL ASSETS	$1,036,333	$ 2,556,005
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIENCY)		
Current liabilities		
Accounts payable	$993,767	$ 1,008,493
Accrued expenses	172,721	296,512
Total current liabilities	1,166,488	1,305,005
Deferred rent	13,328	14,472
TOTAL LIABILITIES	1,179,816	1,319,477
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY (DEFICIENCY)		
Common stock - $0.001 par value: 40,000,000 shares authorized, 11,408,274 shares issued and outstanding at June 30, 2012 and December 31, 2011	11,408	11,408
Deferred stock issuances	(146)	(146)
Additional paid-in capital	44,327,183	44,172,818

Deficit accumulated during the development stage	(44,481,928)	(42,947,552)
TOTAL STOCKHOLDERS' EQUITY (DEFICIENCY)	(143,483)	1,236,528
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIENCY)	$1,036,333	$ 2,556,005

See Notes to Unaudited Condensed Financial Statements.

CorMedix Inc.
(A Development Stage Company)

CONDENSED STATEMENTS OF OPERATIONS
(Unaudited)

	For the Three Months Ended June 30, 2012	For the Three Months Ended June 30, 2011	For the Six Months Ended June 30, 2012	For the Six Months Ended June 30, 2011	Cumulative Period from July 28, 2006 (inception) Through June 30, 2012
OPERATING EXPENSES					
Research and development	$ 248,190	$ 1,582,348	$ 623,046	$ 2,757,890	$ 22,778,719
General and administrative	376,617	898,024	912,871	1,732,506	11,831,826
Total Operating Expenses	624,807	2,480,372	1,535,917	4,490,396	34,610,545
LOSS FROM OPERATIONS	(627,807)	(2,480,372)	(1,535,917)	(4,490,396)	(34,610,545)
OTHER INCOME (EXPENSE)					
Other income, net				29,819	420,987
Interest income	592	3,259	1,541	8,426	125,883
Interest expense, including amortization and write-off of deferred financing costs and debt discounts	-	-	-	-	(11,193,028)
LOSS BEFORE INCOME TAXES	(624,215)	(2,477,113)	(1,534,376)	(4,452,151)	(45,256,703)
State income tax benefit	-	-	-	-	774,775
NET LOSS	$ (624,215)	$ (2,477,113)	$ (1,534,376)	$ (4,452,151)	$ (44,481,928)
NET LOSS PER SHARE – BASIC AND DILUTED	$ (0.05)	$ (0.22)	$ (0.13)	$ (0.39)	
WEIGHTED AVERAGE SHARES OUTSTANDING – BASIC AND DILUTED	11,408,274	11,408,274	11,408,274	11,408,274	

See Notes to Unaudited Condensed Financial Statements.

CorMedix Inc.
(A Development Stage Company)

CONDENSED STATEMENT OF CHANGES IN
STOCKHOLDERS' EQUITY (DEFICIENCY)

(Unaudited)
For the Six Months Ended June 30, 2012

	Common Stock		Deferred Stock Issuances	Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Total Stockholders' Equity (Deficiency)
	Shares	Amount				
Balance at January 1, 2012	11,408,274	$11,408	$ (146)	$44,172,818	$(42,947,552)	$1,236,528
Stock-based compensation				154,365		154,365
Net loss					(1,534,376)	(1,534,376)
Balance at June 30, 2012	11,408,274	$11,408	$ (146)	$44,327,183	$(44,481,928)	$(143,483)

See Notes to Unaudited Condensed Financial Statements.

CorMedix Inc.
(A Development Stage Company)

CONDENSED STATEMENTS OF CASH FLOWS
(Unaudited)

	For the Six Months Ended June 30, 2012	For the Six Months Ended June 30, 2011	Cumulative Period from July 28, 2006 (Inception) Through June 30, 2012
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (1,534,376)	$ (4,452,151)	$ (44,481,928)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	154,365	431,087	2,479,245
Stock issued in connection with license agreements	-	-	6,613,718
Stock issued in connection with consulting agreement	-	-	158,262
Amortization of deferred financing costs	-	-	2,047,881
Amortization of debt discount	-	-	4,979,461
Non-cash charge for beneficial conversion feature	-	-	1,137,762
Non-cash interest expense	-	-	3,007,017
Expenses paid on behalf of the Company satisfied through the issuance of notes	-	-	51,253
Depreciation	3,511	6,165	53,531
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	439,763	348,357	(105,877)
Security deposits	-	-	(13,342)
Accounts payable	(14,726)	297,541	993,767
Accrued expenses	(123,791)	(173,682)	172,721
Deferred rent	(1,144)	(1,143)	13,328
Net cash used in operating activities	(1,076,398)	(3,543,826)	(22,893,201)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of equipment	-	(1,625)	(61,708)
Net cash used in investing activities	-	(1,625)	(61,708)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from notes payable to related parties	-	-	2,465,749
Proceeds from senior convertible notes	-	-	13,364,973
Proceeds from Galenica, Ltd. promissory note	-	-	1,000,000
Deferred financing costs	(15,000)	-	(1,462,400)
Repayment of amounts loaned under related party notes	-	-	(1,981,574)
Proceeds from sale of equity securities, net of issuance costs	-	-	10,457,270
Proceeds from receipt of stock subscriptions and issuances of common stock	-	-	4,827

Net cash provided by (used in) financing activities	(15,000)	-	23,848,845
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(1,091,398)	(3,545,451)	893,936
CASH AND CASH EQUIVALENTS – BEGINNING OF PERIOD	1,985,334	8,283,684	-
CASH AND CASH EQUIVALENTS – END OF PERIOD	$ 893,936	$ 4,738,233	$ 893,936
Cash paid for interest	$ -	$ -	$ 18,425
Supplemental Disclosure of Non-Cash Financing Activities:			
Conversion of notes payable and accrued interest to common stock	$ -	$ -	$ 18,897,167
Reclassification of deferred financing costs to additional paid-in capital	$ -	$ -	$ 148,014
Stock issued to technology finders and licensors	$ -	$ -	$ 155
Warrants issued to placement agent	$ -	$ -	$ 748,495
Debt discount on senior convertible notes	$ -	$ -	$ 4,979,461

See Notes to Unaudited Condensed Financial Statements.

CorMedix Inc.
(A Development Stage Company)

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

Note 1 — Organization, Business and Basis of Presentation:

Organization and Business:

CorMedix Inc., incorporated in July 2006 under the laws of the State of Delaware (referred to herein as "we," "us," "our" and the "Company"), is a development stage pharmaceutical and medical device company that seeks to in-license, develop and commercialize therapeutic products for the treatment of cardiac and renal dysfunction, specifically in the dialysis and non-dialysis areas.

Basis of Presentation:

The accompanying unaudited condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America and the rules of the Securities and Exchange Commission ("SEC") for interim financial information. Accordingly, the unaudited condensed financial statements do not include all information and footnotes required by accounting principles generally accepted in the United States of America for complete annual financial statements. In the opinion of management, the accompanying unaudited condensed financial statements reflect all adjustments, consisting of normal recurring adjustments, considered necessary for a fair presentation of such interim results. Interim operating results are not necessarily indicative of results that may be expected for the full year ending December 31, 2012 or for any subsequent period. These unaudited condensed financial statements should be read in conjunction with the audited financial statements and notes thereto of the Company which are included in the Company's Annual Report on Form 10-K filed with the SEC on March 19, 2012. The accompanying condensed balance sheet as of December 31, 2011 has been derived from the audited financial statements included in such Form 10-K.

The Company's primary activities since incorporation have been organizational activities, including recruiting personnel, establishing office facilities, acquiring licenses for its pharmaceutical compound pipeline, performing business and financial planning, performing research and development and raising funds through the issuance of debt and common stock. The Company has not generated any revenues and, accordingly, the Company is considered to be in the development stage.

The Company's unaudited condensed financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the settlement of liabilities and commitments through the normal course of business. The unaudited condensed financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities. The Company has sustained losses since its inception and expects that such losses will continue over the next several years. Management believes that the Company's recent decision to focus the majority of the Company's resources, including the Company's research and development efforts primarily on the CE Marking approval and commercialization of Neutrolin® (CRMD003) in Europe will result in the currently available capital resources of the Company being sufficient to meet the Company's operating needs into the fourth quarter of 2012. The Company intends to raise additional funds through various potential sources, such as equity and/or debt financings, strategic relationships, or out-licensing of its products, however, the Company can provide no assurances that such financing will be available on acceptable terms, or at all. If adequate financing is not available, the Company may be required to terminate or significantly curtail or cease its operations, or enter into arrangements with collaborative partners or others that may require the Company to relinquish rights to certain of its technologies, or potential markets that the Company would not otherwise relinquish.

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NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

These matters, among others, raise substantial doubt about the Company's ability to continue as a going concern. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

For the six months ended June 30, 2012 and the period from July 28, 2006 (inception) to June 30, 2012, the Company incurred net losses of $1,534,376 and $44,481,928, respectively.

Note 2 — Summary of Significant Accounting Policies:

Use of Estimates:

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

Loss per common share:

Basic earnings (loss) per common share excludes dilution and is computed by dividing net income (loss) by the weighted average number of common shares outstanding during the period. Diluted earnings per common share reflect the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that then shared in the earnings of the entity. Since the Company has only incurred losses, basic and diluted loss per share are the same. The amount of potentially dilutive securities excluded from the calculation was 6,160,826 and 6,897,250 underlying outstanding warrants and stock options at June 30, 2012 and 2011, respectively.

Stock-Based Compensation:

Stock-based compensation cost is measured at grant date, based on the estimated fair value of the award, and is recognized as expense over the employee's requisite service period on a straight-line basis.

The Company accounts for stock options granted to non-employees on a fair value basis using the Black-Scholes option pricing method. The non-cash charge to operations for non-employee options with vesting is revalued at the end of each reporting period based upon the change in the fair value of the options and amortized to consulting expense over the related contract service period.

During the six months ended June 30, 2012 and 2011, options to purchase an aggregate of 380,000 and 826,000 shares of common stock, respectively, were granted to the Company's employees, directors and consultants.

CorMedix Inc.
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NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

Note 3 — Stockholders' Equity:

Common Stock Options:

During the six months ended June 30, 2012, stock options to purchase an aggregate of 50,000 shares of common stock were awarded to a consultant of the Company. The exercise price of these options was $0.29 per share based on the fair value on the date of grant (as reported on the NYSE-Amex close of business May 14th, 2012). Vesting is contingent upon the receipt of the Company's Neutrolin CE Mark. Since such Neutrolin CE Mark was not received as of June 30, 2012, no expense related to this grant was recorded by the Company during the six months ended June 30, 2012.

During the six months ended June 30, 2012, stock options to purchase an aggregate of 150,000 shares of common stock were granted to the Company's directors under the Amended and Restated 2006 Stock Incentive Plan ("Plan"). These options, with an exercise price of $0.29, vest on the one-year anniversary of the grant date, January 6, 2013.

During the six months ended June 30, 2012, the Company granted a total of 180,000 ten-year term stock options to its former Chief Operating Officer/Chief Financial Officer ("COO/CFO"), under the Plan with an exercise price of $0.49, vesting on the following schedule:

- 25% on March 20, 2012, the date of grant, which were fully expensed;
- 25% on the closing of a financing by the Company with gross proceeds in excess of $1.5 million which includes either the issuance of equity, debt or any combination thereof, with an expectation by the Company, that it is probable that such objective will be achieved and the Company is expensing the vesting of such options through the end of 2012;
- 25% vest upon CE Mark approval for CRMD003 (Neutrolin®), with an expectation by the Company that it is probable that such objective will be achieved and the Company is expensing the vesting of such options through the end of 2012, and;
- 25% vest upon the launch of Neutrolin® in Europe, provided, however, that each of the events described above occur on or before December 31, 2012, for which the Company has not determined if such options will vest by year end 2012 which will occur only if and until CE Marking is achieved, as such the Company has not recognized any

expense for such options.

As a result of the Company's COO/CFO's resignation in April 2012, 135,000 of these options were forfeited and the remaining 45,000 stock options were amended to extend the exercise period up to and through May 31, 2014. The Company re-measured and recorded as an expense the value of the 45,000 stock options and reversed the recorded expense of the forfeited stock options.

During the six months ended June 30, 2011, options to purchase an aggregate of 150,000 shares of common stock were granted to the Company's directors under the Plan with an exercise price of $2.10 per share. These options vested on the one-year anniversary of the grant date, January 14, 2011, and have a ten-year term. Additionally, during the six months ended June 30, 2011, options to purchase 356,000 shares of common stock were granted to the Company's Chief Medical Officer ("CMO") under the Plan with an exercise price of $1.61 per share. These options vest in equal installments on each of the first three annual anniversaries of the grant date, March 1, 2011, and have a ten-year term.

During the six months ended June 30, 2011, the Company also granted market based stock options to a non-employee consultant to purchase 320,000 shares of common stock under the Plan with an exercise price of $1.72 per share with a five-year term. As of June 30, 2011, no non-employee stock options had vested, as the vesting of such stock options was contingent upon various performance metrics which were not achieved as of June 30, 2011.

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(A Development Stage Company)

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

During the six months ended June 30, 2012 and 2011 and the period from July 28, 2006 (inception) to June 30, 2012, the Company recorded compensation expense, in connection with common stock and stock options issued to employees, directors and consultants, of $154,365, $431,087 and $2,479,245, respectively.

The Company records compensation expense associated with stock options and other forms of equity compensation using the Black-Scholes option-pricing model and the following assumptions:

	Six Months Ended June 30, 2012	**Six Months Ended June 30, 2011**
Expected Term	5 years	5 years
Volatility	98% - 115%	109% - 114%
Dividend yield	0.0%	0.0%
Risk-free interest rate	0.27% - 2.11%	1.75% - 2.11%

The Company estimated the expected term of the stock options granted based on anticipated exercises in future periods assuming the success of its business model as currently forecasted for employees and directors. The expected term of the stock options granted to consultants is based upon the contractual terms established within the operative agreements with the Company. Given the Company's short period of publicly-traded stock history, management's estimate of expected volatility is based on the average expected volatilities of a sampling of five companies with similar attributes to the Company, including: industry, stage of life cycle, size and financial leverage. The Company will continue to analyze the expected stock price volatility and expected term assumptions as more historical data for the Company's common stock becomes available. The expected dividend yield of 0.0% reflects the Company's current and expected future policy for dividends on the Company's common stock. To determine the risk-free interest rate, the Company utilized the U.S. Treasury yield curve in effect at the time of grant with a term consistent with the expected term of the Company's awards. The Company has experienced forfeitures of stock options issued to its former President and Chief Executive Officer, former CMO, former Chairman and Board member, former COO/CFO and other employees. As a result of such forfeitures during 2011, the Company has established a forfeiture rate of 40% and 55% for stock option expense for the three and six months ended June 30, 2012, respectively. The Company will continue to evaluate the estimated forfeiture rate derived from previous forfeitures of employees and directors and may adjust such forfeiture rate accordingly.

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(A Development Stage Company)

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

A summary of the Company's option activity under the Plan and related information is as follows:

	Six Months Ended June 30, 2012		Six Months Ended June 30, 2011	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at beginning of period	1,236,342	$ 2.47	1,662,827	$ 3.15
Forfeited	(263,050)	$ 1.71	(399,111)	$ 3.25
Granted	380,000	0.40	826,000	$ 1.74
Outstanding at end of period	1,353,292	$ 2.10	2,089,716	$ 2.20
Options exercisable	875,958	$ 2.60	454,808	$ 3.21
Weighted-average fair value of options granted during the period		$ 0.32		$ 1.38

The weighted average remaining contractual life of stock options outstanding at June 30, 2012 is 8.4 years. The weighted average remaining contractual life of stock options exercisable at June 30, 2012 is 8.1 years. The aggregate intrinsic value is calculated as the difference between the exercise prices of the underlying options and the quoted closing price of the common stock of the Company as of June 30, 2012 for those options that have an exercise price below the quoted closing price. As of June 30, 2012, all stock options have an exercise price above the quoted closing price of the common stock of the Company, resulting in no intrinsic value.

As of June 30, 2012, the compensation expense related to non-vested options not yet recognized totaled $649,367. The weighted-average vesting period over which the total compensation expense related to non-vested options not yet recognized at June 30, 2012 was approximately 1.3 years.

Note 4 — Licensors:

In accordance with the terms of agreements with the Company's licensors, Shiva Biomedical, LLC ("Shiva") and ND Partners, LLC ("ND Partners"), the Company was obligated to issue additional shares of common stock to each licensor sufficient to maintain an ownership percentage of 7% of the outstanding common stock of the Company on a

fully-diluted basis. As a result of the automatic conversion of all of the Company's outstanding convertible notes into Units (as defined below) and shares of common stock in connection with the closing of the Company's initial public offering (the "IPO"), on March 30, 2010, the Company issued an aggregate of 828,024 shares of common stock to Shiva and ND Partners as a result of anti-dilution adjustments pursuant to their respective agreements, of which 145,543 are being held in escrow for ND Partners pending the achievement of certain regulatory and sales-based milestones. This obligation terminated upon the closing of the IPO. On December 1, 2011, the Company issued Shiva a notice of termination letter of the license agreement and, as such, has no further financial obligation to Shiva.

CorMedix Inc.
(A Development Stage Company)

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

Note 5 — Commitments:

Employment and Severance Agreements

On April 27, 2012, in connection with Brian Lenz's resignation as the Company's Chief Operating Officer and Chief Financial Officer effective April 30, 2012, the Company and Mr. Lenz entered into a Memorandum of Understanding (the "MOU") on May 2, 2012 whereby Mr. Lenz provided certain transition services to the Company through May 31, 2012, and remained reasonably available to the Company, as requested from time to time by the Company from and after May 31, 2012. In exchange for providing such services to the Company, the Company agreed to compensate Mr. Lenz in the amount of $10,417, less applicable taxes and withholdings, in accordance with the regular payroll processing of the Company. Additionally, in consideration of Mr. Lenz's execution of the MOU and performance of the undertakings contained therein, on May 1, 2012, the Compensation Committee of the Board of Directors of the Company approved an extension of Mr. Lenz's right to exercise his 45,000 vested stock options (the "Options") through and including May 31, 2014, in accordance with the terms of the Company's Plan. The Options granted to Mr. Lenz on March 20, 2012 have an exercise price of $0.49. Mr. Lenz will have 90 days to exercise any other remaining vested options from April 30, 2012, with unvested options being forfeited effective April 30, 2012.

On February 29, 2012, the Company and Dr. Mark A. Klausner, the Company's Chief Medical Officer, agreed to amend Dr. Klausner's employment agreement (the "Employment Agreement") in order to reduce the Company's overhead expenditures and help achieve the Company's strategic focus of achieving CE Mark approval for the Company's Neutrolin® product candidate. The amendment to the Employment Agreement (the "Amendment"), effective as of March 1, 2012, provides for a fifty percent (50%) reduction in both Dr. Klausner's services to the Company and his compensation. Pursuant to the Amendment, the Company shall pay Dr. Klausner an annual base salary equal to $155,000 (the "Base Salary") and, at the sole discretion of the Board of Directors of the Company, the Company shall pay Dr. Klausner an additional cash bonus each calendar year during the Term (as defined below) in an amount equal to up to 35% of the aggregate Base Salary. The Amendment maintained the term of the Employment Agreement (the "Term"), which commenced on March 1, 2011 and shall continue for two (2) years, unless earlier terminated. Except as discussed above, the terms and conditions of the Employment Agreement shall otherwise remain in full force and effect.

Note 6 — Fair Value Measurements:

The fair value of the Company's cash and cash equivalents, and accounts payable at June 30, 2012 are estimated to approximate their carrying values due to the relative liquidity and short-term nature of these instruments.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our 2011 Annual Report on Form 10-K filed with the Securities and Exchange Commission, or the SEC, on March 19, 2012.

Forward Looking Statements

This Quarterly Report on Form 10-Q contains "forward-looking statements" that involve risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. The statements contained in this Quarterly Report on Form 10-Q that are not purely historical are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended or the Exchange Act. Forward-looking statements are often identified by the use of words such as, but not limited to, "anticipate," "believe," "can," "continue," "could," "estimate," "expect," "intend," "may," "will," "plan," "project," "seek," "sh "would," and similar expressions or variations intended to identify forward-looking statements. These statements are based on the beliefs and assumptions of our management based on information currently available to management. Such forward-looking statements are subject to risks, uncertainties and other important factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed in the section titled "Risk Factors" included in this quarterly report on Form 10-Q. Furthermore, such forward-looking statements speak only as of the date of this report. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

Overview

CorMedix Inc. (referred to herein as "we," "us," "our" and the "Company"), is a development stage pharmaceutical and medical device company that seeks to in-license, develop and commercialize therapeutic products for the treatment of cardiac and renal dysfunction, specifically in the dialysis and non-dialysis areas. Specifically, our goal is to treat kidney disease by reducing the commonly associated cardiovascular and metabolic complications — in effect, "Treating the kidney to treat the heart." As of the date of this report, we have licensed all of the product candidates in our pipeline.

We have the worldwide rights to develop and commercialize our product candidates, CRMD003 (Neutrolin®) and CRMD004 that address significant market opportunities in the instances in which a central venous catheter is used, such as hemodialysis, intensive care units, oncology and total parenteral nutrition patients.

Our primary product candidate in development is CRMD003 (Neutrolin®) for the prevention of catheter related infections in the dialysis and non-dialysis markets, which we believe addresses a large unmet medical need and market opportunity. CRMD003 is a liquid formulation designed to prevent central venous catheter infection and maintenance of catheter patency in central venous catheters (initially in hemodialysis catheters). There are approximately 780,000 hemodialysis patients in the United States and the European Union. We believe the patients undergoing hemodialysis using a tunneled central vein catheter will be our initial target market. We project 91,000 patients in the European Union and 104,000 patients in the United States. These patients represent nearly 30 million hemodialysis sessions per year and we believe has a market potential of approximately $300 - $400 million.

During the third quarter of 2011, we received a notice from the U.S. Food and Drug Administration, or the FDA, that our product candidate, CRMD003, Neutrolin® had been assigned to the Center for Drug Evaluation and Research, or CDER. As a result of this notice and our current capital position, we decided to change our business strategy and focus the majority of our resources on the research and development of CRMD003 and seek regulatory and commercialization approval for Neutrolin® in Europe through a CE Mark application. During the first half of 2011, we submitted our design dossier to TÜV SÜD the European notified body managing our CE Mark application. In the fourth quarter of 2011 we successfully completed our stage 1 audit with TÜV. Upon the successful completion of the stage 2 audit and the implementation and approval of our quality management system and approval of our design dossier, we anticipate being in a position to obtain a CE Mark approval by the end of the fourth quarter of 2012. If we obtain CE Mark approval in Europe, we intend to be in a position to launch Neutrolin® for the prevention of Catheter Related Bloodstream Infections, or CRBI and maintenance of catheter patency in hemodialysis patients in Europe by fourth quarter 2012/first quarter 2013. We cannot be assured of CE Mark approval of Neutrolin® on that timeline or at all. We are currently exploring the various methods of launching Neutrolin® in Europe, whether through a distributorship or partnership arrangement, or otherwise.

We are a development stage company. We were organized as a Delaware corporation on July 28, 2006 under the name “Picton Holding Company, Inc.” and we changed our corporate name to “CorMedix Inc.” on January 18, 2007. Since our inception, we have had no revenue from product sales. Our operations to date have been primarily limited to organizing and staffing, licensing product candidates, developing clinical trials for our product candidates, establishing manufacturing for our product candidates and maintaining and improving our patent portfolio. We have generated significant losses to date, and we expect to continue to generate losses as we progress towards the commercialization of our product candidate CRMD003. As of June 30, 2012, we had an accumulated deficit of $44,481,928. Since we do not generate revenue from any of our product candidates, our losses will continue as we advance our product candidates towards regulatory approval and eventual commercialization. As a result, our operating losses are likely to be substantial over the next several years. We are unable to predict the extent of any future losses or when we will become profitable, if at all.

In March 2010, we completed our Initial Public Offering, or the IPO, whereby we sold 1,925,000 units, each unit consisting of two shares of our common stock and a warrant to purchase one share of common stock, each a Unit, at $6.50 per Unit resulting in gross proceeds of $12,512,500 and net proceeds to us of $10,457,270 after deducting underwriting discounts and commissions and offering expenses payable by us. All of our convertible notes and accrued interest thereon and all of our outstanding shares of Non-Voting Subordinated Class A Common Stock automatically converted into Units or common stock upon the completion of the IPO. We believe that as a result of our recent decision to focus the majority of our resources, including our research and development efforts primarily on CE Marking approval and the commercialization of Neutrolin® (CRMD003) in Europe, the net proceeds from the IPO and existing cash will be sufficient to fund our projected operating requirements into the fourth quarter of 2012. We intend to raise additional funds through various potential sources, such as equity and/or debt financings, strategic relationships, or out-licensing of our products, however, we can provide no assurances that such financing will be available on acceptable terms, or at all.

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Financial Operations Overview

Revenue

We have not generated any revenue since our inception. As of June 30, 2012, we have funded our operations primarily through debt financings and the IPO, and our receipt of a total of approximately $490,000 from Federal grants under the Qualifying Therapeutic Discovery Project program and a total of approximately $775,000 from the sale of our unused net operating losses through the State of New Jersey's Economic Development Authority Technology Business Tax Certificate Transfer Program and a total of approximately $35,000 from qualified research and development expenditures refunded to us through the New York State Department of Taxation and Finance under the Qualifying Emerging Technology Incentive Program.

If our product development efforts result in clinical success, regulatory approval and successful commercialization of any of our products, we could generate revenue from sales or licenses of any such products.

Research and Development Expense

Research and development, or R&D, expense consists of: (i) internal costs associated with our development activities; (ii) payments we make to third party contract research organizations, contract manufacturers, investigative sites, and consultants; (iii) technology and intellectual property license costs; (iv) manufacturing development costs; (v) personnel related expenses, including salaries, stock–based compensation expense, benefits, travel and related costs for the personnel involved in drug development; (vi) activities relating to regulatory filings and the advancement of our product candidates through preclinical studies and clinical trials; and (vii) facilities and other allocated expenses, which include direct and allocated expenses for rent, facility maintenance, as well as laboratory and other supplies. All R&D is expensed as incurred.

Conducting a significant amount of R&D is central to our business model. Through June 30, 2012, we incurred $22,778,719 in R&D expenses since our inception in July 2006. Product candidates in later-stage clinical development generally have higher development costs than those in earlier stages of development, primarily due to the significantly increased size and duration of the clinical trials. As a result of our recent strategic changes, we expect our R&D expenditures to decrease and be primarily attributed to the CE Marking approval and commercialization of Neutrolin® in Europe. If the CE Marking approval and commercialization for Neutrolin® is successful, we intend to increase our R&D expenses for the foreseeable future in order to complete development of CRMD003 in the United States.

The following table summarizes the percentages of our R&D payments related to our two most advanced product candidates and other projects. The percentages summarized in the following table reflect payments directly attributable to each development candidate, which are tracked on a project basis. A portion of our internal costs, including indirect costs relating to our product candidates, are not tracked on a project basis and are allocated based on management's estimate.

	Six Months Ended June 30,		Period from July 28, 2006 (Inception) through June 30, 2012
	2012	2011	
CRMD001	24 %	32 %	54 %
CRMD002	0 %	0 %	0 %
CRMD003	70 %	66 %	43 %
CRMD004	6 %	2 %	3 %

The process of conducting pre-clinical studies and clinical trials necessary to obtain FDA approval is costly and time consuming. The probability of success for each product candidate and clinical trial may be affected by a variety of factors, including, among others, the quality of the product candidate's early clinical data, investment in the program, competition, manufacturing capabilities and commercial viability. As a result of the uncertainties discussed above, the uncertainty associated with clinical trial enrollments and the risks inherent in the development process, we are unable to determine the duration and completion costs of current or future clinical stages of our product candidates or when, or to what extent, we will generate revenues from the commercialization and sale of any of our product candidates.

Development timelines, probability of success and development costs vary widely. In addition, our current focus on CE Marking approval and commercializing Neutrolin® in Europe by the CE Marking process may impact our other development efforts and timelines. If we are successful in the CE Marking designation for Neutrolin® in Europe and commercialization, we plan on continuing to develop CRMD003 for the prevention of CRBI and maintenance of catheter patency in the United States. We expect to raise additional funds at a later date in order to fully complete the development of CRMD003 or to develop any new product candidates.

General and Administrative Expense

General and administrative, or G&A, expense consists primarily of salaries and other related costs, including stock-based compensation expense, for persons serving in our executive, finance and accounting functions. Other G&A expense includes facility-related costs not otherwise included in R&D expense, promotional expenses, costs associated with industry and trade shows, and professional fees for legal services and accounting services. We expect that our G&A expenses will remain unchanged for the remainder of 2012. From our inception on July 28, 2006 through June 30, 2012, we spent $11,831,826 on G&A expense.

Interest Income and Interest Expense

Interest income consists of interest earned on our cash and cash equivalents. Interest expense consists of interest incurred on our convertible notes up to their automatic conversion into Units or common stock upon the completion of the IPO on March 30, 2010, as well as the amortization and write-off of deferred financing costs and debt discounts and a charge for the beneficial conversion feature relating to our convertible notes.

Results of Operations

Three months ended June 30, 2012 compared to three months ended June 30, 2011

Research and Development Expense. R&D expense was $248,190 for the three months ended June 30, 2012, a decrease of $1,334,158, from $1,582,348 for the three months ended June 30, 2011. The decrease was attributable to our strategic change of direction during September 2011, which is to focus primarily on CE Marking approval for Neutrolin®. During the fourth quarter of 2011, we also discontinued the development of CRMD001, deferirprone and returned the product candidate to the licensor in December 2011. Our strategic change of direction also resulted in lower clinical research organization, manufacturing and regulatory expenses related to the development of CRMD003 during the second quarter of 2012 and lower personnel costs as a result of our Chief Medical Officer (“CMO”)

transitioning to a part-time status and a 50% reduction of salary effective March 2012.

General and Administrative Expense. G&A expense was $376,617 for the three months ended June 30, 2012, a decrease of $521,407 from $898,024 for the three months ended June 30, 2011. The decrease was primarily attributable to lower compensation and stock-based compensation expense as a result of the separation of our former President and Chief Executive Officer in September 2011 and the resignation of our Chief Financial Officer in April 2012 and lower expenses related to investor relations.

Interest Income. Interest income was $592 for the three months ended June 30, 2012, a decrease of $2,667, from $3,259 for the three months ended June 30, 2011. The decrease was attributable to having lower interest-bearing cash balances during the second quarter of 2012 compared to the same quarter of 2011.

Six months ended June 30, 2012 compared to six months ended June 30, 2011

Research and Development Expense. R&D expense was $623,046 for the six months ended June 30, 2012, a decrease of $2,134,844, from $2,757,890 for the six months ended June 30, 2011. The decrease was attributable to our strategic change of direction during September 2011, which was to focus primarily on CE Marking approval for Neutrolin®. During the fourth quarter of 2011, we also discontinued the development of CRMD001, deferiprone and returned the product candidate to the licensor in December 2011. Our strategic change of direction also resulted in lower clinical research organization, manufacturing and regulatory expenses related to the development of CRMD003 during the first half of 2012 and lower personnel costs as a result of our Chief Medical Officer transitioning to a part-time status and a 50% reduction of salary effective March 2012.

General and Administrative Expense. G&A expense was $912,871 for the six months ended June 30, 2012, a decrease of $819,635 from $1,732,506 for the six months ended June 30, 2011. The decrease was primarily attributable to lower compensation and stock-based compensation expense as a result of the separation of our former President and Chief Executive Officer in September 2011 and the resignation of our Chief Financial Officer in April 2012 and lower expenses related to investor relations.

Interest Income. Interest income was $1,541 for the six months ended June 30, 2012, a decrease of $6,885 from $8,426 for the six months ended June 30, 2011. The decrease was attributable to having lower interest-bearing cash balances during the six months period ended June 30, 2012 compared to the same period last year.

Liquidity and Capital Resources

Sources of Liquidity

As a result of our significant R&D expenditures and the lack of any approved products to generate product sales revenue, we have not been profitable and have generated operating losses since we were incorporated in July 2006. Prior to the IPO, we had funded our operations principally with $14,364,973 in convertible notes sold in private placements and $625,464 in related party notes, which were also convertible. All of our convertible notes were automatically converted into 1,237,293 shares of common stock and 2,338,576 Units comprised of 4,677,152 shares

of common stock and 2,841,603 warrants at an exercise price of $3.4375. We received net proceeds of $10,457,270 from the IPO, after deducting underwriting discounts, commissions and offering expenses payable by us upon the closing of the IPO on March 30, 2010. Additionally, we received a total of approximately $490,000 from Federal grants under the Qualifying Therapeutic Discovery Project program and a total of approximately $775,000 from the sale of our unused net operating losses through the State of New Jersey's Economic Development Authority Technology Business Tax Certificate Transfer Program and a total of approximately $35,000 from qualified R&D expenditures refunded to us through the New York State Department of Taxation and Finance under the Qualifying Emerging Technology Incentive Program.

Net Cash Used in Operating Activities

Net cash used in operating activities was $1,076,398 for the six months ended June 30, 2012. The net loss of $1,534,376 for the six months ended June 30, 2012 was higher than cash used in operating activities by $457,978. The difference is attributable primarily to a stock-based compensation charge of $154,365, a decrease in prepaid expenses and other current assets of $439,763, which consisted primarily of collection of other receivables related to the sale of our unused net operating losses through the State of New Jersey's Economic Development Authority Technology Business Tax Certificate Transfer Program and the amortization of insurance premiums during the six months ended June 30, 2012. These were offset by a decrease in accounts payable of $14,726 and accrued expenses of $123,791 related to the reversal of year end 2011 bonuses accrued but not paid as a result of conserving cash during the period.

Net Cash Used in Investing Activities

Net cash used in investing activities was $0 for the six months ended June 30, 2012 and 2011.

Net Cash Provided By(Used In) in Financing Activities

Net cash used in financing activities was $15,000 for the six months ended June 30, 2012 as compared to $0 for the same period last year, attributable to the efforts of the Company to raise additional funds.

Funding Requirements

Our total cash and cash equivalents as of June 30, 2012 was $893,936, compared to $1,985,334 at December 31, 2011. Since our business does not generate positive operating cash flow, we will need to either raise additional capital before we exhaust our current cash resources in order to continue to fund our R&D, including our long-term plans for clinical trials and new product development, as well as to fund operations generally. Our continued operations will depend on whether we are able to raise additional funds through various potential sources, such as equity and or debt financing, strategic relationships, or out-licensing of our products. As of June 30, 2012, we have funded our operations primarily through debt financings, the IPO, and our receipt of a total of approximately $490,000 from Federal grants under the Qualifying Therapeutic Discovery Project program, approximately $775,000 from the sale of our unused net operating losses through the State of New Jersey's Economic Development Authority Technology Business Tax Certificate Transfer Program and $35,000 from qualified R&D expenditures refunded to us through the New York State Department of Taxation and Finance under the Qualifying Emerging Technology Incentive Program.

We expect to continue to fund operations from cash and cash equivalents and through either capital raising sources as described above, which may be dilutive to existing stockholders, or through generating revenues from the licensing of our products or strategic alliances. We plan to seek additional debt and/or equity financing, but can provide no assurances that such financing will be available on acceptable terms, or at all. Moreover, the incurrence of indebtedness in connection with a debt financing would result in increased fixed obligations and could also result in covenants that would restrict our operations. These matters, among others, raise substantial doubt about our ability to continue as a going concern.

Our actual cash requirements may vary materially from those now planned, however, because of a number of factors including the changes in the focus and direction of our R&D, the acquisition and pursuit of development of new product candidates, competitive and technical advances, costs of commercializing any of the product candidates, and costs of filing, prosecuting, defending and enforcing any patent claims and any other intellectual property rights.

We do not anticipate that we will generate any product revenue for 2012. In the absence of additional funding, we expect our continuing operating losses to result in increases in our cash used in operations over the next several quarters and years. If adequate financing is not available, the Company may be required to terminate or significantly curtail or cease its operations, or enter into arrangements with collaborative partners or others that may require the Company to relinquish rights to certain of its technologies, or potential markets that the Company would not otherwise relinquish.

Based on our cash resources at June 30, 2012 and our current plan of expenditures on the CE Marking approval process for Neutrolin®, along with limited development of Neutrolin® in the United States, we believe that we have sufficient capital to fund our operations into the fourth quarter of 2012, and will need additional financing until we can achieve profitability, if ever. If we are unable to raise additional funds when needed, we may not be able to market our products as planned or continue development and regulatory approval of our products, or we could be required to delay, scale back or eliminate some or all of our R&D programs. Each of these alternatives would likely have a material adverse effect on the prospects of our business. These matters, among others, raise substantial doubt about our ability to continue as a going concern.

Critical Accounting Policies

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. On an ongoing basis, we evaluate these estimates and judgments, including those described below. We base our estimates on our historical experience and on various other assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results and experiences may differ materially from these estimates.

While our significant accounting policies are more fully described in our Annual Report on Form 10-K filed with the SEC on March 19, 2012, we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our reported financial results and affect the more significant judgments and estimates that we use in the preparation of our financial statements.

Stock-Based Compensation

Stock-based compensation cost is measured at grant date, based on the estimated fair value of the award, and is recognized as expense over the employee's requisite service period on a straight-line basis.

We account for stock options granted to non-employees on a fair value basis using the Black-Scholes option pricing method. The fair value of non-employee options with vesting are revalued at the end of each reporting period based upon the change in the fair value of the options and amortized to consulting expense over the related contract service period.

For the purpose of valuing options and warrants granted to our employees, directors and officers during the six months ended June 30, 2012, we used the Black-Scholes option pricing model. We granted options to purchase an aggregate of 380,000 and 826,000 shares of common stock to our employees, directors and officers and consultants during the six months ended June 30, 2012 and 2011, respectively. Of the 380,000 options issued during the six months ended June 30, 2012, we granted 180,000 performance based options to our Chief Operating Officer and Chief Financial Officer with an exercise price of $0.49, of which 25% vested on March 20, 2012, the date of grant, and were fully expensed, 25% vest upon the closing of a financing by the Company with gross proceeds in excess of $1.5 million which includes either the issuance of equity, debt or any combination thereof with an expectation by the Company it is probable that such objective will be achieved and the Company will be expensing the vesting of such options through the end of 2012, 25% vest upon CE Mark approval for CRMD003 (Neutrolin®) with an expectation by the Company it is probable that such objective will be achieved and the Company will be expensing the vesting of such options through the end of 2012 and 25% vest upon the launch of Neutrolin® in Europe, provided, however, that each of the events described occur on or before December 31, 2012, of which the Company has not determined if such options will vest by year end 2012 which will occur only if and until CE Marking is achieved, as such the Company has not recognized any expense for such options. To determine the risk-free interest rate, we utilized the U.S. Treasury yield curve in effect at the time of grant with a term consistent with the expected term of our awards. We estimated the expected term of the options granted based on anticipated exercises in future periods assuming the success of our business model as currently forecasted. The expected dividend yield reflects our current and expected future policy for dividends on our common stock. The expected stock price volatility for our stock options was calculated by examining historical volatilities for publicly traded industry peers, since we do not have any trading history for our common stock. We will continue to analyze the expected stock price volatility and expected term assumptions as more historical data for our common stock becomes available. The Company has experienced forfeitures of stock options issued to its former President and Chief Executive Officer, former Chief Medical Officer, former Chairman and Board member, former Chief Operating Officer/Chief Financial Officer and employees. As a result of such forfeitures, we established a forfeiture rate of 40% and 55% for stock option expense for the three and six months ended June 30, 2012, respectively. The Company will continue to evaluate the estimated forfeiture rate derived from previous forfeitures of employees and board of directors and may adjust such forfeiture rate accordingly.

During the quarter ended June 30, 2012, 135,000 stock options issued to the former Chief Financial Officer were forfeited as a result of his resignation in April 2012. The expiration of the remaining 45,000 stock options were extended by the board of directors of the Company to expire on May 31, 2014.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this report, our management, including our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended ("Exchange Act")). Based on their evaluation of our disclosure controls and procedures, our management, including our principal executive officer and principal financial officer, have concluded that our disclosure controls and procedures were effective as of June 30, 2012 to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is (a) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (b) accumulated and communicated to management, including our principal executive officer and principal financial officer, as appropriate to allow for timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

During the three months ended June 30, 2012, there were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) and 15d – 15(f) under the Exchange Act), or in other factors that could significantly affect these controls, that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II
OTHER INFORMATION

Item 1. Legal Proceedings.

On April 19, 2012, CorMedix was served with a lawsuit by the Superior Court of New Jersey regarding non-payment of services to Xerimis, a vendor of the Company. The Company settled the outstanding balance in May 2012 in the amount of $80,986.93.

Item 1A. Risk Factors.

Described below are various risks and uncertainties that may affect our business. These risks and uncertainties are not the only ones we face. You should recognize that other significant risks and uncertainties may arise in the future, which we cannot foresee at this time. Also, the risks that we now foresee might affect us to a greater or different degree than expected. Certain risks and uncertainties, including ones that we currently deem immaterial or that are similar to those faced by other companies in our industry or business in general, may also affect our business. If any of the risks described below actually occur, our business, financial condition or results of operations could be materially and adversely affected.

Risks Related to Our Financial Position and Need for Additional Capital

We have a limited operating history and a history of escalating operating losses, and expect to incur significant additional operating losses.

We were established in July 2006 and have only a limited operating history. Therefore, there is limited historical financial information upon which to base an evaluation of our performance. Our prospects must be considered in light of the uncertainties, risks, expenses, and difficulties frequently encountered by companies in their early stages of operations. We incurred net losses of approximately $1.5 million and $4.5 million for the six months ended June 30, 2012 and 2011, respectively. As of June 30, 2012, we had an accumulated deficit of approximately $44.5 million. We expect to incur substantial additional operating expenses over the next several years as our research, development, pre-clinical testing, and clinical trial activities increase. The amount of future losses and when, if ever, we will achieve profitability are uncertain. We have no products that have generated any commercial revenue, do not expect to generate revenues from the commercial sale of products in the near future, and might never generate revenues from the sale of products. Our ability to generate revenue and achieve profitability will depend on, among other things, the following: successful completion of the development of our product candidates; obtaining necessary regulatory approvals from the FDA and international regulatory agencies; establishing manufacturing, sales, and marketing arrangements, either alone or with third parties; and raising sufficient funds to finance our activities. We might not succeed at any of these undertakings. If we are unsuccessful at some or all of these undertakings, our business, prospects, and results of operations may be materially adversely affected. Development timelines, probability of success and development costs vary widely. In addition, our current focus on CE Marking approval and commercializing Neutrolin® in Europe by the CE Marking process may impact our other development efforts and timelines.

We are not currently profitable and may never become profitable.

We have a history of losses and expect to incur substantial losses and negative operating cash flow for the foreseeable future, and we may never achieve or maintain profitability. Even if we succeed in developing and commercializing one or more product candidates, we expect to incur substantial losses for the foreseeable future and may never become profitable. We also expect to continue to incur significant operating and capital expenditures and anticipate that our expenses will increase substantially in the foreseeable future as we continue to undertake development of our product candidates, undertake clinical trials of our product candidates, seek regulatory approvals for product candidates, implement additional internal systems and infrastructure, and hire additional personnel.

We also expect to experience negative cash flow for the foreseeable future as we fund our operating losses and capital expenditures. As a result, we will need to generate significant revenues in order to achieve and maintain profitability. We may not be able to generate these revenues or achieve profitability in the future. Our failure to achieve or maintain profitability would negatively impact the value of our securities.

We will need to finance our future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. Any additional funds that we obtain may not be on terms favorable to us or our stockholders and may require us to relinquish valuable rights.

We have no approved product on the market and have generated no product revenues. Unless and until we receive approval from the FDA and other regulatory authorities for our product candidates, we cannot sell our products and will not have product revenues. Therefore, for the foreseeable future, we will have to fund all of our operations and capital expenditures from cash on hand, licensing fees and grants.

We believe that existing cash will be sufficient to enable us to fund our projected operating requirements into the fourth quarter of 2012, based upon our recent decision to focus the majority of our resources, including our research and development efforts primarily on the CE Marking approval and commercialization of Neutrolin® (CRMD003) in Europe. However, we may need to raise additional funds more quickly if one or more of our assumptions prove to be incorrect or if we choose to expand our product development efforts more rapidly than we presently anticipate, and we may decide to raise additional funds even before we need them if the conditions for raising capital are favorable.

We may seek to sell additional equity or debt securities, obtain a bank credit facility, or enter into a corporate collaboration or licensing arrangement. The sale of additional equity or debt securities, if convertible, could result in dilution to our stockholders. The incurrence of indebtedness would result in increased fixed obligations and could also result in covenants that would restrict our operations. Raising additional funds through collaboration or licensing arrangements with third parties may require us to relinquish valuable rights to our technologies, future revenue

streams, research programs or product candidates, or to grant licenses on terms that may not be favorable to us or our stockholders.

Risks Related to the Development and Commercialization of Our Product Candidates

Our product candidates are still in development.

We are a development stage pharmaceutical company with product candidates in various stages of development. We have recently changed our strategy to primarily focus on the commercialization of Neutrolin® in Europe through the CE Marking process and have reprioritized our other product candidates' development until we have obtained CE Marking approval in Europe. Our product candidates are currently at the following stages:

- CRMD003 (Neutrolin®) - submitted a CE Mark application for the approval in Europe
- CRMD004 - currently in the pre-clinical phase

Our product development methods may not lead to commercially viable products for any of several reasons. For example, our product candidates may fail to be proven safe and effective in clinical trials, or we may have inadequate financial or other resources to pursue development efforts for our product candidates. Our product candidates will require significant additional development, clinical trials, regulatory clearances and investment by us or our collaborators before they can be commercialized.

Successful development of our products is uncertain.

Our development of current and future product candidates is subject to the risks of failure and delay inherent in the development of new pharmaceutical products, including but not limited to the following:

- delays in product development, clinical testing, or manufacturing;
- unplanned expenditures in product development, clinical testing, or manufacturing;
- failure to receive regulatory approvals;
- emergence of superior or equivalent products;

- inability to manufacture our product candidates on a commercial scale on our own, or in collaboration with third parties; and

- failure to achieve market acceptance.

Because of these risks, our development efforts may not result in any commercially viable products. If a significant portion of these development efforts are not successfully completed, required regulatory approvals are not obtained or any approved products are not commercialized successfully, our business, financial condition, and results of operations may be materially harmed.

Clinical trials required for our product candidates are expensive and time-consuming, and their outcome is uncertain.

In order to obtain FDA approval to market a new drug or device product, we must demonstrate proof of safety and effectiveness in humans. To meet these requirements, we must conduct "adequate and well-controlled" clinical trials. Conducting clinical trials is a lengthy, time-consuming, and expensive process. The length of time may vary substantially according to the type, complexity, novelty, and intended use of the product candidate, and often can be several years or more per trial. Delays associated with products for which we are directly conducting clinical trials may cause us to incur additional operating expenses. The commencement and rate of completion of clinical trials may be delayed by many factors, including, for example:

- inability to manufacture sufficient quantities of qualified materials under the FDA's current Good Manufacturing Practices requirements, referred to herein as cGMP, for use in clinical trials;

- slower than expected rates of patient recruitment;

- failure to recruit a sufficient number of patients;

- modification of clinical trial protocols;

- changes in regulatory requirements for clinical trials;

- lack of effectiveness during clinical trials;

- emergence of unforeseen safety issues;

- delays, suspension, or termination of clinical trials due to the institutional review board responsible for overseeing the study at a particular study site; and

- government or regulatory delays or "clinical holds" requiring suspension or termination of the trials.

The results from early clinical trials are not necessarily predictive of results to be obtained in later clinical trials. Accordingly, even if we obtain positive results from early clinical trials, we may not achieve the same success in later clinical trials.

Our clinical trials may be conducted in patients with serious or life-threatening diseases for whom conventional treatments have been unsuccessful or for whom no conventional treatment exists, and in some cases, our product is expected to be used in combination with approved therapies that themselves have significant adverse event profiles. During the course of treatment, these patients could suffer adverse medical events or die for reasons that may or may not be related to our products. We cannot ensure that safety issues will not arise with respect to our products in clinical development.

Clinical trials may not demonstrate statistically significant safety and effectiveness to obtain the requisite regulatory approvals for product candidates. The failure of clinical trials to demonstrate safety and effectiveness for the desired indications could harm the development of our product candidates. Such a failure could cause us to abandon a product candidate and could delay development of other product candidates. Any delay in, or termination of, our clinical trials

would delay the filing of our New Drug Applications or Premarket Approval Applications with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues. Any change in, or termination of, our clinical trials could materially harm our business, financial condition, and results of operations.

We do not have, and may never obtain, the regulatory approvals we need to market our product candidates.

·In the United States, we have not applied for or received the regulatory approvals required for the commercial sale of any of our products. None of our product candidates has been determined to be safe and effective in the United States, and we have not submitted a New Drug Application or Premarket Approval Application to the FDA.

We have recently filed a design dossier submission with TUV, the European Notified Body as part of the regulatory CE Marking approval process in Europe for Neutrolin®.

It is possible that none of our product candidates will be approved for marketing. Failure to obtain regulatory approvals, or delays in obtaining regulatory approvals, may adversely affect the successful commercialization of any drugs or biologics that we or our partners develop, impose additional costs on us or our collaborators, diminish any competitive advantages that we or our partners may attain, and/or adversely affect our receipt of revenues or royalties.

If we fail to comply with international regulatory requirements we could be subject to regulatory delays, fines or other penalties.

Regulatory requirements in foreign countries for international sales of medical devices often vary from country to country. The occurrence and related impact of the following factors would harm our business:

- delays in receipt of, or failure to receive, foreign regulatory approvals or clearances;
- the loss of previously obtained approvals or clearances; or
- the failure to comply with existing or future regulatory requirements.

The CE Mark is a mandatory conformity mark for products that are positioned for sale in the European Economic Area. Currently, 30 countries in Europe require products to bear CE Marking. To market in Europe, a product must first obtain the certifications necessary to affix the CE Mark. The CE Mark is an international symbol of adherence to the Medical Device Directives and the manufacturer’s declaration that the product complies with essential requirements. Compliance with these requirements is ascertained within a certified Quality Management System (QMS) pursuant to International Standards Organization (ISO) 13485. In order to obtain and to maintain a CE Mark, a product must be in compliance with the applicable quality assurance provisions of the aforementioned International Standards Organization and obtain certification of its quality assurance systems by a recognized European Union notified body. However, certain individual countries within the European Union require further approval by their national regulatory agencies. We are in the process of applying for CE Mark registration for our Neutrolin product candidate. Failure to receive or maintain the right to affix the CE Mark or other requisite approvals could prohibit us from marketing and selling Neutrolin in the European Union or elsewhere.

Even if approved, our products will be subject to extensive post-approval regulation.

Once a product is approved, numerous post-approval requirements apply. Depending on the circumstances, failure to meet these post-approval requirements can result in criminal prosecution, fines, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, or refusal to allow us to enter into supply contracts, including government contracts. In addition, even if we comply with FDA and other requirements, new information regarding the safety or effectiveness of a product could lead the FDA to modify or withdraw product approval.

The successful commercialization of our products will depend on obtaining coverage and reimbursement for use of these products from third-party payors.

Sales of pharmaceutical products largely depend on the reimbursement of patients' medical expenses by government health care programs and private health insurers. Without the financial support of the government or third-party payors, the market for our products will be limited. These third-party payors are increasingly challenging the price and examining the cost effectiveness of medical products and services. Recent proposals to change the health care system in the United States have included measures that would limit or eliminate payments for medical products and services or subject the pricing of medical treatment products to government control. Significant uncertainty exists as to the reimbursement status of newly approved health care products. Third-party payors may not reimburse sales of our products or enable our collaborators to sell them at profitable prices.

Physicians and patients may not accept and use our products.

Even if the FDA approves one or more of our product candidates, physicians and patients may not accept and use it. Acceptance and use of our products will depend upon a number of factors including the following:

- perceptions by members of the health care community, including physicians, about the safety and effectiveness of our drug or device product;
- cost-effectiveness of our product relative to competing products;
- availability of reimbursement for our product from government or other healthcare payers; and
- effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

Because we expect sales of our current product candidates, if approved, to generate substantially all of our product revenues for the foreseeable future, the failure of these products to find market acceptance would harm our business and could require us to seek additional financing.

Risks Related to Our Business and Industry

Competition and technological change may make our product candidates and technologies less attractive or obsolete.

We compete with established pharmaceutical and biotechnology companies that are pursuing other forms of treatment for the same indications we are pursuing and that have greater financial and other resources. Other companies may succeed in developing products earlier than we do, obtaining FDA or any other regulatory agency approval for products more rapidly, or developing products that are more effective than our product candidates. Research and development by others may render our technology or product candidates obsolete or noncompetitive, or result in treatments or cures superior to any therapy we develop. We face competition from companies that internally develop competing technology or acquire competing technology from universities and other research institutions. As these companies develop their technologies, they may develop competitive positions that may prevent, make futile, or limit our product commercialization efforts, which would result in a decrease in the revenue we would be able to derive from the sale of any products.

There can be no assurance that any of our product candidates will be accepted by the marketplace as readily as these or other competing treatments. Furthermore, if our competitors' products are approved before ours, it could be more difficult for us to obtain approval from the FDA or any other regulatory agency. Even if our products are successfully developed and approved for use by all governing regulatory bodies, there can be no assurance that physicians and patients will accept our product(s) as a treatment of choice.

Furthermore, the pharmaceutical industry is diverse, complex, and rapidly changing. By its nature, the business risks associated therewith are numerous and significant. The effects of competition, intellectual property disputes, market acceptance, and FDA or other regulatory agency regulations preclude us from forecasting revenues or income with certainty or even confidence.

We face the risk of product liability claims and the amount of insurance coverage we hold now or in the future may not be adequate to cover all liabilities we might incur.

Our business exposes us to the risk of product liability claims that are inherent in the development of drugs. If the use of one or more of our or our collaborators' drugs harms people, we may be subject to costly and damaging product liability claims brought against us by clinical trial participants, consumers, health care providers, pharmaceutical companies or others selling our products.

We currently carry product liability insurance that covers our clinical trial. We cannot predict all of the possible harms or side effects that may result and, therefore, the amount of insurance coverage we hold may not be adequate to cover all liabilities we might incur. Our insurance covers bodily injury and property damage arising from our clinical trials, subject to industry-standard terms, conditions and exclusions. This coverage does not include the sale of commercial products. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing.

If we are unable to obtain insurance at an acceptable cost or otherwise protect against potential product liability claims, we may be exposed to significant liabilities, which may materially and adversely affect our business and financial position. If we are sued for any injury allegedly caused by our or our collaborators' products and do not have sufficient insurance coverage, our liability could exceed our total assets and our ability to pay the liability. A successful product liability claim or series of claims brought against us would decrease our cash and could cause the value of our capital stock to decrease.

We may be exposed to liability claims associated with the use of hazardous materials and chemicals.

Our research, development and manufacturing activities and/or those of our third party contractors may involve the controlled use of hazardous materials and chemicals. Although we believe that our safety procedures for using, storing, handling and disposing of these materials comply with federal, state and local laws and regulations, we cannot completely eliminate the risk of accidental injury or contamination from these materials. In the event of such an accident, we could be held liable for any resulting damages and any liability could materially adversely affect our business, financial condition and results of operations. In addition, the federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous or radioactive materials and waste products may require us to incur substantial compliance costs that could materially adversely affect our business, financial condition and results of operations.

Recent healthcare policy changes may have an adverse effect on our business, financial condition and results of operations.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the Healthcare Reform Act, substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The Healthcare Reform Act contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse, which will impact existing government healthcare programs and will result in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program. We anticipate that if we obtain approval for our products, some of our revenue may be derived from U.S. government healthcare programs, including Medicare. Furthermore, beginning in 2011, the Healthcare Reform Act will impose a non-deductible excise tax on pharmaceutical manufacturers or importers who sell "branded prescription drugs," which includes innovator drugs and biologics (excluding orphan drugs or generics) to U.S. government programs. We expect that the Healthcare Reform Act and other healthcare reform measures that may be adopted in the future could have an adverse effect on our industry generally and our products specifically.

In addition to the Healthcare Reform Act, we expect that there will continue to be proposals by legislators at both the federal and state levels, regulators and third-party payors to keep healthcare costs down while expanding individual healthcare benefits. Certain of these changes could impose limitations on the prices we will be able to charge for any products that are approved or the amounts of reimbursement available for these products from governmental agencies or third-party payors or may increase the tax requirements for life sciences companies such as ours. While it is too early to predict what effect the recently enacted Healthcare Reform Act or any future legislation or regulation will have on us, such laws could have an adverse effect on our business, financial condition and results of operations.

If we lose key management or scientific personnel, cannot recruit qualified employees, directors, officers, or other personnel or experience increases in compensation costs, our business may materially suffer.

We are highly dependent on the principal members of our management and scientific staff, specifically, Richard Cohen, our Interim Chief Executive Officer and Interim Chief Financial Officer and Dr. Mark Klausner, our part-time Chief Medical Officer. While we have an employment agreement Dr. Klausner, employment agreements cannot insure our retention of the employees covered by such agreements. Furthermore, our future success will also depend in part on our ability to identify, hire, and retain additional personnel. We experience intense competition for qualified personnel and may be unable to attract and retain the personnel necessary for the development of our business. Moreover, our work force is located in the New Jersey metropolitan area, where competition for personnel with the scientific and technical skills that we seek is extremely high and is likely to remain high. Because of this competition, our compensation costs may increase significantly. In addition, we have only limited ability to prevent former employees from competing with us.

Recent changes in our management may lead to instability and may negatively affect our business.

During September 2011, John Houghton, our former President and Chief Executive Officer, separated from the Company and in April 2012 Brian Lenz, our former Chief Financial Officer and Chief Operating Officer resigned. Our board of directors appointed Richard Cohen to serve as our Interim Chief Executive Officer and Interim Chief Financial Officer. The board of directors also appointed Randy Milby to serve as our Chief Operating Officer. We cannot be certain that the changes in management will not negatively affect our business in the future or that additional changes in management and in the composition of our board of directors will not occur. Additionally, we may be negatively impacted by a lack of accounting expertise, lack of internal control processes (which include lack of segregation of duties for cash disbursements and cash reconciliations), lack of accuracy and timeliness of financial reporting as a result of the resignation of our former Chief Financial Officer and Chief Operating Officer.

If we are unable to hire additional qualified personnel, our ability to grow our business may be harmed.

Over time, we will need to hire additional qualified personnel with expertise in clinical testing, clinical research and testing, government regulation, formulation and manufacturing, and sales and marketing. We compete for qualified individuals with numerous pharmaceutical companies, universities and other research institutions. Competition for such individuals is intense, and we cannot be certain that our search for such personnel will be successful. Attracting and retaining such qualified personnel will be critical to our success.

We may not successfully manage our growth.

Our success will depend upon the expansion of our operations and the effective management of our growth, which will place a significant strain on our management and our administrative, operational and financial resources. To manage this growth, we must expand our facilities, augment our operational, financial and management systems and hire and train additional qualified personnel. If we are unable to manage our growth effectively, our business may be materially harmed.

Risks Related to Our Intellectual Property

If we materially breach or default under any of our license agreements, the licensor party to such agreement will have the right to terminate the license agreement, which termination may materially harm our business.

Our commercial success will depend in part on the maintenance of our license agreements. Each of our license agreements provides the licensor with a right to terminate the license agreement for our material breach or default under the agreement. Additionally, our license agreement with Dr. Hans-Dietrich Polaschegg (referred to herein as the "Polaschegg License Agreement") provides for a right of termination for, among other things, our failure to make a product with respect to a particular piece of technology (there are two) available to the market by the later of eight years after (i) the date of the Polaschegg License Agreement and our intellectual property licensed under the Polaschegg License Agreement serves as a basis for CRMD004. Should the licensor party to any of our license agreements exercise such a termination right, we would lose our right to the intellectual property under the license agreement at issue, which loss may materially harm our business.

If we and our licensors do not obtain protection for and successfully defend our respective intellectual property rights, our competitors may be able to take advantage of our research and development efforts to develop competing products.

Our commercial success will depend in part on obtaining further patent protection for our products and other technologies and successfully defending any patents that we currently have or will obtain against third-party challenges. The patents most material to our business are as follows:

- U.S. Registration No. 7,696,182 (expiring in May 2025) - use of Neutrolin® for preventing infection and maintenance of catheter patency in hemodialysis catheters (for CRMD003)

- U.S. Registration No. 6,166,007 (expiring May 2019) - a method of inhibiting or preventing infection and blood coagulation at a medical prosthetic device (for CRMD003)

- European Registration No. 1442753 (expiring February 2023) - use of a thixotropic gel as a catheter locking composition, and method of locking a catheter (for CRMD004)

We are currently seeking further patent protection for numerous compounds and methods of treating diseases. However, the patent process is subject to numerous risks and uncertainties, and there can be no assurance that we will be successful in protecting our products by obtaining and defending patents. These risks and uncertainties include those stated below.

- Patents that may be issued or licensed may be challenged, invalidated, or circumvented, or otherwise may not provide any competitive advantage.

- Our competitors, many of which have substantially greater resources than we have and many of which have made significant investments in competing technologies, may seek, or may already have obtained, patents that will limit, interfere with, or eliminate our ability to make, use, and sell our potential products either in the United States or in international markets.

- There may be significant pressure on the United States government and other international governmental bodies to limit the scope of patent protection both inside and outside the United States for treatments that prove successful as a matter of public policy regarding worldwide health concerns.

- Countries other than the United States may have less restrictive patent laws than those upheld by United States courts, allowing foreign competitors the ability to exploit these laws to create, develop, and market competing products.

In addition, the United States Patent and Trademark Office (the “PTO”) and patent offices in other jurisdictions have often required that patent applications concerning pharmaceutical and/or biotechnology-related inventions be limited or narrowed substantially to cover only the specific innovations exemplified in the patent application, thereby limiting the scope of protection against competitive challenges. Thus, even if we or our licensors are able to obtain patents, the patents may be substantially narrower than anticipated.

The patent applications in our patent portfolio are exclusively licensed to us. To support our patent strategy, we have engaged in a review of patentability and freedom to operate issues, including performing certain searches. However, patentability and freedom to operate issues are inherently complex, and we cannot provide assurances that a relevant patent office and/or relevant court will agree with our conclusions regarding patentability issues or with our conclusions regarding freedom to operate issues, which can involve subtle issues of claim interpretation and/or claim liability. Furthermore, we may not be aware of all patents, published applications or published literature that may affect our business either by blocking our ability to commercialize our product candidates, preventing the patentability of our product candidates to us or our licensors, or covering the same or similar technologies that may invalidate our patents, limit the scope of our future patent claims or adversely affect our ability to market our product candidates.

In addition to patents, we also rely on trade secrets and proprietary know-how. Although we take measures to protect this information by entering into confidentiality and inventions agreements with our employees, scientific advisors, consultants, and collaborators, we cannot provide any assurances that these agreements will not be breached, that we will be able to protect ourselves from the harmful effects of disclosure if they are breached, or that our trade secrets will not otherwise become known or be independently discovered by competitors. If any of these events occurs, or we otherwise lose protection for our trade secrets or proprietary know-how, the value of this information may be greatly reduced.

Patent protection and other intellectual property protection is important to the success of our business and prospects, and there is a substantial risk that such protections will prove inadequate.

Intellectual property disputes could require us to spend time and money to address such disputes and could limit our intellectual property rights.

The biotechnology and pharmaceutical industries have been characterized by extensive litigation regarding patents and other intellectual property rights, and companies have employed intellectual property litigation to gain a competitive advantage. We may become subject to infringement claims or litigation arising out of patents and pending applications of our competitors, or additional proceedings initiated by third parties or the PTO to reexamine the patentability of our licensed or owned patents. The defense and prosecution of intellectual property suits, PTO proceedings, and related legal and administrative proceedings are costly and time-consuming to pursue, and their outcome is uncertain. Litigation may be necessary to enforce our issued patents, to protect our trade secrets and know-how, or to determine the enforceability, scope, and validity of the proprietary rights of others. An adverse determination in litigation or PTO proceedings to which we may become a party could subject us to significant liabilities, require us to obtain licenses from third parties, restrict or prevent us from selling our products in certain markets, or invalidate or render unenforceable our licensed or owned patents. Although patent and intellectual property disputes might be settled through licensing or similar arrangements, the costs associated with such arrangements may be substantial and could include our paying large fixed payments and ongoing royalties. Furthermore, the necessary licenses may not be available on satisfactory terms or at all.

In February 2007, Geistlich Söhne AG für Chemische Industrie, Switzerland ("Geistlich") brought an action against the Sodemann patent covering our Neutrolin® product candidate which is owned by ND Partners, LLC and licensed to us pursuant to the License and Assignment Agreement between ND Partners LLC and CorMedix Inc. on January 30, 2008. The action that was brought against the Sodemann patent in Germany at the Board of the European Patent Office opposition division was for lack of inventiveness in the use of citric acid and a pH value in the range of 4.5 to 6.5 with having the aim to provide an alternative lock solution through having improved anticoagulant characteristics compared to the lock solutions described in the Lehner patent. The Board of the European Patent Office opposition division rejected the opposition by Geistlich. On August 27, 2008, Geistlich appealed the court's ruling, alleging the same arguments as presented during the opposition proceedings. We filed a response to the appeal of Geistlich on March 25, 2009 where we requested a dismissal of the appeal and to maintain the patent as granted. As of the date of this Quarterly Report, no further petitions have been filed by ND Partners, LLC or Geistlich. Therefore, it can be

expected that a summons to attended oral proceedings before the Board of Appeal will be issued during 2012. Though we intend to vigorously defend ourselves and believe that Geistlich's claims are without merit, we can provide no assurances regarding the outcome of this matter.

If we infringe the rights of third parties we could be prevented from selling products and forced to pay damages and defend against litigation.

If our products, methods, processes and other technologies infringe the proprietary rights of other parties, we could incur substantial costs and we may have to do one or more of the following:

- obtain licenses, which may not be available on commercially reasonable terms, if at all;
- abandon an infringing product candidate;
- redesign our products or processes to avoid infringement;
- stop using the subject matter claimed in the patents held by others;
- pay damages; or

defend litigation or administrative proceedings, which may be costly whether we win or lose, and which could result in a substantial diversion of our financial and management resources.

Risks Related to Our Dependence on Third Parties

If we are not able to develop collaborative marketing relationships with licensees or partners, or create an effective sales, marketing, and distribution capability, we may be unable to market our products successfully.

Our business strategy may rely on out-licensing product candidates to or collaborating with larger firms with experience in marketing and selling pharmaceutical products. There can be no assurance that we will be able to successfully establish marketing, sales, or distribution relationships, that such relationships, if established, will be successful, or that we will be successful in gaining market acceptance for our products. To the extent that we enter into any marketing, sales, or distribution arrangements with third parties, our product revenues will be lower than if we marketed and sold our products directly, and any revenues we receive will depend upon the efforts of such third-parties. If we are unable to establish such third-party sales and marketing relationships, or choose not to do so, we will have to establish our own in-house capabilities. We currently have no sales, marketing, or distribution infrastructure. To market any of our products directly, we would need to develop a marketing, sales, and distribution

force that has both technical expertise and the ability to support a distribution capability. The establishment of a marketing, sales, and distribution capability would significantly increase our costs, possibly requiring substantial additional capital. In addition, there is intense competition for proficient sales and marketing personnel, and we may not be able to attract individuals who have the qualifications necessary to market, sell, and distribute our products. There can be no assurance that we will be able to establish internal marketing, sales, or distribution capabilities. If we are unable to, or choose not to establish these capabilities, or if the capabilities we establish are not sufficient to meet our needs, we will be required to establish collaborative marketing, sales, or distribution relationships with third parties.

If we or our collaborators are unable to manufacture our products in sufficient quantities or are unable to obtain regulatory approvals for a manufacturing facility, we may be unable to meet demand for our products and we may lose potential revenues.

Completion of our clinical trials and commercialization of our product candidates require access to, or development of, facilities to manufacture a sufficient supply of our product candidates. All of our manufacturing processes currently are, and we expect them to continue to be, outsourced to third parties. If, for any reason, we become unable to rely on our current sources for the manufacture of our product candidates, either for clinical trials or, at some future date, for commercial quantities, then we would need to identify and contract with additional or replacement third-party manufacturers to manufacture compounds for pre-clinical, clinical, and commercial purposes. We may not be successful in identifying such additional or replacement third-party manufacturers, or in negotiating acceptable terms with any that we do identify. Such third-party manufacturers must receive FDA approval before they can produce clinical material or commercial product, and any that are identified may not receive such approval. We may be in competition with other companies for access to these manufacturers' facilities and may be subject to delays in manufacturing if the manufacturers give other clients higher priority than they give to us. If we are unable to secure and maintain third-party manufacturing capacity, the development and sales of our products and our financial performance may be materially affected.

Before we can begin to commercially manufacture our product candidates, we must obtain regulatory approval of the manufacturing facility and process. Manufacturing of drugs for clinical and commercial purposes must comply with current Good Manufacturing Practices, referred to herein as cGMP, and applicable non-U.S. regulatory requirements. The cGMP requirements govern quality control and documentation policies and procedures. Complying with cGMP and non-U.S. regulatory requirements will require that we expend time, money, and effort in production, recordkeeping, and quality control to assure that the product meets applicable specifications and other requirements. We, or our contracted manufacturing facility, must also pass a pre-approval inspection prior to FDA or other regulatory agency approval. Failure to pass a pre-approval inspection may significantly delay FDA approval of our products. If we fail to comply with these requirements, we would be subject to possible regulatory action and may be limited in the jurisdictions in which we are permitted to sell our products. As a result, our business, financial condition, and results of operations may be materially adversely affected.

Corporate and academic collaborators may take actions that delay, prevent, or undermine the success of our products.

Our operating and financial strategy for the development, clinical testing, manufacture, and commercialization of product candidates is heavily dependent on our entering into collaborations with corporations, academic institutions, licensors, licensees, and other parties. Our current strategy assumes that we will successfully establish these collaborations or similar relationships. However, there can be no assurance that we will be successful establishing such collaborations. Some of our existing collaborations are, and future collaborations may be, terminable at the sole discretion of the collaborator. Replacement collaborators might not be available on attractive terms, or at all. The activities of any collaborator will not be within our control and may not be within our power to influence. There can be no assurance that any collaborator will perform its obligations to our satisfaction or at all, that we will derive any

revenue or profits from such collaborations, or that any collaborator will not compete with us. If any collaboration is not pursued, we may require substantially greater capital to undertake development and marketing of our proposed products and may not be able to develop and market such products effectively, if at all. In addition, a lack of development and marketing collaborations may lead to significant delays in introducing proposed products into certain markets and/or reduced sales of proposed products in such markets.

Data provided by collaborators and others upon which we rely that has not been independently verified could turn out to be false, misleading, or incomplete.

We rely on third-party vendors, scientists, and collaborators to provide us with significant data and other information related to our projects, clinical trials, and business. If such third parties provide inaccurate, misleading, or incomplete data, our business, prospects, and results of operations could be materially adversely affected.

Risks Related to Our Common Stock

Our stock price has fluctuated considerably and is likely to remain volatile, in part due to the limited market for our common stock.

During the period from the completion of the IPO on March 30, 2010 through June 30, 2012, the high and low sales prices for our common stock were $4.00 and $0.15, respectively. There is a limited public market for our common stock and we cannot provide assurances that an active trading market will develop. As a result of low trading volume in our common stock, the purchase or sale of a relatively small number of shares could result in significant share price fluctuations.

Additionally, the market price of our common stock may continue to fluctuate significantly in response to a number of factors, some of which are beyond our control, including the following:

- general economic conditions;
- economic conditions in our industry and in the industries that typically comprise our customers and suppliers;
- changes in financial estimates or investment recommendations by securities analysts relating to our common stock;
- announcements by our competitors of significant developments, strategic partnerships, joint ventures or capital commitments; and
- changes in key personnel.

If the prices of our securities are volatile, purchasers of our securities could incur substantial losses.

The prices of our securities are likely to be volatile. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their securities at or above the price they paid for such securities. The market prices of our securities may be influenced by many factors, including but not limited to the following:

- results of clinical trials of our product candidates or those of our competitors;
- our entry into or the loss of a significant collaboration;
- regulatory or legal developments in the United States and other countries, including changes in the healthcare payment systems;
- variations in our financial results or those of companies that are perceived to be similar to us;

- market conditions in the pharmaceutical and biotechnology sectors and issuance of new or changed securities analysts' reports or recommendations;

- general economic, industry and market conditions;

- developments or disputes concerning patents or other proprietary rights;

- future sales or anticipated sales of our securities by us or our stockholders; and

- any other factors described in this "Risk Factors" section.

For these reasons and others, you should consider an investment in our securities as risky and invest only if you can withstand a significant loss and wide fluctuations in the value of your investment.

A significant number of additional shares of our common stock may become eligible for sale at a later date, and their sale could depress the market price of our common stock.

The Units we issued in the IPO and upon conversion of certain of our convertible notes in connection therewith consisted of two shares of common stock and a warrant to purchase one share of common stock. The warrants that were issued as part of the Units have an exercise price of $3.4375 per share and expire on March 24, 2015. As of June 30, 2012, there were 4,263,569 of these warrants outstanding, which if executed, would result in the issuance of an additional 4,263,569 shares of common stock. In connection with the IPO, we also issued a warrant to purchase 2,406 Units to the underwriters of the IPO that, if exercised, would result in the issuance of an additional 4,812 shares of common stock and warrants to purchase an additional 2,406 shares of common stock.

In addition, in connection with our private placement of convertible notes in October and November 2009, we issued warrants to the investors in such private placement, which warrants have an exercise price of $3.4375 per share and expire on October 29, 2014. As of June 30, 2012, the number of shares of common stock issuable upon exercise of these warrants was 503,034 shares.

As of June 30, 2012, we also had outstanding other warrants that, if exercised, would result in the issuance of an additional 17,869 shares of common stock at an exercise price of $10.66 per share and 18,250 shares of common stock at an exercise price of $7.84 per share.

As of June 30, 2012, options to purchase 1,353,292 shares of our common stock, which were issued to our officers, directors, employees and non-employee consultants, were outstanding under our Amended and Restated 2006 Stock Incentive Plan with a weighted average exercise price of $2.10 per share. Options to purchase 875,958 of such shares are currently exercisable or will be exercisable within 60 days of the date of this report.

The sale or even the possibility of sale of the shares of common stock described above could substantially reduce the market price for our common stock or our ability to obtain future financing.

Future sales and issuances of our equity securities or rights to purchase our equity securities, including pursuant to equity incentive plans, would result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be further diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to existing stockholders.

Pursuant to our Amended and Restated 2006 Stock Incentive Plan, our Board of Directors is authorized to award up to a total of 2,300,000 shares of common stock or options to purchase shares of common stock to our officers, directors employees and non-employee consultants. As of June 30, 2012, options to purchase 1,353,292 shares of common stock issued under the Amended and Restated 2006 Stock Incentive Plan at a weighted average exercise price of $2.10 per share, were outstanding. Stockholders will experience dilution in the event that additional shares of common stock are issued under the Amended and Restated 2006 Stock Incentive Plan, or options previously issued or to be issued under the Amended and Restated 2006 Stock Incentive Plan are exercised.

If our existing securityholders exercise their registration rights, they may substantially reduce the market price of our common stock. The existence of these rights may make it more difficult for us to effect future offerings.

Holders of 6,429,746 shares of common stock and warrants to purchase an additional 505,440 shares of common stock are entitled to certain “demand” and “piggyback” registration rights. If these holders exercise their registration rights, the presence of these additional shares of common stock eligible for trading in the public market may substantially reduce the market price of our common stock. In addition, the existence of these holders’ piggyback registration rights may make it more difficult for us to effect future public offerings and may reduce the amount of capital that we are able to raise for our own account in these offerings.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult.

Provisions in our Amended and Restated Certificate of Incorporation and Amended and Restated By-laws, as well as provisions of the General Corporation Law of the State of Delaware (“DGCL”), may discourage, delay or prevent a merger, acquisition or other change in control of our company, even if such a change in control would be beneficial to our stockholders. These provisions include the following:

- prohibiting our stockholders from fixing the number of our directors; and

- establishing advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our Board of Directors.

Additionally, Section 203 of the DGCL, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. We have not opted out of the restrictions under Section 203.

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We received notice from the NYSE AMEX that we fail to comply with certain of its continued listing standards, which may result in a delisting of our common stock from the exchange.

Our common stock is currently listed for trading on the NYSE AMEX, or AMEX, and the continued listing of our common stock on the AMEX is subject to our compliance with a number of listing standards. These listing standards include the requirement for avoiding sustained losses. We incurred a net loss of approximately $1.5 million for the six months ended June 30, 2012 and, as of June 30, 2012, we have a deficit accumulated during the development stage of approximately $44.5 million. On April 20, 2012, the AMEX notified us that we are not in continuing compliance with certain AMEX listing standards and requested that we submit a plan to regain compliance with such listing standards by August 22, 2012, which we submitted on May 17, 2012. On June 27, 2012, the AMEX notified us that (i) it had accepted our plan, and (ii) until August 22, 2012, it will periodically review our progress with respect to such plan. If we are not in compliance with the continued listing standards on August 22, 2012, or if we do not make progress consistent with the plan before August 22, 2012, the AMEX may initiate delisting proceedings. Although we believe to date we are making progress with the plan and that we will be in compliance with the continued listing standards on August 22, 2012, there can be no assurance that we will be able to make progress consistent with such plan and/or be in compliance with the continued listing standards on August 22, 2012. Unless we can raise capital through various potential sources, such as equity, debt financing, strategic relationships, out-licensing or distribution arrangements of our products, we may receive further notice from the AMEX informing us that we are not in compliance with the AMEX listing standards. If we are not in compliance with the continued listing standards at the end of the plan period, or if we do not make progress consistent with the plan during the plan period, the AMEX staff may initiate delisting proceedings. If the we do not regain compliance with Section 1003(a)(iv) by August 22, 2012, then the AMEX may initiate delisting procedures. We may appeal a staff determination to initiate delisting proceedings in accordance with Section 1010 and Part 12 of the AMEX Company Guide.

If our common stock were no longer listed on the AMEX, investors might only be able to trade on the OTC Bulletin Board® or in the Pink Sheets® (a quotation medium operated by Pink Sheets LLC). This would impair the liquidity of our securities not only in the number of shares that could be bought and sold at a given price, which might be depressed by the relative illiquidity, but also through delays in the timing of transactions and reduction in media coverage.

Because the average daily trading volume of our common stock is low, the ability to sell our shares in the secondary trading market may be limited.

Because the average daily trading volume of our common stock on the AMEX is low, the liquidity of our common stock may be impaired. As a result, prices for shares of our common stock may be lower than might otherwise prevail if the average daily trading volume of our common stock was higher. The average daily trading volume of our common stock may be low relative to the stocks of exchange-listed companies, which could limit investors' ability to sell shares in the secondary trading market.

Penny stock regulation may impose certain restriction on marketability of our securities.

The SEC has adopted regulations which generally define a "penny stock" to be any equity security that has a market price of less than $5.00 per share or an exercise price of less than $5.00 per share, subject to certain exceptions. As a result, our common stock is subject to rules that impose additional sales practice requirements on broker dealers who sell such securities to persons other than established customers and accredited investors (generally those with assets in excess of $1,000,000 or annual income exceeding $200,000, or $300,000 together with their spouse). For transactions covered by such rules, the broker dealer must make a special suitability determination for the purchase of such securities and have received the purchaser's written consent to the transaction prior to the purchase. Additionally, for any transaction involving a penny stock, unless exempt, the rules require the delivery, prior to the transaction, of a risk disclosure document mandated by the SEC relating to the penny stock market. The broker dealer must also disclose the commission payable to both the broker dealer and the registered representative, current quotations for the securities and, if the broker dealer is the sole market maker, the broker dealer must disclose this fact and the broker dealer's presumed control over the market. Finally, monthly statements must be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks. Broker-dealers must wait two business days after providing buyers with disclosure materials regarding a security before effecting a transaction in such security. Consequently, the "penny stock" rules restrict the ability of broker dealers to sell our securities and affect the ability of investors to sell our securities in the secondary market and the price at which such purchasers can sell any such securities, thereby affecting the liquidity of the market for our common stock.

Stockholders should be aware that, according to the SEC, the market for penny stocks has suffered in recent years from patterns of fraud and abuse. Such patterns include:

- control of the market for the security by one or more broker-dealers that are often related to the promoter or issuer;
- manipulation of prices through prearranged matching of purchases and sales and false and misleading press releases;
- "boiler room" practices involving high pressure sales tactics and unrealistic price projections by inexperienced sales persons;
- excessive and undisclosed bid-ask differentials and markups by selling broker-dealers; and
- the wholesale dumping of the same securities by promoters and broker-dealers after prices have been manipulated to a desired level, along with the inevitable collapse of those prices with consequent investor losses.

Our management is aware of the abuses that have occurred historically in the penny stock market.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Not Applicable.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not Applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

The following is a list of exhibits filed as part of this Form 10-Q:

Exhibit Number	Description
31.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*

99.1	Memorandum of Understanding dated May 2, 2012, by and between CorMedix and Brian Lenz. (Incorporated by reference to Exhibit 99.2 to the Current Report on Form 8-K, filed May 3, 2012).
101	The following materials from CorMedix Inc. Form 10-Q for the quarter ended June 30, 2012, formatted in Extensible Business Reporting Language (XBRL): (i) Condensed Balance Sheets at June 30, 2012 and December 31, 2011, (ii) Condensed Statements of Operations for the three and six months ended June 30, 2012 and 2011, and for the Cumulative Period from July 28, 2006 (inception) through June 30, 2012, (iii) Condensed Statement of Changes in Stockholders' Equity (Deficiency) for the six months ended June 30, 2012, (iv) Condensed Statements of Cash Flows for the six months ended June 30, 2012 and 2011, and for the Cumulative Period from July 28, 2006 (inception) through June 30, 2012 and (v) Notes to the Unaudited Condensed Financial Statements.**

* Filed herewith.

** Pursuant to Rule 406T of Regulation S-T, the Interactive Data Files in Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended and otherwise are not subject to liability under those sections.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

CORMEDIX INC.

Date: August 13, 2012

By: /s/ Richard M. Cohen

Name: Richard M. Cohen

Title: Executive Chairman and Interim Chief Executive Officer and Interim Chief Financial Officer
(Principal Executive Officer and Principal Financial Officer)

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