CorMedix Inc.
Form 10-Q
November 10, 2011

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 September 30, 2011

¨ 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 ¨ No x

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 November 10, 2011 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

	September 30, 2011 (Unaudited)	December 31, 2010 (Note 1)
ASSETS		
Current assets		
Cash and cash equivalents	$ 2,889,923	$ 8,283,684
Prepaid research and development expenses	13,977	205,404
Other prepaid expenses and current assets	99,058	323,060
Total current assets	3,002,958	8,812,148
Property and equipment, net	14,647	22,310
Security deposit	13,342	13,342
TOTAL ASSETS	$ 3,030,947	$ 8,847,800
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 990,054	$ 1,139,276
Accrued expenses	1,288,005	436,367
Total current liabilities	2,278,059	1,575,643
Deferred rent	15,044	16,759
TOTAL LIABILITIES	2,293,103	1,592,402
COMMITMENTS		
STOCKHOLDERS' EQUITY		
Common stock - $0.001 par value: 40,000,000 shares authorized, 11,408,274 shares issued and outstanding at September 30, 2011 and December 31, 2010	11,408	11,408
Deferred stock issuances	(146)	(146)
Additional paid-in capital	44,014,630	43,480,415
Deficit accumulated during the development stage	(43,288,048)	(36,236,279)
TOTAL STOCKHOLDERS' EQUITY	737,844	7,255,398
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 3,030,947	$ 8,847,800

See Notes to Unaudited Condensed Financial Statements.

CORMEDIX INC.
(A Development Stage Company)

CONDENSED STATEMENTS OF OPERATIONS
(Unaudited)

	For the Three Months Ended September 30, 2011	For the Three Months Ended September 30, 2010	For the Nine Months Ended September 30, 2011	For the Nine Months Ended September 30, 2010	Cumulative Period from July 28, 2006 (inception) Through September 30, 2011
OPERATING EXPENSES					
Research and development	$ 1,724,797	$ 760,533	$4,482,687	$4,048,232	$22,540,136
General and administrative	877,020	642,254	2,609,526	1,906,872	10,379,720
Total Operating Expenses	2,601,817	1,402,787	7,092,213	5,955,104	32,919,856
LOSS FROM OPERATIONS	(2,601,817)	(1,402,787)	(7,092,213)	(5,955,104)	(32,919,856)
OTHER INCOME (EXPENSE)					
Other income, net	-	-	29,819	-	420,987
Interest income	2,199	10,375	10,625	16,086	122,929
Interest expense, including amortization and write-off of deferred financing costs and debt discounts	-	-	-	(3,093,763)	(11,193,028)
LOSS BEFORE INCOME TAXES	(2,599,618)	(1,392,412)	(7,051,769)	(9,032,781)	(43,568,968)
State income tax benefit	-	-	-	-	280,920
NET LOSS	$ (2,599,618)	$ (1,392,412)	$(7,051,769)	$ (9,032,781)	$(43,288,048)
NET LOSS PER SHARE – BASIC AND DILUTED	$ (0.23)	$ (0.12)	$(0.62)	$ (1.06)	
WEIGHTED AVERAGE SHARES OUTSTANDING – BASIC AND DILUTED	11,408,274	11,408,274	11,408,274	8,546,248	

See Notes to Unaudited Condensed Financial Statements.

CORMEDIX INC.
(A Development Stage Company)

CONDENSED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY
(Unaudited)

For the Nine Months Ended September 30, 2011

	Common Stock Shares	Common Stock Amount	Deferred Stock Issuances	Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Total Stockholders' Equity
Balance at January 1, 2011	11,408,274	$11,408	$(146)	$43,480,415	$(36,236,279)	$7,255,398
Stock-based compensation				534,215		534,215
Net loss					(7,051,769)	(7,051,769)
Balance at September 30, 2011	11,408,274	$11,408	$(146)	$44,014,630	$(43,288,048)	$737,844

See Notes to Unaudited Condensed Financial Statements.

CORMEDIX INC.
(A Development Stage Company)

CONDENSED STATEMENTS OF CASH FLOWS
(Unaudited)

	For the Nine Months Ended September 30, 2011	For the Nine Months Ended September 30, 2010	Cumulative Period from July 28, 2006 (Inception) Through September 30, 2011
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (7,051,769)	$ (9,032,781)	$ (43,288,048)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	534,215	816,010	2,166,693
Stock issued in connection with license agreements	-	2,217,924	6,613,718
Stock issued in connection with consulting agreement	-	130,091	158,262
Amortization of deferred financing costs	-	358,495	2,047,881
Amortization of debt discount	-	1,135,076	4,979,461
Non-cash charge for beneficial conversion feature	-	1,137,762	1,137,762
Non-cash interest expense	-	462,430	3,007,017
Expenses paid on behalf of the Company satisfied through the issuance of notes	-	-	51,253
Depreciation	9,288	8,770	47,062
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	415,429	6,592	(113,035)
Security deposits	-	(1,609)	(13,342)
Accounts payable	(149,222)	(32,516)	990,054
Accrued expenses	851,638	345,808	1,288,005
Deferred rent	(1,715)	18,101	15,044
Net cash used in operating activities	(5,392,136)	(2,429,847)	(20,912,213)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of equipment	(1,625)	(10,361)	(61,709)
Net cash used in investing activities	(1,625)	(10,361)	(61,709)
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	-	-	(1,447,400)
Repayment of amounts loaned under related party notes	-	-	(1,981,574)
Proceeds from sale of equity securities, net of issuance costs	-	10,457,270	10,457,270
Proceeds from receipt of stock subscriptions and issuances of common stock	-	-	4,827
Net cash provided by financing activities	-	10,457,270	23,863,845
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(5,393,761)	8,017,062	2,889,923
	8,283,684	1,505,179	-

CASH AND CASH EQUIVALENTS – BEGINNING OF PERIOD			
CASH AND CASH EQUIVALENTS – END OF PERIOD	$ 2,889,923	$ 9,522,241	$ 2,889,923
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	$ 18,897,167
Reclassification of deferred financing fees to additional paid-in capital	$ -	$ 148,014	$ 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. ("CorMedix" or the "Company") was incorporated in the State of Delaware on July 28, 2006. CorMedix is a development-stage pharmaceutical company that seeks to fulfill selected, significant unmet medical needs in the therapeutic areas at the crossroads of cardiac and kidney (renal) disease.

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, 2011 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 11, 2011. The accompanying condensed balance sheet as of December 31, 2010 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.

On February 24, 2010, the Company effected a 1-for-7.836 reverse stock split of its common stock. All share and per-share information in these unaudited condensed financial statements have been adjusted to give effect to the reverse stock split.

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. For the nine months ended September 30, 2011 and the period from July 28, 2006 (inception) to September 30, 2011, the Company incurred net losses of $7,051,769 and $43,288,048, respectively.

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NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

Correction of Immaterial Error

The Company identified an immaterial error in its previously issued unaudited condensed financial statements for the nine months ended September 30, 2010, as follows:

- the improper recording of licensor escrowed shares to research and development expense when such shares were not earned.

The error in the accounting for the licensor escrowed shares resulted in an overstatement of non-cash research and development expenses of $369,652 and an overstatement of net loss per share of $0.04 for the nine months ended September 30, 2010. The licensor shares were not earned as of September 30, 2011.

The Company reviewed the accounting error utilizing SEC Staff Accounting Bulletin No. 99, “Materiality” (“SAB 99”) and SEC Staff Accounting Bulletin No. 108, “Effects of Prior Year Misstatements on Current Year Financial Statements” (“SAB 108”) and determined the impact of the errors to be immaterial to any prior period’s presentation. The accompanying 2011 and 2010 unaudited condensed financial statements reflect the corrections of the aforementioned immaterial error.

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 6,382,457 and 6,472,767 underlying outstanding warrants and stock options at September 30, 2011 and 2010, 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.

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NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

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 nine months ended September 30, 2011 and 2010 options to purchase an aggregate of 856,000 and 1,639,215 shares of common stock, respectively, were granted to the Company's employees, directors and consultants.

Note 3 — Stockholders' Equity:

Common Stock Options and Warrants:

During the nine months ended September 30, 2011, options to purchase an aggregate of 150,000 and 30,000 shares of common stock were granted to the Company's directors under the Amended and Restated 2006 Stock Incentive Plan ("Plan") with an exercise price of $2.10 and $1.10 per share, respectively. The grant of 150,000 options vest on the one-year anniversary of the grant date, January 14, 2011. The grant of 30,000 options vest in equal installments on the grant date of August 11, 2011, the first anniversary of the grant date and the second anniversary of the grant date. These options each have ten-year terms. Additionally, during the nine months ended September 30, 2011, options to purchase 356,000 shares of common stock were granted to the Company's new 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 anniversaries of the grant date, March 1, 2011 and have a ten-year term.

During the nine months ended September 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 September 30, 2011, there were no non-employee stock options that had vested, as the vesting of such stock options is contingent upon various performance metrics which had not been achieved as of September 30, 2011. To estimate the number of stock options expected to vest, the Company used the Monte Carlo stock price simulation method. The Monte Carlo analysis uses several random simulations along with performance vesting metrics, an initial stock price of $1.72, expected volatility of 100% for the one-year period of the vesting contingency and a one-year risk-free rate of 0.25%. The Company then used the results of the Monte Carlo analysis together with the Black-Scholes option pricing method to estimate the fair value of the options issued. The Black-Scholes option pricing method criteria to determine the related non-cash charge to operations included: a current stock price of $0.91, volatility of 113%, a one year contractual service period, an expected exercise term of 4.7 years and a risk free rate of 1.00%. On September 26, 2011, the Company terminated the consulting agreement; however, the exercise period for the 320,000 options is through November 10, 2011, pursuant to the agreement.

During the nine months ended September 30, 2010, the Company granted options to purchase 1,589,215 and 50,000 shares of common stock under the Plan to various employees, officers and directors with exercise prices of $3.125 and $1.57 per share, respectively. Each option granted to employees during the nine months ended September 30, 2010 has a ten-year term and vests equally over a three-year period. The options granted to directors during the nine months ended September 30, 2010 have ten-year terms and vested one-third on March 30, 2010, the date of grant, and the remaining two-thirds will vest equally over a two-year period.

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CORMEDIX INC.
(A Development Stage Company)

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

During the nine months ended September 30, 2011 and 2010 and the period from July 28, 2006 (inception) to September 30, 2011, the Company recorded compensation expense, in connection with common stock and stock options issued to employees, directors and consultants, of $534,215, $946,101 and $2,324,955, 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:

	Nine Months Ended September 30, 2011	Nine Months Ended September 30, 2010
Expected Term	5 years	5 years
Volatility	109% - 115%	112% - 114%
Dividend yield	0.0%	0.0%
Risk-free interest rate	1.02% - 2.11%	1.5% - 2.6%

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 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. During the nine months ended September 30, 2011, the Company has experienced forfeitures of stock options issued to its former President and Chief Executive Officer, Chief Medical Officer, Chairman and Board member. Since the stock options currently outstanding are primarily held by senior management and directors of the Company, the Company will continue to evaluate the effects of such future potential forfeitures, as they may arise, to ascertain an estimated forfeiture rate.

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NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

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

	Nine Months Ended September 30, 2011		Nine Months Ended September 30, 2010	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at beginning of period	1,662,827	$3.15	23,612	$8.23
Forfeited	(943,904)	$3.19	-	-
Granted	856,000	$1.72	1,639,215	$3.08
Outstanding at end of period and expected to vest	1,574,923	$2.35	1,662,827	$3.15
Options exercisable	481,262	$3.10	57,231	$4.66
Weighted-average fair value of options granted during the period		$1.37		$2.47

The weighted average remaining contractual life of stock options outstanding and expected to vest at September 30, 2011 is 8.4 years. The weighted average remaining contractual life of stock options exercisable at September 30, 2011 is 8 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 September 30, 2011 for those options that have an exercise price below the quoted closing price. As of September 30, 2011, 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 September 30, 2011, the total compensation expense related to non-vested options not yet recognized totaled $2,891,788. The weighted-average vesting period over which the total compensation expense related to non-vested options not yet recognized at September 30, 2011 was approximately 1.5 years.

Note 4 — Shares Issued to 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 118,289 are being held in escrow for ND Partners pending the achievement of certain regulatory and sales-based milestones. As a result of these issuances, a charge of $2,217,924 was recorded to research and development during the nine months ended September 30, 2010. This obligation terminated upon the closing of the IPO.

CORMEDIX INC.
(A Development Stage Company)

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

Note 5 — Commitments:

Employment and Severance Agreements

On January 14, 2011, the Company entered into an amendment to the employment agreement, effective January 1, 2011, with its President and Chief Executive Officer, John C. Houghton (the "Houghton Amendment"). The Houghton Amendment amended the Amended and Restated Employment Agreement, dated as of November 25, 2009, by and between the Company and Mr. Houghton to (i) increase Mr. Houghton's annual base salary to $350,000 and (ii) increase the amount of the annual bonus payments Mr. Houghton may receive upon the achievement of certain financial, clinical development and business milestones, at the sole discretion of the Company's Board of Directors (the "Board"), to up to 40% of Mr. Houghton's annual base salary. The Houghton Amendment was terminated in connection with the separation and general release agreement described below.

On January 14, 2011, the Company also entered into an amendment to the employment agreement, effective January 1, 2011, with its Chief Financial Officer, Brian Lenz (the "Lenz Amendment"). The Lenz Amendment amended the Employment Agreement, dated as of February 4, 2010, by and between the Company and Mr. Lenz to (i) increase Mr. Lenz's annual base salary to $250,000 and (ii) eliminate Mr. Lenz's annual guaranteed bonus.

On February 25, 2011, the Company entered into an employment agreement with Mark A. Klausner, M.D., the Company's new CMO (the "Klausner Employment Agreement"). Pursuant to the Klausner Employment Agreement, Dr. Klausner will serve as the Company's CMO for an initial term of two years commencing on March 1, 2011, which term will extend automatically for additional one-year periods unless appropriate notice is given by one of the parties. Dr. Klausner will receive an annual base salary of $310,000, and will be eligible for annual bonus payments of up to 35% of his base salary, based upon the achievement of certain milestones as established annually by the Company's Chief Executive Officer, in consultation with the Board and Dr. Klausner.

Pursuant to the Klausner Employment Agreement, if the Company terminates Dr. Klausner as a result of his death or disability (as defined under the Klausner Employment Agreement), Dr. Klausner or his estate, as applicable, will receive his base salary and any accrued but unpaid benefits through the termination date (the "Accrued Compensation"), plus his base salary for a period of 90 days, and all his unvested restricted shares and stock options that are scheduled to vest on or before the next succeeding anniversary of March 1, 2011 will be accelerated and vest as of the termination date. If the Company terminates Dr. Klausner for Cause (as defined under the Klausner Employment Agreement), if Dr. Klausner terminates his employment other than for Good Reason (as defined under the Klausner Employment Agreement), or if Dr. Klausner's employment terminates by expiration of the term of the Klausner Employment Agreement, Dr. Klausner will receive the Accrued Compensation only. If the Company terminates Dr. Klausner within two months prior to or six months following the occurrence of a Change of Control (as defined under the Klausner Employment Agreement), and on the date of termination the fair market value of the Company's common stock on a fully-diluted basis is more than $50 million (as determined by the Board in good faith), Dr. Klausner will receive the Accrued Compensation, his base salary and benefits for a period of three months following his termination, and all his unvested restricted shares and stock options will be accelerated and vest as of the termination date. If the Company terminates Dr. Klausner for reasons other than those stated above or Dr. Klausner terminates his employment for Good Reason, Dr. Klausner will receive the Accrued Compensation and his base salary and benefits for a period of six months following his termination, and all his unvested restricted shares and stock options that are scheduled to vest within the 12 months following his termination will be accelerated and vest as of the termination

date.

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NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

On September 30, 2011, the Company entered into a separation and general release agreement with John C. Houghton, the Company's then President and Chief Executive Officer. The separation and release agreement provides, among other things, Mr. Houghton a continuation of base salary for four months of approximately $118,000; a continuation of Mr. Houghton's health insurance benefits on the same terms and conditions as in effect prior to the separation date through March 31, 2012, resulting in a charge of approximately $21,000; an extension of the period of time in which Mr. Houghton may exercise certain previously granted and vested stock options from ninety (90) days to two and one-half (2.5) years and a waiver and release by Mr. Houghton of any and all claims that he may have against the Company. The extended exercise term qualified as a modification under Accounting Standards Codification ("ASC") 718, Compensation-Stock Compensation and resulted in a non-cash charge of approximately $75,000. The additional non-cash charged was calculated by valuing the vested options before and after the modification using the Black-Scholes option pricing model. In addition, Mr. Houghton shall provide certain transition services to the Company on an as-needed basis through the end of 2011. Also, effective as of September 30, 2011, Mr. Houghton resigned as a member of the Board of Directors of the Company. Richard M. Cohen, a member of the Company's Board of Directors, is serving as the Company's Executive Chairman and has been appointed as the Company's Interim Chief Executive Officer as a full-time employee, effective November 4, 2011.

Revised Director Compensation Policy

On January 14, 2011, the Board adopted revisions to its director compensation policy (the "Director Compensation Policy") based on recommendations from an independent compensation consultant retained by the Compensation Committee of the Board. The Board revised the Director Compensation Policy to provide for an increase in the amount of the annual retainer paid to non-employee directors to $20,000, with the exception of the Chairman of the Board who will be paid $30,000. Under the revised Director Compensation Policy, each non-employee director will be granted annually, at the first Board meeting of the calendar year, an option to purchase 30,000 shares of the Company's common stock at an exercise price equal to the closing price of the common stock on the grant date, which option will vest on the first anniversary of the grant date. In addition, pursuant to the revised Director Compensation Policy, each new non-employee director will be granted, in connection with his or her initial election to the Board, an option to purchase 30,000 shares of the Company's common stock at an exercise price equal to the closing price of the common stock on the grant date, which option will vest as follows: one-third on the grant date; an additional one-third on the first anniversary of the grant date; and the remaining one-third on the second anniversary of the grant date.

Note 6 — Initial Public Offering:

On March 30, 2010, the Company completed its IPO, whereby the Company sold 1,925,000 units, each unit consisting of two shares of its 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. In connection with the IPO, the Company paid underwriting discounts and commissions of $1,063,563, corporate finance fees of $225,250 and reimbursable legal expenses of counsel for the underwriters of $90,000, and the Company incurred other offering costs and expenses, including legal, accounting, printing and filing fees totaling $676,417.

CORMEDIX INC.
(A Development Stage Company)
NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

All of the Company's convertible notes and all of the Company's outstanding shares of Non-Voting Subordinated Class A Common Stock automatically converted into Units or common stock upon the completion of the IPO.

Note 7 — Fair Value Measurements:

The fair value of the Company's cash and cash equivalents, accounts payable and other accrued liabilities at September 30, 2011 are estimated to approximate their carrying values due to the relative liquidity and short-term nature of these instruments.

Note 8 — Subsequent Events:

On November 4, 2011, the Company's Board of Directors appointed Richard M. Cohen as the Interim Chief Executive Officer of the Company. As a result of the increase in Mr. Cohen's day-to-day involvement with the Company, the Board of Directors approved the Company's entering into an at-will employment arrangement with Mr. Cohen. Under this arrangement, Mr. Cohen will be paid $7,500 per month to serve in the capacity as Interim Chief Executive Officer. As an employee of the Company, Mr. Cohen will no longer receive compensation for his services on the Board of Directors. In connection with this new employment arrangement, on November 4, 2011, Mr. Cohen resigned as a member of the Audit Committee of the Board of Directors, and Mr. Steven W. Lefkowitz, a current member of the Audit Committee, was appointed as the Chairman of the Audit Committee and was determined to have the requisite skills and background to be an "audit committee financial expert" as defined by Item 407 of Regulation S-K.

On November 4, 2011, the Board of Directors also approved a three-month consulting arrangement with Dr. Antony Pfaffle, a current member of the Board of Directors, in recognition of his increased day-to-day involvement with the Company. Under the consulting arrangement, Dr. Pfaffle will be paid a monthly fee of $2,500 for his consulting services.

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 unaudited condensed financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or the SEC, on March 11, 2011.

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," "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 company that seeks to in-license, develop and commercialize therapeutic products for the treatment of cardiac and renal dysfunction, also known as Cardiorenal disease. 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 products in our Cardiorenal pipeline.

We have the worldwide rights to develop and commercialize several proprietary product candidates that address significant market opportunities, including our most advanced product candidates, CRMD003 (Neutrolin®) and CRMD001 (a proprietary formulation of deferiprone).

CRMD003 is a liquid designed to prevent central venous Catheter Related Bloodstream Infections, or CRBI, and maintenance of catheter patency in central venous catheters (initially in hemodialysis catheters). During the third quarter of 2011 we received a notice from the U.S. Food and Drug Administration, or the FDA, for CRMD003 that it has been assigned to the Center for Drug Evaluation and Research, or CDER. As a result of the letter received by the FDA, along with our current capital resources, we have decided to focus the majority of our resources and research and development efforts on seeking CE marking approval and commercialization of Neutrolin® in Europe through a CE mark application. During the first half of 2011 we submitted our design dossier with the European notified body managing our CE mark application which upon the successful audit and approval of the design dossier and the implementation and successful audit of our quality management systems, we would anticipate being in a position to obtain a CE mark approval in the first half of 2012. If we obtain CE mark approval in Europe, we expect to be in a position to launch Neutrolin® for the prevention of CRBI and maintenance of catheter patency in hemodialysis

patients in Europe during the first half of 2012. 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.

CRMD001 or deferiprone is our oral formulation of the drug deferiprone, which we have completed a phase 2 study in the prevention of Contrast-Induced Nephropathy, or CIN, which is a common and potentially serious complication arising from the use of iodinated contrast media used in X-ray procedures to identify the status of blood vessels in the heart. In June 2010, we initiated patient dosing in a phase 2 biomarker "proof of concept" study for the CIN indication. As of June 2011, we completed the recruitment of our phase 2 biomarker study of a proprietary formulation of deferiprone for the prevention of CIN also known as Contrast-Induced Acute Kidney Injury or CI-AKI in high risk patients with chronic kidney disease undergoing percutaneous cardiac catheterization with the intent of Percutaneous Coronary Intervention or PCI. The study included patients undergoing cardiac catheterization with the intent of PCI and considered at high risk for CIN who received either deferiprone or placebo twice a day beginning 1-3 hours before the procedure for a total of 8 days. The study was randomized, double-blind and placebo-controlled. Deferiprone was given at a dose of 2700 mg twice per day in the form of 900-mg tablets (1 immediate release and 2 extended release). A total of 61 patients (32 deferiprone, 29 placebo) were enrolled in the study. A variety of biomarkers of kidney injury and function were measured. Clinical events and safety parameters, including Serious Adverse Events or SAEs were followed through day 90. Top-line results were reviewed and interpreted internally, by the principal investigator and by three external academic biomarker experts. In the placebo group, most of the kidney injury biomarkers increased after contrast administration, as expected. Deferiprone tended to reduce acute elevations of the injury biomarkers, particularly in the first 8 hours. Measures of glomerular filtration (serum cystatin C, serum creatinine and Estimated Glomerular Filtration Rate [eGFR]) unexpectedly trended in the opposite direction over the first 8 days, as there was little change in the placebo group and small decreases in renal function in the deferiprone group. Analysis of SAEs indicated no safety signal. Based upon these top-line results, along with the extensive review of our CIN intellectual property position, the review of biomarker expert opinions, and among other factors such as our current cash position, we have decided against pursuing further development of CRMD001 at this time. We plan to explore available options to CRMD001 and are in discussions with Shiva Biomedical, the licensor of CRMD001, to renegotiate the current terms of our applicable license agreement, as amended, to enable us the opportunity to explore other potential opportunities for CRMD001.

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 CRMD003. As of September 30, 2011, we had an accumulated deficit of $43,288,048. 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.

We also effected a 1-for-7.836 reverse stock split of our common stock on February 24, 2010 in connection with the IPO. All shares and per share amounts, except as noted, have been retroactively adjusted to give effect to the reverse stock split.

Financial Operations Overview

Revenue

We have not generated any revenue since our inception. As of September 30, 2011, 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 $281,000 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, 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 September 30, 2011, we incurred $22,540,136 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.

	Nine Months Ended September 30,		Period from July 28, 2006 (Inception) through September 30, 2011
	2011	2010	
CRMD001	45%	45%	57%
CRMD002	0%	1%	0%
CRMD003	53%	53%	40%
CRMD004	2%	1%	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 increase if we add personnel and as a result of the continued reporting obligations applicable to public companies. From our inception on July 28, 2006 through September 30, 2011, we spent $10,379,720 on G&A expense.

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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 relating to our convertible notes.

Results of Operations

Three months ended September 30, 2011 compared to three months ended September 30, 2010

Research and Development Expense. R&D expense was $1,724,797 for the three months ended September 30, 2011, an increase of $964,264, from $760,533 for the three months ended September 30, 2010. The increase was primarily attributable to higher patient recruitment charges for our phase 2 study of CRMD001 which completed enrollment in June 2011, in addition to clinical research organization, manufacturing and regulatory expenses related to the development of CRMD003 and higher personnel costs as a result of hiring two employees in the areas of clinical operations and product development during the third quarter of 2010.

General and Administrative Expense. G&A expense was $877,020 for the three months ended September 30, 2011, an increase of $234,766 from $642,254 for the three months ended September 30, 2010. The increase was primarily attributable to severance related charges of approximately $214,000 from the departure of our previous President and Chief Executive Officer, offset by approximately $86,000 of stock-based compensation expense reversed during the third quarter of 2011 which was attributable to the forfeiture of stock options by our previous President and Chief Executive Officer. The increase was also attributable to increased salary, professional fees and business development expenses.

Interest Income. Interest income was $2,199 for the three months ended September 30, 2011, a decrease of $8,176, from $10,375 for the three months ended September 30, 2010. The decrease was attributable to having a lower interest-bearing cash balance during the third quarter of 2011 compared to the third quarter of 2010.

Nine months ended September 30, 2011 compared to nine months ended September 30, 2010

Research and Development Expense. R&D expense was $4,482,687 for the nine months ended September 30, 2011, an increase of $434,455, from $4,048,232 for the nine months ended September 30, 2010. The increase was primarily attributable to increased clinical, clinical research organization, manufacturing and regulatory expenses related to our phase 2 clinical trial of CRMD001 which completed patient recruitment in June 2011, higher manufacturing, regulatory and clinical research organization costs related to the development of CRMD003 and higher personnel costs as a result of hiring two employees in the areas of clinical operations and product development during the third quarter of 2010.

General and Administrative Expense. G&A expense was $2,609,526 for the nine months ended September 30, 2011, an increase of $702,654 from $1,906,872 for the nine months ended September 30, 2010. The increase was partially attributable to severance related charges of approximately $214,000 from the departure of our previous President and Chief Executive Officer, offset by approximately $86,000 of stock-based compensation expense reversed during the third quarter of 2011 which was attributable to the forfeiture of stock options by our previous president and chief executive officer. The increase was also attributable to increased salary, professional fees and business development expenses.

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Interest Income. Interest income was $10,625 for the nine months ended September 30, 2011, a decrease of $5,461 from $16,086 for the nine months ended September 30, 2011. The decrease was attributable to having a lower interest-bearing cash balance during the nine months ended September 30, 2011 compared to the nine months ended September 30, 2010.

Interest Expense. Interest expense was $0 for the nine months ended September 30, 2011, compared to $3,093,763 for the nine months ended September 30, 2010. The decrease was attributable to the conversion of all our convertible notes during the first quarter of 2010 in connection with the IPO in March 2010.

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 $281,000 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 $5,392,136 for the nine months ended September 30, 2011. The net loss of $7,051,769 for the nine months ended September 30, 2011 was higher than cash used in operating activities by $1,659,633. The primary reasons for the difference is attributed to a stock-based compensation charge of $534,215, a decrease in prepaid expenses and other current assets of $415,429 which consists of manufacturing costs, clinical research organization and insurance premiums during the nine months ended September 30, 2011, and an increase in accrued expenses of $851,638 which resulted from a charge of $900,000 attributed to a licensor expense related to the development of our phase 2 CRMD001 deferiprone study offset by payments made to vendors during the third quarter of 2011. These were offset by a decrease in accounts payable of $149,222 related to increased clinical development costs.

Net Cash Used in Investing Activities

Net cash used in investing activities was $1,625 for the nine months ended September 30, 2011, which was attributable to the purchase of computer equipment.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $0 for the nine months ended September 30, 2011. Net cash provided by financing activities during the nine months ended September 30, 2010 consisted of the sale of equity securities issued in our IPO, through which we received gross proceeds of $12,512,500. The gross proceeds of $12,512,500 were offset by underwriting discounts and commissions of $1,063,563, corporate finance fees of $225,250, and reimbursable legal fees for counsel to the underwriters of $90,000, in addition to other offering costs and expenses of $676,417, consisting primarily of legal, accounting, printing and filing fees. Net cash provided by financing activities was $10,457,270 for the nine months ended September 30, 2010.

Funding Requirements

Our total cash and cash equivalents as of September 30, 2011 was $2,889,923, compared to $8,283,684 at December 31, 2010. 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 September 30, 2011, 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 $281,000 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 previously 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.

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 2011. 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.

Based on our cash resources at September 30, 2011, 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.

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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 11, 2011, 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 non-cash charge to operations for 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, non-employees and directors and officers during the nine months ended September 30, 2011, we used the Black-Scholes option pricing model. For the purpose of valuing performance based options granted to a non-employee during the nine months ended September 30, 2011, we used the standard Monte Carlo stock price simulation method. As of September 30, 2011, there were no non-employee stock options that have vested, as the vesting of such stock options is contingent upon various performance metrics which have not been achieved as of September 30, 2011. To estimate the number of stock options expected to vest, the Company used the Monte Carlo stock price simulation method. The Monte Carlo analysis uses several random simulations along with performance vesting metrics, an initial stock price of $1.72, expected volatility of 100% for the one-year period of the vesting contingency and a one-year risk-free rate of 0.25%. The Company then used the results of the Monte Carlo analysis together with the Black-Scholes option pricing method to estimate the fair value of the options issued. The Black-Scholes option pricing method criteria to determine the related non-cash charge to operations included: a current stock price of $0.91, volatility of 113%, a one year contractual service period, an expected exercise term of 4.7 years and a risk free rate of 1.00%. We granted options to purchase an aggregate of 856,000 and 1,639,215 shares of common stock to our employees, non-employees and directors and officers during the nine months ended September 30, 2011 and 2010, respectively. 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. During the nine months ended September 30, 2011, the Company has experienced forfeitures of stock options issued to its former

President and Chief Executive Officer, Chief Medical Officer, Chairman and Board member. Since the stock options currently outstanding are primarily held by our senior management and directors we will continue to evaluate the effects of such future potential forfeitures, as they may arise, to ascertain an estimated forfeiture rate.

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 September 30, 2011 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 September 30, 2011, 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.

None.

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 $7.1 million, $9.0 million for the nine-month periods ended September 30, 2011 and 2010, respectively. As of September 30, 2011, we had an accumulated deficit of approximately $43.3 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.

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We may 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
- CRMD001 - completed enrollment in phase 2 clinical study
- CRMD002 - 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.

We have decided not to proceed with the development of CRMD001 for the treatment of Chronic Kidney Disease (CKD) or Contrast Induced Nephropathy (CIN) at this time.

We have previously intended to develop CRMD001 for prevention of CIN and possibly CKD, however, as a result of our recent strategic direction changes and our available cash resources, we have reprioritized our product candidate's development. We have recently completed our phase 2 CIN clinical study and have determined against pursuing further development of CRMD001 at this time. This decision was based upon extensive review of our CIN intellectual property position, the review of biomarker expert opinions, and taking into account our current cash position. We plan to explore available options with respect to CRMD001 and are in discussions with Shiva Biomedical, the licensor of CRMD001, to renegotiate the current terms of the applicable license agreement, as amended, to enable us the opportunity to explore other potential opportunities for CRMD001.

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, Brian Lenz, our Chief Financial Officer, and Dr. Mark Klausner, our Chief Medical Officer. While we have employment agreements with Mr. Lenz and 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.

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. Particularly, our amended license agreement with Shiva (referred to herein as the "Shiva Contribution Agreement") provides for a right of termination for, among other things, our failure to make certain milestone payments and achieve development activities within certain timelines. 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 (ii) the priority date of any new patent. Our intellectual property licensed under the Shiva Contribution Agreement serves as the basis for CRMD001 and CRMD002, 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)

- U.S. Patent Nos. 6,933,104, 6,906,052, 6,908,733, 6,995,152, 6,998,396, 7,045,282, 7,037,643, and 7,235,542 (expiring April 2020) - family of patents related to the diagnosis and treatment of CKD and other kidney diseases and disorders (for CRMD001) (the "CKD Patents")

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.

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 November 2, 2011, the high and low sales prices for our common stock were $4.00 and $0.22, 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.

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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 December 31, 2010, 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 executed, 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 December 31, 2010, the number of shares of common stock issuable upon exercise of these warrants was 503,034 shares.

As of December 31, 2010 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 September 30, 2011, options to purchase 1,574,923 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 $2.35 per share. Options to purchase 481,262 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 September 30, 2011, options to purchase 1,574,923 shares of common stock issued under the Amended and Restated 2006 Stock Incentive Plan at a weighted average exercise price of $2.35 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.

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

Use of Proceeds

Our IPO was effected through a Registration Statement on Form S-1, as amended (Registration No. 333-163380), that was declared effective by the SEC on March 24, 2010. The net offering proceeds to us, after deducting underwriting discounts, commissions and offering expenses payable by us, were approximately $10.5 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates. Of the net proceeds of $10.5 million, we have used approximately $6 million for R&D expenditures and approximately $4 million for general working capital expenditures through the end of the third quarter of 2011. We have invested the unused proceeds from the IPO in an interest bearing savings account.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. (Removed and Reserved).

Item 5. Other Information.

On November 4, 2011, the Company’s Board of Directors appointed Richard M. Cohen as the Interim Chief Executive Officer of the Company. As a result of the increase in Mr. Cohen’s day-to-day involvement with the Company, the Board of Directors approved the Company’s entering into an at-will employment arrangement with Mr. Cohen. Under this arrangement, Mr. Cohen will be paid $7,500 per month to serve in the capacity as Interim Chief Executive Officer. As an employee of the Company, Mr. Cohen will no longer receive compensation for his services on the Board of Directors. In connection with this new employment arrangement, on November 4, 2011, Mr. Cohen resigned as a member of the Audit Committee of the Board of Directors and Mr. Steven W. Lefkowitz, a current member of the Audit Committee was appointed as the Chairman of the Audit Committee and was determined to have the requisite skills and background to be an “audit committee financial expert” as defined by Item 407 of Regulation S-K.

On November 4, 2011, the Board of Directors also approved a three-month consulting arrangement with Dr. Antony Pfaffle, a current member of the Board of Directors, in recognition of his increased day-to-day involvement with the Company. Under the consulting arrangement, Dr. Pfaffle will be paid a monthly fee of $2,500 for his consulting services.

The Company has recently completed a phase 2 clinical study of a proprietary formulation of deferiprone or CRMD001 for the prevention of Contrast-Induced Nephropathy ("CIN") also known as Contrast-Induced Acute Kidney Injury ("CI-AKI") in high risk patients with chronic kidney disease undergoing percutaneous cardiac catheterization with the intent of Percutaneous Coronary Intervention ("PCI"). The study included patients undergoing cardiac catheterization with the intent of PCI and considered at high risk for CIN who received either deferiprone or placebo twice a day beginning 1-3 hours before the procedure for a total of 8 days. The study was randomized, double-blind and placebo-controlled. Deferiprone was given at a dose of 2700 mg twice per day in the form of 900-mg tablets (1 immediate release and 2 extended release). A total of 61 patients (32 deferiprone, 29 placebo) were enrolled in the study. A variety of biomarkers of kidney injury and function were measured. Clinical events and safety parameters, including Serious Adverse Events ("SAEs") were followed through day 90. Top-line results were reviewed and interpreted internally, by the principal investigator and by three external academic biomarker experts. In the placebo group, most of the kidney injury biomarkers increased after contrast administration, as expected. Deferiprone tended to reduce acute elevations of the injury biomarkers, particularly in the first 8 hours. Measures of glomerular filtration (serum cystatin C, serum creatinine and Estimated Glomerular Filtration Rate "eGFR") unexpectedly trended in the opposite direction over the first 8 days, as there was little change in the placebo group and small decreases in renal function in the deferiprone group. Analysis of SAEs indicated no safety signal. Based upon these top-line results, along with the extensive review of the Company's CIN intellectual property position, the review of biomarker expert opinions and taking into account the Company's current cash position the Company is not going to pursue further development of CRMD001 at this time. The Company plans to explore available options with respect to CRMD001 and is in discussions with Shiva Biomedical, the licensor of CRMD001, to renegotiate the current terms of the applicable license agreement, as amended, to enable the Company to explore other potential opportunities for CRMD001.

Item 6. Exhibits.

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

Exhibit Number	Description
10.1	Separation and General Release Agreement, effective as of September 30, 2011, by and between CorMedix Inc. and John C. Houghton.*
10.2	Amendment No.3 to Contribution Agreement, dated as of August 31, 2011, by and between CorMedix Inc. and Shiva Biomedical, LLC.+*
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
101	The following materials from CorMedix Inc. Form 10-Q for the quarter ended September 30, 2011, formatted in Extensible Business Reporting Language (XBRL): (i) Condensed Balance Sheets at September 30, 2011 and December 31, 2010, (ii) Condensed Statements

of Operations for the three and nine months ended September 30, 2011 and 2010, and for the Cumulative Period from July 28, 2006 (inception) through September 30, 2011, (iii) Condensed Statements of Changes in Stockholders' Equity for the nine months ended September 30, 2011, (iv) Condensed Statements of Cash Flows for the nine months ended September 30, 2011 and 2010, and for the Cumulative Period from July 28, 2006 (inception) through September 30, 2011, 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.

+Confidential treatment requested. Confidential materials omitted and filed separately with the Securities and Exchange Commission.

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:	November 10, 2011	By:	/s/ Richard M. Cohen	
			Name:	Richard M. Cohen
			Title:	Executive Chairman and Interim Chief Executive Officer (Principal Executive Officer)
Date:	November 10, 2011	By:	/s/ Brian Lenz	
			Name:	Brian Lenz
			Title:	Chief Financial Officer (Principal Financial and Accounting Officer)

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