

CorMedix Inc.
Form 10-Q/A
March 04, 2014

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q/A
Amendment No. 2

(Mark One)

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

For the quarterly period ended March 31, 2013

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
(State or Other Jurisdiction of Incorporation or
Organization)

20-5894890
(I.R.S. Employer Identification No.)

745 Rt. 202-206, Suite 303, Bridgewater, NJ
(Address of Principal Executive Offices)

08807
(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

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

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(§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 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

Smaller reporting company

(Do not check if a smaller reporting company)

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

The number of shares outstanding of the issuer’s common stock, as of May 7, 2013 was 13,202,665.

EXPLANATORY NOTE

CorMedix Inc. (the “Company”) is filing this Amendment No. 2 to its Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2013, filed with the Securities and Exchange Commission (the “Commission”) on May 15, 2013, as amended by Amendment No. 1 to its Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2013, filed with the Commission on November 19, 2013 (the “Original Filing”), to correct its unaudited condensed consolidated financial statements included in the Original Filing. The error was due to an inadvertent over-accrual of a royalty under a license agreement. We also have amended “Part I. Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations” to reflect these adjusted amounts.

We have amended “Part I Item 4. Controls and Procedures” and “Part II Item 1A. Risk Factors” to reflect a material weakness in our internal control over financial reporting which resulted in the restatement of our financial statements on Form 10-Q for the quarter ended March 31, 2013, as amended on Form 10-Q/A for the quarter ended March 31, 2013 filed with the Commission on November 19, 2013.

In addition to the corrections above, this Amendment also restates “Part II. Item 6. Exhibits” to include currently dated certifications pursuant to Section 302 and Section 906 of the Sarbanes-Oxley Act of 2002, which are attached as Exhibits 31.1, 31.2, 32.1 and 32.2 to this Amendment No. 2.

Except as set forth above, the Original Filing has not been amended, updated or otherwise modified, and does not reflect events occurring after May 15, 2013, the date of the Original Filing, or modify or update those disclosures that may have been affected by subsequent events.

CORMEDIX INC.
(A Development Stage Company)

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PART I

FINANCIAL INFORMATION

Item 1. Consolidated Financial Statements.

CORMEDIX INC.
(A Development Stage Company)

CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2013 (Unaudited) (Restated)	December 31, 2012 (Note 1) (Restated)
ASSETS		
Current assets		
Cash	\$ 692,720	\$ 835,471
Prepaid research and development expenses	5,960	11,221
Deferred financing costs	201,490	257,886
Other prepaid expenses and current assets	50,012	30,677
Total current assets	950,182	1,135,255
Property and equipment, net	4,125	4,668
Security deposit	13,342	13,342
TOTAL ASSETS	\$ 967,649	\$ 1,153,265
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 1,217,346	\$ 928,553
Accrued expenses	251,984	261,983
Accrued interest, related parties	15,077	16,175
Senior convertible notes, net of debt discount of \$456,533 at March 31, 2013 and \$647,939 at December 31, 2012	207,467	16,061
Senior convertible notes - related parties, net of debt discount of \$268,961 at March 31, 2013 and \$406,316 at December 31, 2012	391,039	253,684
Total current liabilities	2,082,913	1,476,456
Deferred rent	10,953	12,185
TOTAL LIABILITIES	2,093,866	1,488,641
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' DEFICIT		
Preferred stock - \$0.001 par value: 2,000,000 shares authorized, 287,324 and 0 shares issued and outstanding at March 31, 2013 and December 31, 2012, respectively	287	-
Common stock - \$0.001 par value: 80,000,000 shares authorized, 11,882,379 and 11,408,274 shares issued and outstanding at March 31, 2013 and December 31, 2012, respectively	11,882	11,408
Deferred stock issuances	(146)	(146)
Additional paid-in capital	46,651,989	45,886,596

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Deficit accumulated during the development stage	(47,790,229)	(46,233,234)
TOTAL STOCKHOLDERS' DEFICIT	(1,126,217)	(335,376)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	\$ 967,649	\$ 1,153,265

See Notes to Unaudited Condensed Consolidated Financial Statements.

CORMEDIX INC.
(A Development Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	For the Three Months Ended March 31, 2013 (Restated)	For the Three Months Ended March 31, 2012 (Restated)	Cumulative Period from July 28, 2006 (inception) Through March 31, 2013 (Restated)
OPERATING EXPENSES			
Research and development	\$255,035	\$363,605	\$23,458,340
General and administrative	551,741	536,255	13,327,775
Total Operating Expenses	806,776	899,860	36,786,115
LOSS FROM OPERATIONS	(806,776)	(899,860)	(36,786,115)
OTHER INCOME (EXPENSE)			
Other income, net	-	-	420,987
Interest income	128	949	126,435
Interest expense, including amortization and write-off of deferred financing costs and debt discounts	(440,403)	-	(12,016,367)
LOSS BEFORE INCOME TAXES	(1,247,051)	(898,911)	(48,255,060)
State income tax benefit	-	-	774,775
NET LOSS	(1,247,051)	(898,911)	(47,480,285)
Deemed dividend - beneficial conversion feature	(309,944)	-	(309,944)
NET LOSS ATTRIBUTABLE TO COMMON SHAREHOLDERS	\$(1,556,995)	\$(898,911)	\$(47,790,229)
NET LOSS PER SHARE – BASIC AND DILUTED	\$(0.13)	\$(0.08)	
WEIGHTED AVERAGE SHARES OUTSTANDING – BASIC AND DILUTED			
	11,603,184	11,408,274	

See Notes to Unaudited Condensed Consolidated Financial Statements.

CORMEDIX INC.
(A Development Stage Company)

CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN
STOCKHOLDERS' DEFICIT
(Unaudited)

For the Three Months Ended March 31, 2013

	Common Stock		Non-Voting Preferred Stock – Series A		Deferred Stock Issuances	Additional Paid-in Capital	Deficit Accumulated During the Development Stage (Restated)	Total Stockholders' Deficit (Restated)
	Shares	Amount	Shares	Amount				
Balance at January 1, 2013	11,408,274	\$ 11,408	-	\$ -	\$ (146)	\$ 45,886,596	\$ (46,233,234)	\$ (335,376)
Non-voting preferred stock issued in February 2013 private placement at \$0.70 per share, net			761,429	761		506,372		507,133
Conversion of Series A non-voting preferred stock to common stock	474,105	474	(474,105)	(474)				
Deemed dividend related to beneficial conversion feature of Series A non-voting preferred stock						309,944	(309,944)	-
Repurchase of outstanding warrants						(33,000)		(33,000)
Stock-based compensation						(17,923)		(17,923)
Net loss							(1,247,051)	(1,247,051)

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Balance at

March 31, 2013 11,882,379 \$ 11,882 287,324 \$ 287 \$ (146)\$ 46,651,989 \$ (47,790,229) \$ (1,126,217)

See Notes to Unaudited Condensed Consolidated Financial Statements.

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CORMEDIX INC.
(A Development Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	For the Three Months Ended March 31, 2013 (Restated)	For the Three Months Ended March 31, 2012 (Restated)	Cumulative Period from July 28, 2006 (Inception) Through March 31, 2013 (Restated)
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	\$(1,247,051)	\$ (898,911)	\$(47,480,285)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	(17,923)	96,662	2,581,315
Stock issued in connection with license agreements	-	-	6,613,718
Stock issued in connection with consulting agreement	-	-	158,262
Amortization of deferred financing costs	81,396	-	2,205,909
Amortization of debt discount	328,761	-	5,587,274
Non-cash charge for beneficial conversion feature	-	-	1,137,762
Non-cash interest expense	-	-	3,007,018
Expenses paid on behalf of the Company satisfied through the issuance of notes	-	-	51,253
Depreciation	543	1,755	57,585
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(14,074)	388,749	(55,972)
Security deposits	-	-	(13,342)
Accounts payable	262,926	416,105	1,160,676
Accrued expenses and accrued interest	(11,097)	(133,929)	267,061
Deferred rent	(1,232)	(572)	10,953
Net cash used in operating activities	(617,751)	(130,141)	(24,710,813)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of equipment	-	-	(61,709)
Net cash used in investing activities	-	-	(61,709)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from notes payable to related parties	-	-	3,063,484
Proceeds from senior convertible notes	-	-	13,963,838
Proceeds from Galenica, Ltd. promissory note	-	-	1,000,000
Payments for deferred financing costs	(25,000)	-	(1,542,603)
Repayment of amounts loaned under related party notes	-	-	(1,981,574)
Proceeds from sale of equity securities	533,000	-	10,990,270
Repurchase of outstanding warrants	(33,000)	-	(33,000)
Proceeds from receipt of stock subscriptions and issuances of common stock	-	-	4,827

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Net cash provided by financing activities	475,000	-	25,465,242
NET INCREASE (DECREASE) IN CASH	(142,751)	(130,141)	692,720
CASH – BEGINNING OF PERIOD	835,471	1,985,334	-
CASH – END OF PERIOD	\$692,720	\$ 1,855,193	\$692,720
Cash paid for interest	\$26,938	\$ -	\$45,363
Supplemental Disclosure of Non-Cash Financing Activities:			
Conversion of notes payable and accrued interest to common stock	\$-	\$ -	\$18,897,167
Reclassification of deferred financing fees to additional paid-in capital	\$-	\$ -	\$148,014
Stock issued to technology finders and licensors	\$-	\$ -	\$155
Warrants issued to placement agent	\$-	\$ -	\$854,608
Debt discount on senior convertible notes	\$-	\$ -	\$6,312,768
Deemed dividend – beneficial conversion feature	\$309,944	\$ -	\$309,944
Accrued deferred financing cost	\$-	\$ -	\$30,803
Accrued private placement expenses	\$25,867	\$ -	\$25,867

See Notes to Unaudited Condensed Consolidated Financial Statements.

CORMEDIX INC.
(A Development Stage Company)

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 1 — Organization, Business and Basis of Presentation:

Organization and Business:

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

Basis of Presentation:

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”) for interim financial information and with the instructions for Form 10-Q and Article 10 of Regulation S-X. Accordingly, the unaudited condensed consolidated financial statements do not include all information and footnotes required by GAAP for complete annual financial statements. In the opinion of management, the accompanying unaudited condensed consolidated 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, 2013 or for any subsequent period. These unaudited condensed consolidated 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 Securities and Exchange Commission (“SEC”) on March 27, 2013. The accompanying condensed balance sheet as of December 31, 2012 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, acquiring licenses for its pharmaceutical compound pipeline, performing business and financial planning, performing research and development, establishing office facilities, and raising funds through the issuance of debt and common stock. The Company has not generated any revenues from its product candidates and, accordingly, the Company is considered to be in the development stage.

The Company’s unaudited condensed consolidated 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 consolidated 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 through the second quarter of 2013. The Company intends to raise additional funds through various potential sources, such as equity and/or debt financings, strategic relationships, or out-licensing of its products, however, the Company can provide no assurances that such financing will be available on acceptable terms, or at all. If adequate financing is not available, the Company may be required to terminate or significantly curtail or cease its operations, or enter into arrangements with collaborative partners or

others that may require the Company to relinquish rights to certain of its technologies, or potential markets that the Company would not otherwise relinquish.

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NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

For the three months ended March 31, 2013 and the period from July 28, 2006 (inception) to March 31, 2013, the Company incurred net losses of \$1,247,051 and \$47,480,285, respectively.

Note 2 — Summary of Significant Accounting Policies:

Use of Estimates:

The preparation of financial statements in conformity with GAAP 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.

Basis of Consolidation:

The consolidated financial statements include the accounts of CorMedix Europe GmbH, a wholly owned subsidiary. All significant intercompany accounts and transactions have been eliminated in consolidation.

Loss per common share:

Basic earnings (loss) per common share excludes any potential 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. However, since their effect is anti-dilutive, the Company has excluded potentially dilutive shares. The following potentially dilutive shares have been excluded from the calculation of diluted net loss per share as their effect would be anti-dilutive.

	Three Months Ended	
	March 31,	March 31,
	2013	2012
Convertible notes	3,782,857	-
Series A non-voting preferred stock	287,324	-
Shares underlying outstanding warrants	8,610,665	4,807,534
Shares underlying outstanding stock options	3,298,297	1,547,122
Total	15,979,143	6,354,656

CORMEDIX INC.
(A Development Stage Company)

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Stock-Based Compensation:

Stock-based compensation cost, net of expected forfeitures, granted to employees, officers and directors is measured at the grant date, based on the estimated fair value of the award, and is recognized as expense over the requisite service period on a straight-line basis.

The Company accounts for stock options granted to non-employees on a fair value basis using the Black-Scholes option pricing method. The non-cash charge to operations for non-employee options with service 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 vesting period. For stock options granted to non-employees with vesting contingent upon various performance metrics, the Company used the guidelines in accordance with FASB ASC No. 505-50, "Equity-Based Payments to Non-Employees." For options having performance conditions that are outside of the control of the non-employee, the cost to be recognized is the lowest aggregate fair value prior to the achievement of the performance condition, even if the Company believes it is probable that the performance condition will be achieved.

During the three months ended March 31, 2013 and 2012, options to purchase an aggregate of 1,400,000 and 330,000 shares of common stock, respectively, were granted to the Company's employees, officers, directors and consultants.

Note 3 — Convertible Notes:

During the year ended December 31, 2012, the Company completed a private placement of an aggregate of 1,324 Units, each Unit consisting of (i) a one-year \$1,000 aggregate principal amount 9% Senior Convertible Note (the "Notes"), convertible into shares (the "Conversion Shares") of common stock, at a conversion price of \$0.35 per Note, and (ii) a five-year redeemable Warrant (the "Warrants") to purchase 3,310,000 shares of common stock (the "Warrant Shares"), to certain accredited investors (the "Purchasers") pursuant to Subscription Agreements dated September 20, 2012 and November 13, 2012 (the "Subscription Agreements"). The Company received aggregate gross proceeds of \$1,324,000. The total net proceeds (net of placement agent and legal fees) of the private placement to the Company were \$1,095,600. The Company paid the placement agent for the private placement a total of \$109,900 in fees and issued it warrants to purchase an aggregate of 331,000 shares of its common stock. The placement agent warrants have the same terms as those issued to the investors. The Notes issued have maturity dates of September 20, 2013 and November 13, 2013.

The Notes bear interest at 9% per annum payable quarterly in arrears. The Company has the right to prepay, in certain instances, all (but not less than all, subject to certain share ownership limitations) of the then outstanding Notes by paying 120% of the principal and accrued but unpaid interest through and including the date each Note is repaid.

The Purchasers were issued Warrants to purchase the Company's common stock, exercisable for a period of five years at an initial exercise price of \$0.40, subject to adjustment. The Warrants provide for customary adjustments to the exercise price in the event of stock splits, stock dividends and other similar corporate events and may be exercised on a cashless basis. The Warrants do not confer any voting rights or any other rights as a shareholder.

The Company, upon thirty-day notice to holders of outstanding Warrants, has the right, subject to certain limitations, to redeem all or any portion of the Warrants then outstanding for consideration of \$0.001 per Warrant if (i) either (a) there is an effective registration statement for resale of all of the Conversion Shares, or (b) all of the Conversion Shares may be resold pursuant to Rule 144 without any restrictions or limitations, and (ii) for the ten consecutive trading days prior to the date that the Company notifies such holders of such redemption, (a) the daily volume-weight adjusted market price of the Common Stock is equal to or greater than 140% of the then exercise price, and (b) the average daily value of the trading volume is not less than \$100,000.

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(A Development Stage Company)

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

The Company accounts for the beneficial conversion feature (“BCF”) and warrant valuation in accordance with FASB ASC 470-20, Debt with Conversion and Other Options. The Company records a BCF related to the issuance of convertible debt that has conversion features at fixed rates that are “in-the-money” when issued and the fair value of warrants issued in connection with those instruments. The BCF for the convertible instruments is recognized and measured by allocating a portion of the proceeds to warrants, based on their relative fair value, and as a reduction to the carrying amount of the convertible debt equal to the intrinsic value of the conversion feature. The discount recorded in connection with the BCF and warrant valuation is recognized as non-cash interest expense and is amortized over the terms of the convertible notes. The Company recorded an aggregate of \$1,333,307 for the calculated fair value of the warrants and BCF, in conjunction with the convertible notes issued on September 20, 2012 and November 13, 2012.

The Company valued the warrants using the fair value method, at the date the warrants were issued, using the Black-Scholes valuation model and the following assumptions:

	September 20, 2012	November 13, 2012
Contractual Term	5 years	5 years
Volatility	117.57 %	119.15 %
Dividend yield	0.0 %	0.0 %
Risk-free interest rate	0.70 %	0.63 %

Senior convertible notes consist of the following at March 31, 2013:

9% Senior convertible notes	\$664,000
Debt discount/beneficial conversion feature	(456,533)
Balance	\$207,467
Accrued interest	\$15,168
9% Senior convertible notes, related parties	\$660,000
Debt discount/beneficial conversion feature	(268,961)
Balance	\$391,039
Accrued interest, related parties	\$15,077

Note 4 — Stockholders’ Equity:

Common Stock

On January 9, 2013, the Company filed a registration statement with the SEC to register the resale of the shares of common stock issuable upon the conversion of the Notes and the exercise of the Warrants, which filing was within 60 days after the final closing, as required. The registration statement was declared effective on April 4, 2013. Because the registration statement was not declared effective within 120 days after the date of the final closing, which is March 13, 2013, the Company was obligated to pay aggregated liquidated damages of \$551.

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NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Preferred Stock

On February 19, 2013, the Company sold 761,429 shares of its newly created Series A Non-Voting Convertible preferred stock and a warrant to purchase up to 400,000 shares of the Company's common stock, for gross proceeds of \$533,000. The Series A shares and the warrant were sold together at a price of \$0.70 per share for each share of Series A stock. Each share of Series A Stock is convertible into one share of the Company's common stock at any time at the holder's option. However, the holder will be prohibited from converting Series A Stock into shares of common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 3.99% of the total number of shares of the Company's common stock then issued and outstanding. In the event of the Company's liquidation, dissolution, or winding up, holders of the Series A Stock will receive a payment equal to \$0.001 per share of Series A Stock before any proceeds are distributed to the holders of common stock. Shares of the Series A Stock will not be entitled to receive any dividends, unless and until specifically declared by the Company's board of directors, and will rank:

senior to all common stock;

senior to any class or series of capital stock hereafter created specifically by its terms junior to the Series A Stock;

on parity with our Series A Preferred Stock and any class or series of capital stock hereafter created specifically ranking by its terms on parity with the Series A Stock; and

junior to any class or series of capital stock hereafter created specifically ranking by its terms senior to the Series A Stock;

in each case, as to distributions of assets upon our liquidation, dissolution or winding up whether voluntarily or involuntarily.

The warrant is exercisable immediately upon issuance and has an exercise price of \$1.50 per share and a term of five years. However, the holder will be prohibited from exercising the warrant if, as a result of such exercise, the holder, together with its affiliates, would own more than 3.99% of the total number of shares of the Company's common stock then issued and outstanding.

On February 22, 2013, an aggregate of 474,105 shares of the Series A non-voting convertible preferred stock was converted into 474,105 shares of common stock.

During the three months ended March 31, 2013, because the Series A non-voting preferred stock is immediately convertible at the option of the holder, we recorded deemed dividend of \$309,944 from the beneficial conversion feature associated with the issuance of the Series A non-voting convertible preferred stock and the warrant.

Stock Options

On March 20, 2013, the Company's board of directors approved the 2013 Stock Incentive Plan (the "2013 Plan"). The 2013 Plan provides for the issuance of equity grants in the form of options, restricted stock, stock awards and other forms of equity compensation. Awards may be made to directors, officers, employees and consultants under the 2013 Plan. An aggregate of 5,000,000 shares of the Company's common stock is reserved for issuance under the 2013 Plan. The 2013 Plan is subject to shareholders' approval at the next annual shareholders' meeting of the Company.

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NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

During the three months ended March 31 2013, the Company granted to its officers and directors ten-year non-qualified stock options under the 2013 Plan, covering an aggregate of 1,020,000 shares of the Company's common stock with an exercise price of \$0.90 per share. The 310,000 options granted to four directors vest quarterly over two years. The remaining 710,000 options vest upon specified milestones. The Company recorded the pro rata expense during the three months ended March 31, 2013.

During the three months ended March 31 2013, the Company granted to various non-officer consultants ten-year non-statutory stock options under the 2013 Plan, covering an aggregate of 380,000 shares of the Company's common stock with an exercise price of \$0.90 per share. Of these options, 260,000 vest upon specified performance milestones, and 120,000 options vest in three years. For the three months ended March 31, 2013, the Company recorded the pro rata expense for the 120,000 options and no expense was recognized for the options that were subject to performance milestones since such milestones were not achieved as of March 31, 2013.

In March 2013, the Company's board of directors amended the vesting schedule of the options granted on December 5, 2012. Given the anticipated final approval for the CE Mark certification for Neutrolin® during the second quarter of 2013, 50% of such options will now vest on the date of issuance of the CE Mark certification for Neutrolin® in Europe, if the CE Mark approval is obtained on or before June 30, 2013 (as opposed to March 31, 2013 as previously provided by our Board). During the three months ended March 31, 2013, the Company recorded the pro rata expense and will amortize the remaining expense through the second quarter of 2013.

During the three months ended March 31, 2013, an aggregate of 237,333 unvested stock options granted to its former Chief Medical Officer under the Amended and Restated 2006 Stock Incentive Plan (the "2006 Plan") were forfeited as a result of his departure from the Company. The Company reversed the recorded expense related to the forfeited stock options during the three months ended March 31, 2013.

During the three months ended March 31, 2012, stock options to purchase an aggregate of 150,000 shares of common stock were granted to the Company's directors under the 2006 Plan with an exercise price of \$0.29 which vest on the one-year anniversary of the grant date, January 6, 2013. Additionally, the Company granted 180,000 stock options to its former Chief Operating Officer/Chief Financial Officer ("COO/CFO") with an exercise price of \$0.49 per share. As a result of the Company's COO/CFO's resignation in April 2012, all of the options mentioned above except for the 45,000 vested options were forfeited. The vested 45,000 stock options were amended to extend the exercise period up to and through May 31, 2014. The Company re-measured and recorded as an expense the value of the 45,000 stock options and reversed the recorded expense of the forfeited stock options.

During the three months ended March 31, 2013, total compensation expense for stock options issued to employees, directors, officers and consultants was \$70,764 offset by the reversal of \$88,687 of previously recognized expense related to stock options forfeited, and for the three months ended March 31, 2012 and the period from July 28, 2006 (inception) to March 31, 2013, compensation expense recorded was \$96,662 and \$2,581,315, respectively.

CORMEDIX INC.
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NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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:

	Three Months Ended March 31, 2013	Three Months Ended March 31, 2012		
Expected Term	5 years	5 years		
Volatility	118% - 131	113% - 114	%	%
Dividend yield	0.0	0.0	%	%
Risk-free interest rate	0.81% - 1.96	0.86% - 1.22	%	%

The Company estimated the expected term of the stock options granted based on anticipated exercises in future periods. The expected term of the stock options granted to consultants is based upon the contractual terms established within agreements with the Company. Given the Company's short period of publicly-traded stock history, management's estimate of expected volatility is based on the average expected volatilities of a sampling of five companies with similar attributes to the Company, including: industry, stage of life cycle, size and financial leverage. The Company will continue to analyze the expected stock price volatility and expected term assumptions as more historical data for the Company's common stock becomes available. The expected dividend yield of 0.0% reflects the Company's current and expected future policy for dividends on the Company's common stock. To determine the risk-free interest rate, the Company utilized the U.S. Treasury yield curve in effect at the time of grant with a term consistent with the expected term of the Company's awards. The Company has experienced forfeitures of stock options issued to its former officers, board member and employees. Consistent with its historical forfeiture experience, the Company has applied a forfeiture rate of approximately 39% and 40% to calculate stock option expense for the three month periods ended March 31, 2013 and 2012, respectively. The Company will continue to evaluate the estimated forfeiture rate derived from previous forfeitures of officers, directors and employees and may adjust the forfeiture rate based upon actual forfeitures that may occur in the future.

A summary of the Company's stock options activity and related information is as follows:

	Three Months Ended March 31, 2013		Three Months Ended March 31, 2012	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at beginning of period	2,135,630	\$ 1.26	1,236,342	\$ 2.47
Forfeited	(237,333)	\$ 1.61	(19,220)	\$ 1.89
Granted	1,400,000	\$ 0.90	330,000	\$ 0.40
Outstanding at end of period	3,298,297	\$ 1.08	1,547,122	\$ 2.03

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Expected to vest	1,476,200	\$0.78	402,698	\$2.03
Options exercisable	878,297	\$1.91	875,958	\$2.60
Weighted-average fair value of options granted during the period		\$0.77		\$0.32

The weighted average remaining contractual life of stock options outstanding and expected to vest at March 31, 2013 is 8.3 years. The weighted average remaining contractual life of stock options exercisable at March 31, 2013 is 5 years. The aggregate outstanding stock options intrinsic value of \$316,700 is calculated as the difference between the exercise prices of all underlying outstanding stock options and the quoted closing price of the common stock of the Company as of March 31, 2013 for those options that have an exercise price below the quoted closing price.

As of March 31, 2013, the total compensation expense related to non-vested options not yet recognized totaled \$1,562,392. The weighted-average vesting period over which the total compensation expense related to non-vested options not yet recognized at March 31, 2013 was approximately 0.9 years.

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NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Warrants

In February 2013, the Company repurchased outstanding warrants to purchase an aggregate of 220,000 shares of the Company's common stock at a purchase price of \$0.15 per share underlying the warrant. The warrants were issued in the Company's initial public offering and had an exercise price of \$3.4375. The repurchased warrants were cancelled.

The following table is the summary of warrants outstanding at March 31, 2013:

	Number of Warrants	Exercise Price	Expiration Date
Issued to co-placement agents in connection with previous convertible note financings	18,250	7.84	10/29/2014
Issued in connection with 2009 private placement	503,034	3.4375	10/29/2014
Issued in connection with IPO	4,043,569	3.4375	3/24/2015
Issued to IPO underwriters that, if exercised, would result in the issuance of an additional 4,812 shares of common stock and warrants to purchase an additional 2,406 shares of common stock	4,812	3.90	3/24/2015
Issued in connection with September 20, 2012 private placement of convertible notes	2,125,000	0.40	9/20/2017
Issued to placement agent in connection with September 20, 2012 private placement of convertible notes	212,500	0.40	9/20/2017
Issued in connection with November 13, 2012 private placement of convertible notes	1,185,000	0.40	11/13/2017
Issued to placement agent in connection with November 13, 2012 private placement of convertible notes	118,500	0.40	11/13/2017
Issued in connection with February 2013 private placement	400,000	1.50	2/19/2018
Total warrants outstanding at March 31, 2013	8,610,665		

Note 5 — Commitments and Contingencies:

In February 2007, Geistlich Söhne AG für Chemische Industrie, Switzerland, or Geistlich, brought an action against the Sodemann patent covering the Company's Neutrolin® product candidate which is owned by ND Partners, LLC and licensed to the Company pursuant to the License and Assignment Agreement between the Company and ND Partners LLC. The action that was brought against the Sodemann patent in Germany at the Board of the European Patent Office opposition division was for lack of inventiveness in the use of citric acid and a pH value in the range of 4.5 to 6.5 with having the aim to provide an alternative lock solution through having improved anticoagulant characteristics compared to the lock solutions described in the Lehner patent. The Board of the European Patent Office opposition division rejected the opposition by Geistlich. On August 27, 2008, Geistlich appealed the court's ruling, alleging the same arguments as presented during the opposition proceedings. The Company filed a response to the appeal of Geistlich on March 25, 2009 where the Company requested a dismissal of the appeal and to maintain the patent as

granted. To date, no further petitions have been filed by ND Partners or Geistlich. On October 10, 2012, the Company became aware that the Board of Appeals of the European Patent Office issued on September 4, 2012, a summons for oral proceedings. On November 28, 2012, the Board of Appeals of the European Patent Office held oral proceedings and verbally upheld the Sodemann patent covering Neutrolin®, but remanded the proceeding to the lower court to consider restricting certain of the Sodemann patent claims. The Company received the Appeals Board final written decision on March 28, 2013 which was consistent with the oral proceedings. The Company intends to continue to vigorously defend the patent. However, the Company can provide no assurances regarding the outcome of this matter.

Navinta LLC, a U.S.-based Active Pharmaceutical Ingredient (“API”) developer, provides API manufacturing (manufactured in India at an FDA-compliant facility) and a Drug Master File for CRMD003, pursuant to a supply agreement dated December 7, 2009 (the “Navinta Agreement”). The Navinta Agreement provides that Navinta will supply taurolidine (the API for CRMD003) to the Company on an exclusive worldwide basis in the field of the prevention and treatment of human infection and/or dialysis so long as the Company purchased a minimum of \$350,000 of product from Navinta by December 30, 2010, which the Company achieved, and following the Company’s first commercial sale of a product incorporating taurolidine, purchase a minimum of \$2,250,000 of product on an annual basis for five years. The Company is also required to make certain cash payments to Navinta upon the achievement of certain sales-based milestones. The maximum aggregate amount of such payments, assuming achievement of all milestones, is \$1,975,000. The Navinta Agreement has a term of five years, but may be terminated by either party upon 30 days written notice.

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NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 6 — Fair Value Measurements:

The fair value of the Company's cash, convertible notes, and accounts payable at March 31, 2013 are estimated to approximate their carrying values due to the relative liquidity and short-term nature of these instruments.

Note 7 — Subsequent Events:

On April 10, 2013, the Company entered into an amendment to the License and Assignment Agreement, dated January 30, 2008, between the Company and ND Partners, LLC. Under Article 6 of the License Agreement, the Company is obligated to make a milestone payment of \$500,000 to ND Partners upon the first issuance of a CE Marking for a licensed product, which payment is payable to ND Partners within 30 days after such issuance. Pursuant to the terms of the amendment, the Company and ND Partners agreed to delay such milestone payment to a time, to be chosen by the Company, anytime within 12 months after the achievement of such issuance. As consideration for the amendment, the Company issued ND Partners a warrant to purchase 125,000 shares of its common stock at an exercise price of \$1.50 per share. The warrant is exercisable immediately upon issuance and has a term of five years. The warrant contains a cashless exercise feature and standard adjustment features in the event of a stock split, stock dividend, recapitalization or similar events.

On April 18, 2013, the Company received notice from the NYSE MKT LLC ("NYSE MKT") that it granted the Company an extension until June 30, 2013 to regain compliance with continued listing standards of the NYSE MKT, during which time the NYSE MKT will continue its listing. The NYSE MKT previously notified the Company on April 20, 2012 that the Company was not in compliance with Section 1003(a)(iv) of the NYSE MKT Company Guide in that the Company had sustained losses which are so substantial in relation to its overall operations or its existing financial resources, or its financial condition had become so impaired that it appeared questionable, in the opinion of the NYSE MKT, as to whether the Company will be able to continue operations and/or meet its obligations as they mature. The Company was afforded an opportunity to submit a plan of compliance to the NYSE MKT and, on May 17, 2012, the Company presented a plan to the NYSE MKT. On June 27, 2012, the NYSE MKT accepted the Company's plan to regain compliance with its continued listing standards and granted an extension until August 22, 2012. On September 21, 2012, the NYSE MKT notified the Company that it granted them another extension to January 31, 2013 and on February 1, 2013, NYSE MKT notified that the Company was further granted extension until April 15, 2013 to regain compliance with the continued listing standards of the NYSE MKT.

Separately, the NYSE MKT notified the Company on April 5, 2013, that, based on its Form 10-K for the fiscal year ended December 31, 2012, filed on March 27, 2013, the Company did not meet an additional continued listing standard of the NYSE MKT as set forth in Part 10 of the NYSE MKT Company Guide ("Company Guide"). Specifically, the Company is not in compliance with Section 1003(a)(i) of the Company Guide because it reported stockholders' equity of less than \$2 million as of December 31, 2012, and losses from continuing operations and/or net losses in two of its three most recent fiscal years viewed prospectively from the date of its initial listing. As a result, the Company again become subject to the procedures and requirements of Section 1009 of the Company Guide. The Company had to submit to the NYSE MKT no later than May 6, 2013, which the Company did, a plan of compliance to address how it intend to regain compliance with Section 1003(a)(i) of the Company Guide by October 20, 2013. If that plan is accepted by NYSE MKT, the Company may be able to continue its listing through October 20, 2103, during which time it will be subject to periodic review to determine whether it is making progress consistent

with the Plan.

The Company remains subject to the conditions set forth in the NYSE MKT's letters dated April 20, 2012 and April 5, 2013. If the Company is not in compliance with all of the NYSE MKT's continued listing standards of both Section 1003(a)(i) and Section 1003(a)(iv) within the respective timeframes provided, or do not make progress consistent with either plan during the respective plan period, the NYSE MKT will initiate delisting proceedings.

In April and through May 2, 2013, \$409,600 senior convertible notes payable were converted resulting in the issuance of 1,170,286 shares of the Company's common stock.

On May 1 and 2, 2013, a total of 150,000 warrants were exercised for \$0.40 per share resulting in aggregate gross proceeds of \$60,000 to the Company.

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NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 8 — Restatement of Condensed Consolidated Financial Statements:

The Company has identified an error resulting in the understatement of the non-cash deemed dividend – beneficial conversion feature in the amount of \$129,442 for the three months ended March 31, 2013 and the cumulative period from July 28, 2006 (Inception) to March 31, 2013. The following table illustrates the effect on each line item as of and for the three months ended March 31, 2013 and the cumulative period from July 28, 2006 (Inception) to March 31, 2013:

	As Previously Reported (\$)	As Restated (\$)
Condensed Consolidated Balance Sheets as of March 31, 2013 (Unaudited)		
Additional paid-in capital	46,522,547	46,651,989
Deficit accumulated during the development stage	(47,810,787)	(47,940,229)
Condensed Consolidated Statements of Operations for the Three Months Ended March 31, 2013 (Unaudited)		
Deemed dividend – beneficial conversion feature	(180,502)	(309,944)
Net loss attributable to common shareholders	(1,437,553)	(1,566,995)
Net loss per share – basic and diluted	(0.12)	(0.14)
Condensed Consolidated Statements of Operations Cumulative Period from July 28, 2006 (Inception) through March 31, 2013 (Unaudited)		
Deemed dividend – beneficial conversion feature	(180,502)	(309,944)
Net loss attributable to common shareholders	(47,810,787)	(47,940,229)
Condensed Consolidated Statement of Changes in Stockholders' Deficit for the Three Months Ended March 31, 2013 (Unaudited)		
Additional Paid-in Capital		
Deemed dividend related to beneficial conversion feature of Series A non-voting preferred stock	180,502	309,944
Balance at March 31, 2013	46,522,547	46,651,989
Condensed Consolidated Statement of Changes in Stockholders' Deficit for the Three Months Ended March 31, 2013 (Unaudited)		
Deficit Accumulated During the Development Stage		
Deemed dividend related to beneficial conversion feature of Series A non-voting preferred stock	(180,502)	(309,944)
Balance at March 31, 2013	(47,810,787)	(47,940,229)
Condensed Consolidated Statement of Cash Flows For the Three Months Ended March 31, 2013 (Unaudited)		
Supplemental Disclosure of Non-Cash Financing Activities		
Deemed dividend – beneficial conversion feature	180,502	309,944
Condensed Consolidated Statement of Cash Flows For the Cumulative Period from July 28, 2006 (Inception) through March 31, 2013 (Unaudited)		

Supplemental Disclosure of Non-Cash Financing Activities

Deemed dividend – beneficial conversion feature	180,502	309,944
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The Company has identified an error resulting in decreases in liabilities, deficit accumulated during the development stage and stockholders' deficit at March 31, 2013, and decreases in research and development expense and net loss for the three months ended March 31, 2013 and 2012, and for the cumulative period from July 28, 2006 (Inception) through March 31, 2013. The following table illustrates the effect on each line item as of and for the three months ended March 31, 2013 and 2012 and the cumulative period from July 28, 2006 (Inception) to March 31, 2013:

	March 31, 2013		March 31, 2012		Cumulative Period from July 28, 2006 (Inception) Through March 31, 2013	
	As Previously Reported (\$)	As Restated (\$)	As Previously Reported (\$)	As Restated (\$)	As Previously Reported (\$)	As Restated (\$)
Balance Sheets (Unaudited):						
Accounts payable	1,312,346	1,217,346	-	-	-	-
Accrued expense	306,984	251,984	-	-	-	-
T o t a l c u r r e n t l i a b i l i t i e s	2,232,913	2,082,913	-	-	-	-
T o t a l L i a b i l i t i e s	2,243,866	2,093,866	-	-	-	-
Deficit accumulated during the development stage	(47,940,229)	(47,790,229)	-	-	-	-
T o t a l S t o c k h o l d e r s ' D e f i c i t	(1,276,217)	(1,126,217)	-	-	-	-
Statement of Operations (Unaudited):						
R e s e a r c h a n d d e v e l o p m e n t	265,035	255,035	374,855	363,605	23,608,340	23,458,340
T o t a l O p e r a t i n g E x p e n s e s	816,776	806,776	911,110	899,860	36,936,115	36,786,115
L o s s f r o m O p e r a t i o n s	(816,776)	(806,776)	(911,110)	(899,860)	(36,936,115)	(36,786,115)
L o s s B e f o r e I n c o m e T a x e s	(1,257,051)	(1,247,051)	(910,161)	(898,911)	(48,405,060)	(48,255,060)
N e t L o s s	(1,257,051)	(1,247,051)	(910,161)	(898,911)	(47,630,285)	(47,480,285)

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

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

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," "s," "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 and in our most recent annual report on Form 10-K, as well as any amendments thereto, as filed with the SEC and which are incorporated herein by reference. Furthermore, such forward-looking statements speak only as of the date of this report. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

Overview

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

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

Our primary product candidate in development is CRMD003 (Neutrolin®) for the prevention of catheter related infections in the dialysis and non-dialysis markets, which we believe addresses a medical need and a potentially large market opportunity. Neutrolin is a liquid formulation designed to prevent central venous catheter infection as well as catheter obstruction, also referred to as maintenance of catheter patency, in central venous catheters, which we initially plan for use in hemodialysis catheters.

During the third quarter of 2011, we received a notice from the U.S. Food and Drug Administration, or FDA, that Neutrolin had been assigned to the Center for Drug Evaluation and Research, or CDER. As a result of this, and given

our limited resources, we decided to change our business strategy and focus the majority of our resources on the research and development of Neutrolin rather than CRMD004 and to seek regulatory and commercialization approval for Neutrolin in Europe through a CE Mark application rather than pursue FDA approval at this time.

We anticipate receiving a CE Mark approval in the second quarter of 2013. If we obtain CE Mark approval in Europe, we intend to launch Neutrolin for the prevention of Catheter Related Bloodstream Infections, or CRBI and maintenance of catheter patency in hemodialysis patients in Europe during 2013. However, we cannot be assured of CE Mark approval of Neutrolin on that timeline or at all.

Our other product candidate is CRMD004, which is the gel formulation of Neutrolin that we intend to develop for the prevention of catheter-related blood stream infections and maintenance of catheter patency in hemodialysis patients who are asymptomatic for catheter-related blood stream infections using both incident and prevalent catheters with any brand of central venous catheter. CRMD004 is in the pre-clinical stage. However, at this time, we intend to defer the development of CRMD004 until after we receive the CE Mark for Neutrolin in the European Union and have commenced the FDA regulatory approval process for Neutrolin.

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 funded our operations primarily with debt and equity financings. We have generated significant losses to date, and we expect to continue to generate losses as we progress towards the commercialization of our product candidate Neutrolin. As of March 31, 2013, we had a deficit accumulated during the development stage of \$47,790,229. 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.

Financial Operations Overview

Revenue

We have not generated any revenue since our inception. If our product development efforts result in clinical success, regulatory approval and successful commercialization of any of our products, we could generate revenue from sales or licenses of any such products.

Research and Development Expense

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

Conducting a significant amount of R&D is central to our business model. Through March 31, 2013, we incurred approximately \$23.5 million 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 Neutrolin in the United States.

The following table summarizes the percentages of our R&D expenses 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.

	Three Months Ended March 31,		Period from July 28, 2006 (Inception) through March 31, 2013
	2013	2012	
CRMD001	0%	5%	48%
CRMD002	0%	0%	0%
CRMD003	92%	89%	49%
CRMD004	8%	6%	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. In addition, development timelines, probability of success and development costs vary widely. As a result of these uncertainties, 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.

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 will need and plan to raise additional funds at a later date to fully complete the development of CRMD003 in both Europe and the U.S. as well as to pursue development of any other product candidates.

General and Administrative Expense

General and administrative, or G&A, expense consists primarily of salaries and other related costs, including stock-based compensation expense, for persons serving in our executive, finance and accounting functions. Other G&A expense includes facility-related costs not otherwise included in R&D expense, promotional expenses, costs associated with industry and trade shows, and professional fees for legal services and accounting services. We expect that our G&A expenses will remain consistent for the remainder of 2013. From our inception on July 28, 2006 through March 31, 2013, we incurred G&A expenses of approximately \$13.3 million.

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 conversion into units or common stock, as well as the amortization and write-off of deferred financing costs and debt discounts and a charge for the beneficial conversion related to our convertible notes.

Results of Operations

Three months ended March 31, 2013 compared to three months ended March 31, 2012

Research and Development Expense. R&D expense was \$255,035 for the three months ended March 31, 2013, a decrease of \$108,570, from \$363,605 for the three months ended March 31, 2012. The decrease was attributable to our strategic change of development, which focused primarily on CE Marking approval for Neutrolin®. Our strategic change of direction also resulted in lower personnel costs as a result of our former Chief Medical Officer transitioning to a part-time status and a 50% reduction of salary effective March 2012 and the termination of his employment on February 28, 2013.

General and Administrative Expense. G&A expense was \$551,741 for the three months ended March 31, 2013, an increase of \$15,486 from \$536,255 for the three months ended March 31, 2012. The increase was primarily attributable to accounting fees related to filing of registration statements and risk management assessment.

Interest Income. Interest income was \$128 for the three months ended March 31, 2013, a decrease of \$821, from \$949 for the three months ended March 31, 2012. The decrease was attributable to having a lower interest-bearing cash balance during the first quarter of 2013 compared to the first quarter of 2012.

Interest Expense. Interest expense was \$440,403 for the three months ended March 31, 2013 as compared to \$0 for the same period last year. The interest expense consisted primarily of a beneficial conversion feature charge of \$328,761 related to the senior convertible notes and warrants issued in September and November 2012, amortization of deferred financing fees of \$81,396 and accrued interest of \$30,245 related to the senior convertible notes.

Liquidity and Capital Resources

Sources of Liquidity

As a result of our R&D and G&A 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 approximately \$490,000 from Federal grants under the Qualifying Therapeutic Discovery Project program, approximately \$775,000 from the sale of our unused net operating losses through the State of New Jersey's Economic Development Authority Technology Business Tax Certificate Transfer Program and 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.

During the year ended December 31, 2012, we completed two tranches of a private placement for a total of 1,324 units, each unit consisting of (i) a one-year \$1,000 aggregate principal amount 9% senior convertible note, convertible into shares of common stock, at a conversion price of \$0.35 per note, and (ii) a five-year redeemable warrant, to purchase 3,310,000 shares of common stock at an initial exercise price of \$0.40 per share. We received gross proceeds of \$1,324,000 or net proceeds of approximately \$1,095,600 from the private placement. The notes issued have maturity dates of September 20, 2013 for 850 units and November 13, 2013 for 474 units.

On February 19, 2013, we sold 761,429 shares of our newly created Series A Non-Voting Convertible preferred stock and a warrant to purchase up to 400,000 shares of our common stock, for gross proceeds of \$533,000.

Net Cash Used in Operating Activities

Net cash used in operating activities was \$617,751 for the three months ended March 31, 2013. The net loss of \$1,247,051 for the three months ended March 31, 2013 was higher than cash used in operating activities by \$629,300.

The difference is attributable primarily to amortization of debt discount and deferred financing costs of \$410,157 and an increase in accounts payable of \$262,926.

Net Cash Used in Investing Activities

There was no cash used in investing activities for the three months ended March 31, 2013 and 2012.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was \$475,000 for the three months ended March 31, 2013 as compared to \$0 for the same period last year. The increase was attributable to the gross proceeds from the private placement of Series A preferred stock of \$533,000 offset by repurchase of outstanding warrants of \$33,000 and deferred financing costs of \$25,000.

Funding Requirements

Our total cash on hand as of March 31, 2013 was \$692,720, compared to \$835,471 at December 31, 2012. Because our business does not generate positive operating cash flow, we will need to raise additional capital before we exhaust our current cash resources in order to continue to fund our research and 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 or debt financing, strategic relationships, out-licensing or distribution arrangements of our products. Through March 31, 2013, all of our financing has been through equity financing, issuance of convertible notes, our 2010 IPO, previous debt financings and our receipt of a total of approximately \$490,000 from Federal grants under the Qualifying Therapeutic Discovery Project program, a total of approximately \$775,000 from the sale of our unused net operating losses through the State of New Jersey's Economic Development Authority Technology Business Tax Certificate Transfer Program and approximately \$35,000 from the State of New York's Research and Development Tax Credit Program, net of application fees.

Based on our cash resources at March 31, 2013 and our current plan of expenditure on continuing development of Neutrolin®, we believe that we have sufficient capital to fund our operations through the second quarter of 2013, 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 continue development and regulatory approval of our products or market our products as planned, or we could be required to delay, scale back or eliminate some or all of our research and

development programs. Each of these alternatives would likely have a material adverse effect on our business. These matters raise substantial doubt about our ability to continue as a going concern. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Assuming we raise capital in the second quarter of 2013, we expect to continue to fund operations from cash on hand and through either capital raising sources as previously described, 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 research and development programs, the acquisition and pursuit of development of new product candidates, competitive and technical advances, costs of commercializing any of our 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 significant product sales revenue for 2013, if any. 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.

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 27, 2013, 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 expense over the related vesting period.

For the purpose of valuing options and warrants granted to our directors, officers, employees and consultants during the three months ended March 31, 2013, we used the Black-Scholes option pricing model. We granted options to purchase an aggregate of 1,400,000 and 330,000 shares of common stock to our directors, officers, employees and consultants during the three months ended March 31, 2013 and 2012, 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. 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. Stock compensation expense is recognized by applying the expected forfeiture rate during the vesting period to the fair value of the award. We will continue to evaluate the estimated forfeiture rate derived from previous forfeitures of employees, directors and officers and may adjust the forfeiture rate based on actual forfeitures that may occur in the future.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Item 4.

Controls and Procedures.

During the period covered by this report, we identified a material weakness in our internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended (the

“Exchange Act”)), with respect to a lack of accounting expertise related to non-routine, complex accounting matters. This material weakness did not have any impact on our financial statements for the quarter ended March 31, 2013 but did result in a restatement of the financial statements in our September 30, 2012 Quarterly Report on Form 10-Q. We initiated appropriate measures to remediate this weakness by forming an accounting oversight committee (“Oversight Committee”), comprised of members of our senior management, which has engaged a third party GAAP advisor, charged with the task of discussing and reviewing all significant transactions that have financial recognition issues, either to be recorded or disclosed. The third party GAAP advisor assists as well as advises our Chief Financial Officer and the Audit Committee on a timely basis, including quarter-end and year-end reviews of proposed accounting for and disclosure of significant financial transactions and changes in GAAP.

In the fourth quarter of 2013, we identified a material weakness in our internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act), with respect to a spreadsheet formula error which was not detected in the ordinary course of business through existing internal controls over financial reporting. This material weakness resulted in a restatement of the financial statements in our March 31, 2013 Quarterly Report on Form 10-Q. We have taken appropriate measures to remediate this weakness by improving the review of spreadsheets supporting the accounting for significant financial transactions.

In the preparation of our Annual Report for the year ended December 31, 2013, we identified a material weakness in our internal control over financial reporting with respect to the inadvertent over-accrual of a royalty under a license agreement which was not detected in the ordinary course of business through existing internal controls over financial reporting. This material weakness resulted in a restatement of the financial statements in our December 31, 2012 Annual Report on Form 10-K and the financial statements in our March 31, 2013 Quarterly Report on Form 10-Q, as amended by our amended March 31, 2013 Quarterly Report on Form 10-Q/A filed on November 19, 2013.

Evaluation of Disclosure Controls and Procedures

Disclosure control and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) are designed only to provide reasonable assurance that information to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. 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. Based on their evaluation of our disclosure controls and procedures, and as result of the material weaknesses described above, our management, including our principal executive officer and principal financial officer, have concluded that our disclosure controls and procedures were not effective as of March 31, 2013 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

Other than as described above, during the three months ended March 31, 2013, there were no changes in our internal control over financial reporting, 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 1A. Risk Factors.

Except as set forth below, there have been no material changes to the discussion of risk factors included in our most recent Annual Report on Form 10-K.

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 or applicable foreign bodies to reexamine the patentability of our licensed or owned patents. The defense and prosecution of intellectual property suits, PTO or foreign 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 or foreign proceedings to which we may become a party could subject us to significant liabilities, require us to obtain licenses from third parties, restrict or prevent us from selling our products in certain markets, or invalidate or render unenforceable our licensed or owned patents. Although patent and intellectual property disputes might be settled through licensing or similar arrangements, the costs associated with such arrangements may be substantial and could include our paying large fixed payments and ongoing royalties. Furthermore, the necessary licenses may not be available on satisfactory terms or at all.

In February 2007, Geistlich Söhne AG für Chemische Industrie, Switzerland, or Geistlich, brought an action against the Sodemann patent covering our Neutrolin® product candidate which is owned by ND Partners, LLC and licensed to us pursuant to the License and Assignment Agreement between us and ND Partners LLC. The action that was brought against the Sodemann patent in Germany at the Board of the European Patent Office opposition division was for lack of inventiveness in the use of citric acid and a pH value in the range of 4.5 to 6.5 with having the aim to provide an alternative lock solution through having improved anticoagulant characteristics compared to the lock solutions described in the Lehner patent. The Board of the European Patent Office opposition division rejected the opposition by Geistlich. On August 27, 2008, Geistlich appealed the court's ruling, alleging the same arguments as presented during the opposition proceedings. We filed a response to the appeal of Geistlich on March 25, 2009 where we requested a dismissal of the appeal and to maintain the patent as granted. As of March 27, 2013, no further petitions have been filed by ND Partners or Geistlich. On October 10, 2012, we became aware that the Board of Appeals of the European Patent Office issued, on September 4, 2012, a summons for oral proceedings. On November 28, 2012, the Board of Appeals of the European Patent Office held oral proceedings and verbally upheld the Sodemann patent covering Neutrolin®, but remanded the proceeding to the lower court to consider restricting certain of the Sodemann patent claims. We received the Appeals Board final written decision on March 28, 2013 which was consistent with the oral proceedings. We intend to continue to vigorously defend the patent. However, we can provide no assurances regarding the outcome of this matter.