CorMedix Inc.
Form 10-Q
November 19, 2013

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

FORM 10-Q

(Mark One)

þ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES

EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 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	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 þ No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes þ 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 þ

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

The number of shares outstanding of the issuer's common stock, as of November 18, 2013 was 16,164,516.

CORMEDIX INC.
(A Development Stage Company)

INDEX

i

PART I

FINANCIAL INFORMATION

Item 1. Consolidated Financial Statements.

CORMEDIX INC.

(A Development Stage Company)

CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2013	December 31, 2012
ASSETS	(Unaudited)	(Note 1)
Current assets		
Cash	$483,052	$835,471
Restricted cash	220,500	-
Prepaid research and development expenses	2,800	11,221
Inventories	270,506	-
Deferred financing costs	13,729	257,886
Other prepaid expenses and current assets	29,788	30,677
Total current assets	1,020,375	1,135,255
Property and equipment, net	3,039	4,668
Security deposit	13,342	13,342
TOTAL ASSETS	$1,036,756	$1,153,265
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities		
Accounts payable	$969,840	$1,023,553
Accrued expenses	830,083	306,983
Accrued interest, related parties	19,262	16,175
Senior convertible notes, net of debt discount of $647,939 at December 31, 2012	-	16,061
Senior convertible notes - related parties, net of debt discount of $4,015 at September 30, 2013 and $406,316 at December 31, 2012	420,985	253,684
8% senior convertible notes at fair value	311,900	-
8% senior convertible notes at fair value, related party	802,000	-
Warrant liability	582,800	-
Total current liabilities	3,936,870	1,616,456
Deferred rent	8,490	12,185
TOTAL LIABILITIES	3,945,360	1,628,641
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' DEFICIT		
Preferred stock - $0.001 par value: 2,000,000 shares authorized, 454,546 and 0 shares issued and outstanding at September 30, 2013 and December 31, 2012, respectively	455	-
	15,959	11,408

Common stock - $0.001 par value: 80,000,000 shares authorized, 15,959,088 and 11,408,274 shares issued and outstanding at September 30, 2013 and December 31, 2012, respectively		
Deferred stock issuances	(146)	(146)
Additional paid-in capital	49,539,373	45,886,596
Deficit accumulated during the development stage	(52,464,245)	(46,373,234)
TOTAL STOCKHOLDERS' DEFICIT	(2,908,604)	(475,376)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$1,036,756	$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 September 30, 2013	For the Three Months Ended September 30, 2012	For the Nine Months Ended September 30, 2013	For the Nine Months Ended September 30, 2012	Cumulative Period from July 28, 2006 (inception) Through September 30, 2013
OPERATING EXPENSES					
Research and development	$ 760,774	$ 255,738	$ 1,415,983	$ 878,785	$ 24,759,288
General and administrative	504,528	746,653	1,965,006	1,659,522	14,741,040
Total Operating Expenses	1,265,302	1,002,391	3,380,989	2,538,307	39,500,328
LOSS FROM OPERATIONS	(1,265,302)	(1,002,391)	(3,380,989)	(2,538,307)	(39,500,328)
OTHER INCOME (EXPENSE)					
Other income, net	-	-	-	-	420,987
Interest income	61	274	295	1,814	126,602
Foreign currency gain (loss)	1,294	-	390	-	390
Loss on issuance of convertible notes and warrants	(945,892)	-	(945,892)	-	(945,892)
Change in fair value of convertible notes and warrants	45,934	-	45,934	-	45,934
Loss on extinguishment of convertible notes	(33,626)	-	(33,626)	-	(33,626)
Interest expense, including amortization and write-off of deferred financing costs and debt discounts	(312,368)	(26,055)	(1,413,933)	(26,055)	(12,989,897)
LOSS BEFORE INCOME TAXES	(2,509,899)	(1,028,172)	(5,727,821)	(2,562,548)	(52,875,830)
State income tax benefit	-	-	-	-	774,775
NET LOSS	(2,509,899)	(1,028,172)	(5,727,821)	(2,562,548)	(52,101,055)
Deemed dividend – beneficial conversion feature	(53,246)	-	(363,190)	-	(363,190)
NET LOSS ATTRIBUTABLE TO COMMON SHAREHOLDERS	$ (2,563,145)	$ (1,028,172)	$ (6,091,011)	$ (2,562,548)	$ (52,464,245)
	$ (0.18)	$ (0.09)	$ (0.47)	$ (0.22)	

NET LOSS PER SHARE – BASIC AND DILUTED				
WEIGHTED AVERAGE SHARES OUTSTANDING – BASIC AND DILUTED	14,430,374	11,408,274	13,037,814	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 Nine Months Ended September 30, 2013

	Common Stock		Non-Voting Preferred Stock – Series A		Non-Voting Preferred Stock – Series B		Deferred Stock Issuances	Additional Paid-in Capital	Deficit Accumulated During the Development Stage	T Stock D
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at January 1, 2013	11,408,274	$11,408	-	$-	-	$-	$(146)	$45,886,596	$(46,373,234)	$(47
Non-voting preferred stock issued in February 2013 private placement at $0.70 per share, net			761,429	761				506,372		507
Conversion of Series A non-voting preferred stock to common stock	761,429	761	(761,429)	(761)						-
Deemed dividend related to beneficial conversion feature of Series A non- voting preferred stock								309,944	(309,944)	-
Non-voting preferred stock issued in July 2013 private placement at $1.10 per share, net					454,546	455		480,008		480
								53,246	(53,246)	-

Deemed dividend related to beneficial conversion feature of Series B non- voting preferred stock									
Repurchase of outstanding warrants							(33,000)		(33
Stock-based compensation							753,476		753
Warrants issued in connection with license agreement							76,574		76,
Stock issued in connection with senior convertible note conversion at $0.35 per share	2,568,572	2,569					896,431		899
Stock issued in connection with 8% senior convertible note and interest conversion	576,005	576					550,371		550
Stock issued in connection with warrants exercised	644,808	645					59,355		60,
Net loss								(5,727,821)	(5,7
Balance at September 30, 2013	15,959,088	$15,959	-	$-	454,546	$455	$(146)	$49,539,373	$(52,464,245)	$(2,9

See Notes to Unaudited Condensed Consolidated Financial Statements.

CORMEDIX INC.
(A Development Stage Company)
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	For the Nine Months Ended September 30, 2013	For the Nine Months Ended September 30, 2012	Cumulative Period from July 28, 2006 (Inception) Through September 30, 2013
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$(5,727,821)	$(2,562,548)	$(52,101,055)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	753,476	183,177	3,352,714
Stock issued in connection with license agreements	-	-	6,613,718
Stock issued in connection with consulting agreement	-	-	158,262
Amortization of deferred financing costs	269,156	4,410	2,393,669
Amortization of debt discount	1,050,240	19,206	6,308,753
Warrants issued in connection with license agreement	76,574	-	76,574
Loss on issuance of convertible notes and warrants	945,892	-	945,892
Non-cash loss on extinguishment of convertible notes	33,626	-	33,626
Change in fair value of convertible notes and warrants	(45,934)	-	(45,934)
Non-cash charge for beneficial conversion feature	-	-	1,137,762
Non-cash interest expense	28,855	-	3,035,873
Expenses paid on behalf of the Company satisfied through the issuance of notes	-	-	51,253
Depreciation	1,628	5,266	58,670
Changes in operating assets and liabilities:			
Restricted cash	(220,500)	-	(220,500)
Prepaid expenses and other current assets	9,310	456,871	(32,588)
Inventories	(270,506)	-	(270,506)
Security deposit	-	-	(13,342)
Accounts payable	(121,785)	(146,079)	870,965
Accrued expenses and accrued interest	523,102	291,833	846,260
Accrued interest, related parties	3,087	1,587	3,087
Deferred rent	(3,695)	(1,716)	8,490
Net cash used in operating activities	(2,695,295)	(1,747,993)	(26,788,357)
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	-	635,000	3,063,484
Proceeds from senior convertible notes, net	686,250	215,000	14,650,088
Proceeds from senior convertible notes, related party, net	686,250	-	686,250
Proceeds from Galenica, Ltd. promissory note	-	-	1,000,000

Proceeds from exercise of warrants	60,000	-	60,000
Payments for deferred financing costs and private placement expenses	(89,624)	(95,000)	(1,607,227)
Repayment of amounts loaned under related party notes	-	-	(1,981,574)
Proceeds from sale of equity securities	1,033,000	-	11,490,270
Repurchase of outstanding warrants	(33,000)	-	(33,000)
Proceeds from receipt of stock subscriptions and issuances of common stock	-	-	4,827
Net cash provided by financing activities	2,342,876	755,000	27,333,118
NET INCREASE (DECREASE) IN CASH	(352,419)	(992,993)	483,052
CASH – BEGINNING OF PERIOD	835,471	1,985,334	-
CASH – END OF PERIOD	$483,052	$992,341	$483,052
Cash paid for interest	$93,451	$-	$111,876
Supplemental Disclosure of Non-Cash Financing Activities:			
Conversion of notes payable and accrued interest to common stock	$1,416,321	$-	$20,313,488
Conversion of preferred stock to common stock	$533,000		$533,000
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	$-	$701,021	$6,312,768
Deemed dividend – beneficial conversion feature	$363,190	$-	$363,190
Accrued and unpaid deferred financing costs	$48,534	$65,976	$83,095
Accrued and unpaid private placement expenses	$19,538	$-	$45,405

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 (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 cardio- renal and infectious disease, 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 at least through 2014 depending on revenue levels and potential strategic partnerships. As of September 30, 2013, management believes that the majority of the Company's resources, including the Company's research and development efforts, and commercialization of Neutrolin® (CRMD003) in Europe, combined with the Company's receipt of convertible preferred equity financing funds in October 2013 (see Note 7), 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 2014, assuming no sales and/or strategic partnerships occur. 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.

CORMEDIX INC.
(A Development Stage Company)

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 nine months ended September 30, 2013 and the period from July 28, 2006 (inception) to September 30, 2013, the Company incurred net losses of $5,727,821 and $52,101,055, 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.

Foreign Currency:

The consolidated financial statements are presented in U.S. Dollars (USD), the reporting currency of the Company. For the financial statements of the Company's foreign subsidiary, whose functional currency is the USD, foreign currency asset and liability amounts, if any, are remeasured into USD at end-of-period exchange rates, except for inventories, prepaid expenses, property, plant and equipment, goodwill and other intangible assets, which are remeasured at historical rates. Foreign currency income and expenses are remeasured at average exchange rates in effect during the year, except for expenses related to balance sheet amounts remeasured at historical exchange rates. Exchange gains and losses arising from remeasurement of foreign currency-denominated monetary assets and liabilities are included in income in the period in which they occur.

Restricted Cash:

As of September 30, 2013, the Company invested in a twelve-month 0.14% certificate of deposit held by the bank as collateral for a letter of credit in connection with the Company's purchase of raw materials due to be delivered in the next twelve months. The certificate of deposit will terminate without penalties once the transaction covered by the letter of credit is completed. The certificate of deposit is recorded on the balance sheet as restricted cash. The restricted cash account is classified as current if at the end of the reporting period, the restriction is expected to be lifted in the next twelve months or the contractual maturity date of the certificate of deposit is in the next twelve months.

CORMEDIX INC.
(A Development Stage Company)

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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.

	September 30, 2013	September 30, 2012
Convertible notes	2,035,628	2,428,571
Series B non-voting preferred stock	454,546	-
Shares underlying outstanding warrants	8,985,025	6,932,534
Shares underlying outstanding stock options	3,179,630	1,135,630
Total	14,654,829	10,496,735

Inventories:

Inventories are valued at the lower cost or market on a first in, first out basis. Inventories consist of raw materials (including labeling and packaging), work-in-process, and finished goods, if any, for the Neutrolin product. Inventories consist of the following at September 30, 2013:

Raw materials	$216,916
Work-in-process	53,590
Total	$270,506

Accrued Expenses:

Accrued expenses consist of the following:

	September 30, 2013	December 31, 2012
Licensing fee	$500,000	$-
Royalty fee	153,750	90,000
Accrued payroll and payroll taxes	134,562	-
Professional fees	12,000	108,532
Accrued interest	4,455	10,763
Other	25,316	97,688
Total	$830,083	$306,983

Stock-Based Compensation:

Awards granted to employees, officers and directors are measured at the grant date, based on the estimated fair value of the award, and stock-based compensation cost, net of expected forfeitures, 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 nine months ended September 30, 2013 and 2012, options to purchase an aggregate of 1,400,000 and 380,000 shares of common stock, respectively, were granted to the Company's employees, officers, directors and consultants.

CORMEDIX INC.
(A Development Stage Company)

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Fair Value Option:

As permitted under FASB ASC 825, Financial Instruments ("ASC 825"), the Company has elected the fair value option to account for its convertible notes that were issued during the quarter ended September 30, 2013. ASC 825 requires that the entity record the financial asset or financial liability at fair value rather than at historical cost with changes in fair value recorded in the statement of operations. In addition, it requires that upfront costs and fees related to items for which the fair value option is elected be recognized in earnings as incurred and not deferred.

Note 3 — Convertible Notes:

On July 5, 2013, the Company received net proceeds of $1,372,500 upon approval of a CE Mark certification. The Company had entered into an agreement with existing stockholders in May 2013 for an aggregate principal amount of $1,500,000 of senior secured convertible notes and warrants to purchase up to an aggregate of 1,000,000 shares of its common stock. The receipt of net proceeds of $1,372,500 was dependent upon receipt of a CE Mark certification, which occurred on July 5, 2013. The notes bear interest at the rate of 8.0% per annum and will be subject to a "make-whole" upon any conversion of the notes into common stock, as if the notes being converted were outstanding to April 1, 2014. Interest was first payable on September 3, 2013 and is payable on the first trading day of each month thereafter. The notes mature on April 1, 2016 unless redeemed prior to that date, subject to amortization, discussed below. A noteholder may elect to have any interest due prior to April 1, 2014 added to the principal amount of a note; thereafter, interest will be paid in cash only. The warrants are exercisable one year after issuance, have an exercise price of $1.10 per share, subject to anti-dilution adjustment, and a term of five years from the date they are first exercisable. The holders of the notes and warrants will be prohibited from converting the notes into or exercising the warrants for shares of common stock if, as a result of such conversion or exercise, the holder, together with its affiliates, would own more than 4.99% or 9.99%, at the initial holder's election, of the total number of shares of the Company's common stock then issued and outstanding.

The Company will redeem the notes in cash at par value or in shares of stock which are priced in accordance with a pricing formula set forth in the notes, in eight equal monthly installment payments beginning on September 1, 2013, and continuing thereafter on the first business day of each month, ending on April 1, 2014. At the Company's option, and if certain equity conditions are waived or satisfied, the Company may elect to pay these installment payments in shares of common stock, in cash, or in any combination of shares and cash. To the extent the Company pays all or any portion of an installment payment in common stock, the Company will deliver to each noteholder the amount of shares equal to the applicable installment payment being paid in shares of common stock, divided by the lower of (i) the conversion price then in effect, and (ii) 90% of the average of the 10 lowest-volume weighted-average prices of our common stock during the 20 trading day period ending two trading days prior to the applicable payment date(the "Company Conversion Price").

All installment payments are subject to the right of each noteholder to defer payment of some or all of any installment payment to a subsequent installment date or the maturity date, and, with respect to any installment date, convert, at the then-prevailing Company Conversion Price, any amount of principal and capitalized interest up to an amount equal to four installment payments. Each noteholder may also convert, at any time, all or a portion of any deferred installment payment. The Company Conversion Price for any such deferred installment payment shall be the lower of the Company Conversion Price in effect on the date of the original installment date and the Company Conversion Price then in effect.

8

CORMEDIX INC.
(A Development Stage Company)

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Due to the complexity and number of embedded features within the convertible note and as permitted under under ASC 825, the Company elected to account for the convertible notes and all the embedded features (collectively, the "hybrid instrument") under the fair value option. ASC 825 requires the entity to record the financial asset or financial liability at fair value rather than at historical cost with changes in fair value recorded in the statement of operations. In addition, it requires that upfront costs and fees related to items for which the fair value option is elected be recognized in earnings as incurred and not deferred. On the initial measurement date of July 5, 2013, the fair value of the hybrid instrument was estimated at $1,643,500, which was $143,500 higher than the principal amount of $1,500,000. During the quarter ended September 30, 2013, there were redemptions and voluntary conversions of the convertible note, resulting in a $451,250 reduction in the outstanding principal balance to $1,048,750 at September 30, 2013. The corresponding fair value of the outstanding balance of the hybrid instrument at September 30, 2013 was $1,113,900. During the quarter ended September 30, 2013, the Company recorded a gain of $41,134 related to changes in the fair value of the hybrid instrument, of which $35,180 was unrealized and $5,954 was realized in connection with the redemptions and voluntary conversions that occurred during the quarter. The Company also recorded a $33,626 loss on extinguishment of convertible notes related to the conversions and redemptions during the quarter ended September 30, 2013.

The Company used a Monte Carlo model to separately value the warrants issued in connection with the convertible notes in order to take into account the possibility of an adjustment to the exercise price associated with new rounds of financing in the future. The most likely exercise price of the warrants was estimated under various stock price scenarios and the noteholders' payoffs were computed under each scenario. The present value of the mean of such payoffs represents the value of the warrant on any given valuation date. When the stock price was simulated in the model, the possible scenarios were always between the valuation date stock price and the initial exercise price of $1.10. As a result, the Company estimated the fair value of the warrant liability on the issuance date to be $587,600.

A summary of the key assumptions used by the Company in the Monte Carlo simulation model to value the hybrid instrument at each of the relevant measurement dates during the quarter is as follows:

Stock price – Due to the historical volatility of the stock price, a 30 day volume weighted average stock price was used as of each valuation date.

Conversion/redemption strike price – These assumptions incorporate both the initial contractual conversion price as well as subsequent downward adjustments based on management's estimate of the probabilities of additional future financings that would include a stock price or conversion price that is lower than the then existing conversion price.

Volatility – Given that the Company recently received CE Mark approval for Neutrolin, the volatility used in the analysis was a weighted average of 1) the Company's historical volatility, 2) the Company's volatility after the receipt of CE approval and 3) the volatilities of comparable companies following the receipt of product approval. The resulting volatility used in the analysis was 75%.

Term – Based on an evaluation of the terms of the agreement, management has assumed that it would be advantageous for the holders of the Convertible Notes to redeem all installments by April 2014 rather than defer them to a later date.

Probability of Event of Default or Change in Control – Management has concluded that the probability of a change in control or event of default during the term of the hybrid instrument is only 5%.

Risk-free Rate – The US Treasury Bond Rate with a term approximating the term of the instrument was used as the risk-free interest rate in the valuation.

Credit adjusted discount rate – Management believes that its debt, if rated, would be equivalent to Moody's C rated bonds or lower.

Dividend rate - Management does not expect to pay any dividends during the term of the hybrid instrument.

CORMEDIX INC.
(A Development Stage Company)

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

The following table is a rollforward for the quarter ended September 30, 2013 of the balance of the carrying amount of the convertible notes for which the fair value option was elected:

Balance at July 1, 2013	-
Issuance of convertible notes	$1,643,500
Conversion of convertible notes during quarter	(488,466)
Realized gain resulting from change in fair value on converted debt	(5,954)
Unrealized gain resulting from change in fair value on debt outstanding at September 30, 2013	(35,180)
Balance at September 30, 2013	$ 1,113,900

The following table is a rollforward for the quarter ended September 30, 2013 of the carrying amount of the warrant liability that was issued during the quarter in connection with the convertible notes. The warrants are accounted for as a derivative liability and are valued using a Monte Carlo simulation model in order to take into account the possibility of adjustments to the exercise price resulting from additional rounds of financing. During the quarter, there were no exercises of these warrants.

Balance at July 1, 2013	$-
Issuance of warrants	587,600
Unrealized gain resulting from change in fair value	(4,800)
Balance at September 30, 2013	$582,800

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 share, and (ii) a five-year redeemable Warrant (the "Warrants") to purchase 2,500 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. During the nine months ended September 30, 2013, $899,000 of these notes were converted resulting in the issuance of 2,568,572 shares of the Company’s common stock.

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 anti-dilution 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.

The Company accounted for the beneficial conversion feature (“BCF”) and warrant in accordance with FASB ASC 470-20, Debt with Conversion and Other Options. The Company recorded a BCF related to the issuance of convertible debt that had conversion features at fixed rates that were “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 amortized over the terms of the convertible notes and is recognized as non-cash interest expense. 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.

CORMEDIX INC.
(A Development Stage Company)

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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 and its related accrued interest consist of the following at September 30, 2013:

9% senior convertible notes, related parties	$425,000
Debt discount/beneficial conversion feature	(4,015)
Balance	$420,985
Accrued interest, 9% senior convertible notes related parties	$14,262
Accrued interest 9% senior convertible notes	$4,000
8% senior convertible notes at fair value	$311,900
8% senior convertible notes at fair value, related party	$802,000
Accrued intest - 8% Senior convertible notes, related party	$5,000

Note 4 — Stockholders' Equity:

Common Stock

During the nine months ended September 30, 2013, a portion of 9% senior convertible notes in the aggregate principal amount of $899,000 was converted at a conversion price of $0.35 per share resulting in the issuance of an aggregate 2,568,572 shares of the Company's common stock.

During the nine months ended September 30, 2013, the Series A non-voting convertible preferred stock was converted into 761,429 shares of the Company's common stock.

During the nine months ended September 30, 2013, warrants to purchase 150,000 shares of the Company's common stock were exercised resulting in gross proceeds of $60,000 to the Company.

During the nine months ended September 30, 2013, warrants to purchase 827,913 shares of the Company's common stock were exercised on a cashless basis resulting in the issuance of 494,808 shares of common stock.

During the quarter ended September 30, 2013, a portion of 8% senior convertible notes in the aggregate principal amount of $451,250 were converted into common shares and interest in the aggregate amount of $28,855 was paid in common shares resulting in the issuance of an aggregate 576,005 shares of the Company's common stock.

11

CORMEDIX INC.
(A Development Stage Company)

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Preferred Stock

On July 30, 2013, the Company sold 454,546 shares of its Series B non-voting convertible preferred stock and a warrant to purchase up to 227,273 shares of the Company's common stock, for gross proceeds of $500,000. The Series B shares and the warrant were sold together at a price of $1.10 per share for each share of Series B stock. Each share of Series B 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 B 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 B stock will receive a payment equal to $0.001 per share of Series B Stock before any proceeds are distributed to the holders of common stock. Shares of the Series B 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 B stock;
- on parity with our Series B preferred stock and any class or series of capital stock hereafter created specifically ranking by its terms on parity with the Series B stock; and
- junior to any class or series of capital stock hereafter created specifically ranking by its terms senior to the Series B 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.

Because the Series B non-voting preferred stock is immediately convertible at the option of the holder, we recorded a deemed dividend of $53,246 from the beneficial conversion feature associated with the issuance of the Series B non-voting convertible preferred stock and the warrant during the quarter ended September 30, 2013.

On February 19, 2013, the Company sold 761,429 shares of its 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 was convertible into one share of the Company's common stock at any time at the holder's option. However, the holder would 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.

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.

During the nine months ended September 30, 2013, all of the Series A non-voting convertible preferred stock was converted into 761,429 shares of common stock.

During the nine months ended September 30, 2013, because the Series A non-voting preferred stock was immediately convertible at the option of the holder, we recorded a 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.

CORMEDIX INC.
(A Development Stage Company)

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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 was approved by the stockholders on July 30, 2013.

During the nine months ended September 30, 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 for these options during the nine months ended September 30, 2013.

During the nine months ended September 30, 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. During the nine months ended September 30, 2013, 172,000 of these performance options were achieved and therefore the Company recorded the value of the options on the date the performance was achieved. Additionally, the Company recorded the pro rata expense for the 120,000 options during the nine months ended September 30, 2013. No expense was recognized for the options subject to performance milestones that were not achieved as of September 30, 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 were amended to vest on the date of issuance of the CE Mark certification for Neutrolin® in Europe, if the CE Mark approval was obtained on or before June 30, 2013 (as opposed to March 31, 2013 as previously provided by our Board). In June 2013, these options were further modified such that vesting would occur if the CE Mark was issued on or before July 14, 2013 (as opposed to June 30, 2013). During the quarter ended June 30, 2013, the Company reversed the expense recorded related to the previous value of the options and recorded the pro rata expense related to the modified value of these options. The expense was fully amortized through July 5, 2013, the date the CE Mark certification was received.

In August 2013, the Company's board of directors accelerated the vesting of an aggregate of 70,000 unvested options granted to the Company's former Chief Financial Officer at the time of his departure from the Company. Additionally, the exercise period of his total outstanding options was extended to two years from three months. These modifications resulted in an aggregate expense of $51,079 to the Company.

During the nine months ended September 30, 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 nine months ended September 30, 2013.

During the nine months ended September 30, 2013 and 2012 and the period from July 28, 2006 (inception) to September 30, 2013, total compensation expense for stock options issued to employees, directors, officers and consultants was $753,476, $183,177 and $3,352,714, respectively.

CORMEDIX INC.
(A Development Stage Company)

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:

	Nine Months Ended September 30, 2013	Nine Months Ended September 30, 2012
Expected Term	2 - 10 years	5 years
Volatility	86% - 131%	98% - 115%
Dividend yield	0.0 %	0.0 %
Risk-free interest rate	0.34% - 2.78 %	0.27% - 2.11 %

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 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 39% and 55% to calculate stock option expense for the nine month periods ended September 30, 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 option activity and related information is as follows:

	Nine Months Ended September 30, 2013		Nine Months Ended September 30, 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	(263,050)	$1.71
Expired/Canceled	(118,667)	$1.61	(217,662)	$3.13
Granted	1,400,000	$0.90	380,000	$0.38
Outstanding at end of period	3,179,630	$1.06	1,135,630	$1.82

Expected to vest	965,325	$0.81	875,958	$1.82
Options exercisable	1,597,130	$1.31	286,400	$2.41
Weighted-average fair value of options granted during the period		$0.77		$0.32

At September 30, 2013, the weighted average remaining contractual life of stock options outstanding and expected to vest is 7.5 years and the weighted average remaining contractual life of stock options exercisable is 6 years. The aggregate outstanding stock options intrinsic value of $484,950 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 September 30, 2013 for those outstanding options that have an exercise price below the quoted closing price.

As of September 30, 2013, the total compensation expense related to non-vested options not yet recognized totaled $854,570. The weighted-average vesting period over which the total compensation expense related to non-vested options not yet recognized at September 30, 2013 was approximately 0.64 years.

CORMEDIX INC.
(A Development Stage Company)

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 September 30, 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	15,420	0.40	9/20/2017
Issued in connection with November 13, 2012 private placement of convertible notes	437,500	0.40	11/13/2017
Issued to placement agent in connection with November 13, 2012 private placement of convertible notes	85,167	0.40	11/13/2017
Issued in connection with February 2013 private placement of Series A convertible preferred stock	400,000	1.50	2/19/2018
Issued in connection with license agreement amendment	125,000	1.50	4/11/2018
Issued in connection with July 2013 private placement of Series B convertible preferred stock	227,273	1.50	7/30/2018
Issued in connection with July 2013 private placement of convertible notes	1,000,000	1.10	5/30/2019
Total warrants outstanding at September 30, 2013	8,985,025		

CORMEDIX INC.
(A Development Stage Company)

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 5 — Commitments and Contingencies:

In April 2013, the Company entered into an amendment to the License and Assignment Agreement, dated January 30, 2008, between the Company and ND Partners, LLC ("ND Partners"). Under Article 6 of the License Agreement, the Company was obligated to make a milestone payment of $500,000 to ND Partners upon the first issuance of a CE Mark certification 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. The Company recognized $76,574 expense for the value of the warrants issued as a result of this amendment.

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. In a letter dated September 30, 2013, the Company was notified that the opposition division of the European Patent Office reopened the proceedings before the first instance again, and has given their preliminary non-binding opinion that the patent as amended during the appeal proceedings fulfils the requirements of Clarity, Novelty, and Inventive Step, and invited the parties to provide their comments and/or requests by February 10, 2014.
The Company intends to continue to vigorously defend the patent in a restricted form. 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.

Note 6 — Fair Value Measurements:

The fair value of the Company's cash, convertible notes, and accounts payable at September 30, 2013 are estimated to approximate their carrying values due to the relative liquidity and/or short-term nature of these instruments. The following table presents the fair value hierarchy, carrying amounts and fair values of the Company's financial instruments measured at fair value on a recurring basis as of September 30, 2013. There were no financial instruments measured at fair value on a recurring basis at September 30, 2012.

		September 30, 2013	
	Fair Value Hierarchy	Carrying Amount	Fair Value
Financial Liabilities Measured at Fair Value on a Recurring Basis:			
Convertible debt	3	$1,113,900	$1,113,900
Warrants issued in connection with convertible debt	3	$582,800	$582,800

CORMEDIX INC.
(A Development Stage Company)

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 7 — Subsequent Events:

On October 22, 2013, the Company concluded a sale to existing institutional investors of 150,000 shares of Series C-1 Non-Voting Convertible preferred stock and 150,000 shares of Series C-2 Non-Voting Convertible preferred stock, together with warrants to purchase up to an aggregate of 1,500,000 shares of common stock, for aggregate gross proceeds of $3,000,000.

As a condition to the closing, the Company simultaneously exchanged a 9% senior convertible note held by one of the investors in the principal amount of $400,000 for 57,400 shares of its Series D Non-Voting Convertible Preferred Stock and exchanged an 8% senior convertible note held by the same investor in the principal amount of $750,000 for 53,537 shares (including inducement shares) of its Series E Non-Voting Convertible Preferred Stock. The terms of the Series D and Series E Preferred Stock are designed to provide the holder of the notes exchanged with the similar economic terms of the exchanged notes, including interest, dilution and other protections.

As an inducement to the transaction, the Company also issued 1,667 shares of its Series E Non-Voting Convertible Preferred Stock to the other investor.

As a result of the financing, the anti-dilution provisions of the 8% senior convertible notes and the warrants issued with them caused the conversion price of the 8% senior convertible notes and the exercise price of the warrants to decrease from $1.10 to $1.00.

In October 2013, a portion of an 8% senior convertible note in the principal amount of $93,750 was converted at a conversion price of $0.81 per share. This conversion, plus payment of accrued interest in shares, resulted in the issuance of 118,440 shares of the Company’s common stock.

In October 2013, the Company granted to its various consultants, ten-year non-qualified stock options under the 2013 Plan, covering an aggregate of 414,000 shares of the Company’s common stock with an exercise price of $0.90 per share. These options vest upon specified performance milestones. The Company will recognize the expense for these options when the subject performance milestones are achieved.

On November 13, 2013, the balance of 9% senior convertible notes in the aggregate principal amount of $25,000 were converted at a conversion price of $0.35 per share resulting in the issuance of an aggregate 71,428 shares of the Company’s common stock.

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 2012 Annual Report on Form 10-K filed with the Securities and Exchange Commission, or the SEC, on March 27, 2013.

Forward Looking Statements

This Quarterly Report on Form 10-Q contains "forward-looking statements" that involve risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. The statements contained in this Quarterly Report on Form 10-Q that are not purely historical are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended or the Exchange Act. Forward-looking statements are often identified by the use of words such as, but not limited to, "anticipate," "believe," "can," "continue," "could," "estimate," "expect," "intend," "may," "will," "plan," "project," "seek," "sh "would," and similar expressions or variations intended to identify forward-looking statements. These statements are based on the beliefs and assumptions of our management based on information currently available to management. Such forward-looking statements are subject to risks, uncertainties and other important factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed in the section titled "Risk Factors" included in our quarterly reports on Form 10-Q for the quarters ended March 31, 2013 and June 30, 2013 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 cardio-renal and infectious disease, 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 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, for review as a drug rather than a device. 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. During the first half of 2011, we submitted our design dossier to TÜV SÜD, the European notified body managing our CE Mark application. In the fourth quarter of 2011, we successfully completed our stage 1 audit with TÜV SÜD and we successfully completed the stage 2 audit in the third quarter of 2012.

On October 10, 2012, we received ISO 13485:2003 certification from TÜV SÜD. This certification, which is a stand-alone standard developed by the International Organization for Standardization, is the globally recognized standard that outlines consistent international processes for the design and manufacturing of medical devices, including many supply chain functions such as assembly, packaging, warehousing and distribution. Compliance with ISO 13485 is often seen as a step towards achieving compliance with European regulatory requirements. The conformity of medical devices and in-vitro diagnostic medical devices according to applicable European Union, or EU, standards must be assessed before sale is permitted. The preferred method to prove conformity is the certification by a notified body of the quality management system according to ISO 9001 and/or ISO 13485 and ISO 14971. The result of a positive assessment is the issuance of a certificate of conformity allowing the CE Mark and the permission to sell the medical device in the European Union.

On July 5, 2013, we received CE Mark approval for Neutrolin. As a result, after receipt of final German regional authority approval, we anticipate the commercial launch of Neutrolin for the prevention of catheter-related bloodstream infections, or CRBI, and maintenance of catheter patency in hemodialysis patients in Europe late in the fourth quarter of 2013. However, we cannot be assured of our planned commercialization timeline for Neutrolin.

We have four pillars to our Neutrolin strategy: (i) successfully launch the product in Germany; (ii) expand the product into additional applications; (iii) expand sales into other foreign countries; and (iv) apply for and receive marketing approval and launch the product in the United States.

In anticipation of receiving CE Mark approval, on January 10, 2013, we entered into an agreement with MKM Co-Pharma GmbH, or MKM, regarding Neutrolin, pursuant to which, MKM hired a national sales manager to market Neutrolin in Germany according to a negotiated work plan. While the plan may be revised, it currently provides that the sales manager will market Neutrolin in three phases. In the first phase, which began in January 2013, the sales manager visited hemodialysis centers and doctors to, among other things, provide them information. The sales manager has also produced a market review of our product, negotiated wholesaler relationships for initial stocking of our product, and is determining sales projections for launching Neutrolin. In the second phase, which began with the receipt of CE Mark approval, the sales manager initiated the process to launch Neutrolin in the fourth quarter of 2013, and is to generate sales on a best efforts basis and supervise sales representatives. The sales manager will be responsible for growing Neutrolin sales and expanding the promotional plans.

On November 14, 2013, we met with the FDA to determine the pathway for U.S. approval of Neutrolin, which we expect will entail a Phase 3 clinical trial. We expect to receive minutes of that meeting within 30 days from that date.

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 we launch 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 September 30, 2013, we had a deficit accumulated during the development stage of $52,464,245. As a result of the CE Mark approval in the EU, we expect to generate revenue from sales or licenses of Neutrolin. However, our losses will continue as we advance our product candidates towards commercialization in the EU and regulatory approval in the United States. As a result, our operating losses are likely to continue at least through 2014 depending on the successful launch of Neutrolin in Europe, any resultant revenue levels and potential strategic partnerships. We are unable to predict the extent of any future losses or when we will become profitable, if ever.

Financial Operations Overview

Revenue

We have not generated any revenue since our inception. If the commercialization for Neutrolin in Europe is successful and our product development efforts in the United States result in clinical success, regulatory approval and successful commercialization, 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 September 30, 2013, we incurred $24.8 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. We expect our R&D expenditures to increase for the foreseeable future in order to undertake development of Neutrolin in the United States, if the commercialization for Neutrolin in the EU is successful.

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.

	Nine Months Ended September 30,		Period from July 28, 2006 (Inception) through September 30,
	2013	2012	2013
CRMD001	0 %	24 %	44 %
CRMD002	0 %	0 %	0 %
CRMD003	96 %	70 %	53 %
CRMD004	4 %	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 commercializing Neutrolin® in Europe may impact our other development efforts and timelines. If we are successful in the commercialization of Neutrolin® in Europe, we plan to pursue developing Neutrolin 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 Neutrolin 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 September 30, 2013, we incurred G&A expenses of $14.7 million.

Loss on Issuance of Convertible Notes and Warrants

As discussed in Note 3, we sold convertible notes and warrants during the three months ended September 30, 2013 for which we received net proceeds of $1,372,500 after transaction-related fees and expenses. We elected to account for the convertible notes under the fair value option and the warrants are required to be recorded at fair value as a derivative liability. The loss on the issuance of convertible notes and warrants represents the difference on the issuance date between the combined fair value of the convertible notes and the warrants, and the proceeds that were received net of all fees and expenses related to the issuance.

Change in Fair Value of Convertible Notes and Warrants

The change in the value of convertible notes and warrants represents the change in the fair value of the convertible notes for which we elected the fair value option, and the change in the fair value of warrants that are required to be recorded at fair value on a recurring basis under generally accepted accounting principles. This excludes any reductions in fair value resulting from the redemption or conversion of the convertible notes and the exercise of warrants.

Loss on Extinguishment of Convertible Notes

The loss on extinguishment of convertible notes represents the difference between the fair value of convertible notes redeemed and converted and the cash paid or fair value of shares issued to noteholders in connection with the redemptions and conversions.

Interest Income and Interest Expense

Interest income consists of interest earned on our cash. 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, debt discounts and beneficial conversion charges related to certain of our convertible notes and preferred shares.

Results of Operations

Three months ended September 30, 2013 compared to three months ended September 30, 2012

Research and Development Expense. R&D expense was $760,774 for the three months ended September 30, 2013, an increase of $505,036 from $255,738 for the three months ended September 30, 2012. The increase was primarily attributable to the license fee of $500,000 as a result of the CE Mark approval for Neutrolin in the European Union, or the EU, expenses related to the planned launch of Neutrolin in the EU, and the non-cash value of the warrants issued to ND Partners, LLC as a result of the amendment to the License and Assignment Agreement, dated January 30, 2008 between the Company and ND Partners, LLC.

General and Administrative Expense. G&A expense was $504,528 for the three months ended September 30, 2013, a decrease of $242,125 from $746,653 for the three months ended September 30, 2012. The decrease was primarily attributable to the $325,000 non-cash litigation expense in 2012 which resulted from the board authorization to settle the action in Germany against the Sodemann patent covering Neutrolin, offset by increased stock-based compensation expense.

Loss on Issuance of Convertible Notes and Warrants. The loss on the issuance of convertible notes and warrants represents the difference on the issuance date between the combined fair value of the convertible notes and the warrants of $2,231,100, and the proceeds received, net of all issuance-related fees and expenses, of $1,285,208.

Change in Fair Value of Convertible Notes and Warrants. The change in the value of convertible notes and warrants of $45,934 consists of a decrease in the fair value of warrants between the issuance date and September 30, 2013 of $4,800 and a reduction in the fair value of convertible notes of $41,134. The reduction in the fair value of the convertible notes includes the combined changes in (i) the fair value of the converted and redeemed amounts between the issuance date and the relevant conversion and redemption dates and (ii) the change in fair value of the outstanding convertible notes and warrants at September 30, 2013 between the issuance date and September 30, 2013.

Loss on Extinguishment of Convertible Notes. The $33,626 loss on extinguishment of convertible notes for the three months ended September 30, 2013 represents the excess of the fair value of shares issued in connection with the conversions and redemptions over the fair value of the convertible notes that were converted or redeemed for shares.

Interest Income. Interest income was $61 for the three months ended September 30, 2013, a decrease of $213 from $274 for the three months ended September 30, 2012. The decrease was attributable to having lower interest-bearing cash balances during the third quarter of 2013 compared to the same quarter of 2012.

Interest Expense. Interest expense was $312,368 for the three months ended September 30, 2013, an increase of $286,313 from $26,055 for the same period last year, primarily due to the amortization of beneficial conversion feature and warrants valuation related to the senior convertible notes and warrants issued in 2012 and 2013, amortization of deferred financing fees and accrued interest related to the senior convertible notes.

Nine months ended September 30, 2013 compared to nine months ended September 30, 2012

Research and Development Expense. R&D expense was $1,415,983 for the nine months ended September 30, 2013, an increase of $537,198 from $878,785 for the nine months ended September 30, 2012. The increase was primarily attributable to the license fee of $500,000 as a result of the CE Mark approval for Neutrolin in the EU and the non-cash value of the warrants issued to ND Partners, LLC as a result of the amendment to the License and Assignment Agreement, dated January 30, 2008 between the Company and ND Partners, LLC.

General and Administrative Expense. G&A expense was $1,965,006 for the nine months ended September 30, 2013, an increase of $305,484 from $1,659,522 for the nine months ended September 30, 2012. The increase was primarily attributable to stock-based compensation expense, professional services and filing fees related to SEC filings.

Loss on Issuance of Convertible Notes and Warrants. The loss on the issuance of convertible notes and warrants represents the difference on the issuance date between the combined fair value of the convertible notes and the warrants of $2,231,100, and the proceeds received, net of all issuance-related fees and expenses, of $1,285,208.

Change in Fair Value of Convertible Notes and Warrants. The change in the value of convertible notes and warrants of $45,934 consists of a decrease in the fair value of warrants between the issuance date and September 30, 2013 of $4,800 and a reduction in the fair value of convertible notes of $41,134. The reduction in the fair value of the convertible notes includes the combined changes in (i) the fair value of the converted and redeemed amounts between the issuance date and the relevant conversion and redemption dates and (ii) the change in fair value of the outstanding convertible notes and warrants at September 30, 2013 between the issuance date and September 30, 2013.

Loss on Extinguishment of Convertible Notes. The $33,626 loss on extinguishment of convertible notes for the nine months ended September 30, 2013 represents the excess of the fair value of shares issued in connection with the conversions and redemptions over the fair value of the convertible notes that were converted or redeemed for shares.

Interest Income. Interest income was $295 for the nine months ended September 30, 2013, a decrease of $1,519 from $1,814 for the nine months ended September 30, 2012. The decrease was attributable to having lower interest-bearing cash balances during the nine months period ended September 30, 2013 compared to the same period last year.

Interest Expense. Interest expense was $1,413,933 for the nine months ended September 30, 2013, an increase of $1,387,878 from $26,055 for the same period last year, primarily due to the amortization of beneficial conversion feature and warrants valuation related to the senior convertible notes and warrants issued in 2012 and 2013, amortization of deferred financing fees and accrued interest related to the senior convertible notes.

Liquidity and Capital Resources

Sources of Liquidity

We have not generated product sales revenue. As a result of our R&D and G&A expenditures, we have not been profitable. We received CE Mark approval in July 2013 and are in the process of launching our product in the European Union. We have generated operating losses since we were incorporated in July 2006. Prior to our initial public offering, or IPO, in 2010, we had funded our operations principally with $14,364,973 in convertible notes sold in private placements and $625,464 in related party convertible notes. 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 2,500 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 (all of which were converted to common stock) 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. As of September 30, 2013, all shares of Series A preferred stock were converted to common stock.

On July 5, 2013, upon the CE Mark approval, we received net proceeds of $1,372,500 from the May 2013 financing of senior secured convertible notes in the aggregate principal amount of $1,500,000 and warrants to purchase up to an aggregate of 1,000,000 shares of our common stock. The notes were sold at a discount of $75,000 and the Company paid transaction-related fees of $52,500. The notes bear interest at the rate of 8.0% per annum and are subject to a "make-whole" upon any conversion of the notes into common stock, as if the notes being converted were outstanding to April 1, 2014. Interest was first payable on September 3, 2013 and is payable on the first trading day of each month thereafter. The notes mature on April 1, 2016 unless redeemed prior to that date, subject to amortization. A noteholder may elect to have any interest due prior to April 1, 2014 added to the principal amount of a note; thereafter, interest will be paid in cash only. The warrants are exercisable one year after issuance, have an exercise price of $1.10 per share, subject to adjustment (and decreased to $1.00 in October 2013 as a result of our October 2013 preferred stock financing), and a term of five years from the date they are first exercisable. The holders of the notes and warrants will be prohibited from converting the notes into or exercising the warrants for shares of common stock if, as a result of such conversion or exercise, the holder, together with its affiliates, would own more than 4.99% or 9.99%, at the initial holder's election, of the total number of shares of our common stock then issued and outstanding.

On July 30, 2013, we sold to an existing institutional investor 454,546 shares of our Series B Non-Voting Convertible preferred stock and a warrant to purchase up to 227,273 shares of common stock, for gross proceeds of $500,000. The Series B shares and the warrant were sold together at a price of $1.10 per share for each share of Series B stock.

Net Cash Used in Operating Activities

Net cash used in operating activities was $2,695,295 for the nine months ended September 30, 2013. The net loss of $5,727,821 for the nine months ended September 30, 2013 was higher than cash used in operating activities by $3,032,526. The difference is attributable primarily to a non-cash loss on the issuance of convertible notes and warrants, amortization of debt discount and deferred financing costs, stock-based compensation charge and an increase in accrued expenses.

Net Cash Used in Investing Activities

There was no net cash used in investing activities for the nine months ended September 30, 2013 and 2012.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $2,342,876 for the nine months ended September 30, 2013 as compared to $755,000 provided by financing activities for the same period last year. The increase was attributable to the proceeds of $1,372,500 from the sale of the 8% senior convertible notes, net of discount and expenses of $127,500, proceeds of $1,033,000 from the sale of Series A and Series B preferred stock, and proceeds of $60,000 from the

exercise of warrants, offset by the payment of deferred financing costs and private placement expenses of $89,624 and repurchase of outstanding warrants of $33,000. In comparison, we received $850,000 of proceeds in 2012 from the sale of 9% senior convertible notes partly offset by the payment of deferred financing fees of $95,000.

Funding Requirements

Our total cash on hand as of September 30, 2013 was $483,052, 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 sources, such as equity or debt financing, strategic relationships, out-licensing or distribution arrangements of our products. Through June 30, 2013, all of our financing has been through equity financing, issuance of convertible notes, our 2010 IPO, previous debt financings, 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 September 30, 2013, including the funds we have raised through October 22, 2013, we believe that we have sufficient capital to fund our projected operating requirements through the second quarter of 2014, assuming no sales and/or strategic partnerships occur. We will need additional financing until we can achieve profitability, if ever. If we are unable to raise additional funds, on acceptable terms or at all, 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.

On December 28, 2012, we filed with the SEC a shelf registration statement on Form S-3, under which we may offer shares of our common stock and preferred stock, various series of debt securities and/or warrants to purchase any of such securities, either individually or in units, in one or more offerings, up to a total dollar amount of $30,000,000. Such registration statement, as amended, became effective as of January 10, 2013. We are limited in the dollar amount of securities we may sell under the shelf registration statement, based upon SEC rules for shelf registration statement eligibility, and consequently, we might not be able to sell up to the $30,000,000 registered. Through October 2013, we have sold an aggregate of approximately $5.1 million of securities under the shelf registration statement.

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 sales or 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.

Even with the planned launch of Neutrolin in the fourth quarter of 2013, 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.

24

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.

Fair Value Option

As permitted under ASC 825, we elected the fair value option to account for our convertible notes that were issued during the quarter ended September 30, 2013. ASC 825 requires that the entity record the financial asset or financial liability at fair value rather than at historical cost with changes in fair value recorded in the statement of operations. In addition, it requires that upfront costs and fees related to items for which the fair value option is elected be recognized in earnings as incurred and not deferred.

Stock-Based Compensation

Stock-based compensation cost is based on the estimated fair value of the award, which is measured at grant date, 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 remaining related vesting period.

For the purpose of valuing options and warrants granted to our directors, officers, employees and consultants, we used the Black-Scholes option pricing model. 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 and changes in our expectations regarding future forfeitures.

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.

During the first 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 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 and June 30, 2013 Quarterly Reports on Form 10-Q. We have taken appropriate measures to remediate this weakness by improving the review of spreadsheets supporting the accounting for significant transactions.

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, our management, including our principal executive officer and principal financial officer, have concluded that our disclosure controls and procedures were not effective as of September 30, 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 September 30, 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 1. Legal Proceedings.

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. In a letter dated September 30, 2013, we were notified that the opposition division of the European Patent Office reopened the proceedings before the first instance again, and has given their preliminary non-binding opinion that the patent as amended during the appeal proceedings fulfils the requirements of Clarity, Novelty, and Inventive Step, and invited the parties to provide their comments and/or requests by February 10, 2014. We intend to continue to vigorously defend the patent in a restricted form. However, we can provide no assurances regarding the outcome of this matter.

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.

Risks Related to Our Common Stock

We have identified a material weakness in our internal control over financial reporting, and our internal control over financial accounting and our disclosure controls and procedures may not prevent all possible errors that could occur.

In the fourth quarter of 2013, we identified a material weakness in our internal control over financial reporting 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 and June 30, 2013 Quarterly Reports on Form 10-Q.

A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system’s objectives will be satisfied. Internal control over financial reporting and disclosure controls and procedures are designed to give a reasonable assurance that they are effective to achieve their objectives. We cannot provide absolute assurance that all of our possible future control issues will be detected. These inherent limitations include the possibility that judgments in our decision making can be faulty, and that isolated breakdowns can occur because of simple human error or mistake. The design of our system of controls is based in part upon assumptions

about the likelihood of future events, and there can be no assurance that any design will succeed absolutely in achieving our stated goals under all potential future or unforeseeable conditions. Because of the inherent limitations in a cost effective control system, misstatements due to error could occur and not be detected. This and any future failures could cause investors to lose confidence in our reported financial information, which could have a negative impact on our financial condition and stock price.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not Applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

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

Exhibit Number	Description
31.1	Certification of Principal Executive Officer 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, 2013, formatted in Extensible Business Reporting Language (XBRL): (i) Condensed Consolidated Balance Sheets at September 30, 2013 and December 31, 2012, (ii) Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2013 and 2012, and for the Cumulative Period from July 28, 2006 (inception) through September 30, 2013, (iii) Condensed Consolidated Statement of Changes in Stockholders' Deficit for the nine months ended September 30, 2013, (iv) Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2013 and 2012, and for the Cumulative Period from July 28, 2006 (inception) through September 30, 2013, and (v) Notes to the Unaudited Condensed Consolidated Financial Statements.**

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* Filed herewith.

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

SIGNATURES

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

CORMEDIX INC.

Date:	November 19, 2013	By:	/s/ Randy Milby	
			Name:	Randy Milby
			Title:	Chief Executive Officer (Principal Executive Officer)

Date:	November 19, 2013	By:	/s/ Steven Lefkowitz	
			Name:	Steven Lefkowitz
			Title:	Interim Chief Financial Officer (Principal Financial Officer)

EXHIBIT INDEX

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