

CorMedix Inc.  
Form 10-Q  
November 13, 2014

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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549  
FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2014

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 (I.R.S.  
Jurisdiction of Employer  
Incorporation Identification  
or No.)  
Organization)

745 Rt. 202-206, 08807  
Suite 303,  
Bridgewater, NJ  
(Address of (Zip  
Principal Code)  
Executive  
Offices)

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

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

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

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

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

Large accelerated filer <input type="checkbox"/>	Accelerated filer <input type="checkbox"/>
Non-accelerated filer <input type="checkbox"/>	Smaller reporting company <input checked="" type="checkbox"/>

(Do not check if a smaller reporting company)

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

The number of shares outstanding of the issuer’s common stock, as of November 10, 2014 was 22,383,101.

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## CORMEDIX INC.

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## PART I

## FINANCIAL INFORMATION

## Item 1. Consolidated Financial Statements.

CORMEDIX INC.  
CONDENSED CONSOLIDATED BALANCE SHEETS  
(Unaudited)

	September 30, 2014	December 31, 2013
Assets		
Current assets		
Cash and cash equivalents	\$5,920,020	\$2,373,893
Restricted cash	-	220,586
Trade receivables	46,453	2,339
Inventories	677,417	80,021
Prepaid research and development expenses	-	6,205
Other prepaid expenses and current assets	140,928	232,987
Total current assets	6,784,818	2,916,031
Property and equipment, net	46,875	36,061
Deferred financing costs	-	2,366
Security deposit	13,342	13,342
Total Assets	\$6,845,035	\$2,967,800
Liabilities and Stockholders' Equity (Deficiency)		
Current liabilities		
Accounts payable	\$740,318	\$939,785
Accrued expenses	475,003	713,179
Deferred rent	3,105	-
Deferred revenue	8,823	-
Dividend payable	-	21,117
Total current liabilities	1,227,249	1,674,081
Derivative liabilities	-	5,308,804
Deferred rent, long-term	454	7,258
Deferred revenue, long-term	39,706	-
Total Liabilities	1,267,409	6,990,143
Commitments and Contingencies		
Stockholders' Equity (Deficiency)		
Preferred stock - \$0.001 par value: 2,000,000 shares authorized; 954,948 and 857,160 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	955	857
Common stock - \$0.001 par value: 80,000,000 shares authorized; 22,325,609 and 16,606,695 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	22,325	16,606

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Deferred stock issuances	(146 )	(146 )
Accumulated other comprehensive gain (loss)	116,979	(9,323 )
Additional paid-in capital	79,427,270	51,720,302
Accumulated deficit	(73,989,757)	(55,750,639)
Total Stockholders' Equity (Deficiency)	5,577,626	(4,022,343 )
Total Liabilities and Stockholders' Equity (Deficiency)	\$6,845,035	\$2,967,800

See Notes to Unaudited Condensed Consolidated Financial Statements.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS  
AND COMPREHENSIVE INCOME (LOSS)  
(Unaudited)

	For the Three Months Ended		For the Nine Months Ended	
	September 30, 2014	2013	September 30, 2014	2013
Revenue:				
Net sales	\$52,441	\$-	\$104,373	\$-
Cost of sales	(36,675 )	-	(172,180 )	-
Gross profit (loss)	15,766	-	(67,807 )	-
Operating Expenses:				
Research and development	(292,688 )	(750,774 )	(817,635 )	(1,385,983 )
Selling, general and administrative	(1,586,614 )	(504,528 )	(5,802,364 )	(1,965,006 )
Total Operating Expenses	(1,879,302 )	(1,255,302 )	(6,619,999 )	(3,350,989 )
Loss From Operations	(1,863,536 )	(1,255,302 )	(6,687,806 )	(3,350,989 )
Other Income (Expense):				
Interest income	645	61	2,153	295
Foreign exchange transaction gain (loss)	(122,645 )	1,294	(150,803 )	390
Loss on issuance of preferred stock, convertible notes and warrants	-	(945,892 )	(89,590 )	(945,892 )
Change in fair value of derivative liabilities	(586,440 )	45,934	(8,848,953 )	45,934
Loss on modification of equity instruments and extinguishment of derivative liabilities	(2,462,588 )	(33,626 )	(2,462,588 )	(33,626 )
Interest expense, including amortization of deferred financing costs and debt discounts	(553 )	(312,368 )	(1,531 )	(1,413,933 )
Net Loss	(5,035,117 )	(2,499,899 )	(18,239,118 )	(5,697,821 )
Other Comprehensive Income:				
Foreign currency translation gain	118,319	-	126,302	-
Comprehensive Loss	(4,916,798 )	(2,499,899 )	(18,112,816 )	(5,697,821 )
Net loss	(5,035,117 )	(2,499,899 )	(18,239,118 )	(5,697,821 )
Dividends, including beneficial conversion feature	(27,125 )	(53,246 )	(81,727 )	(363,190 )
Net Loss Attributable To Common Shareholders	\$(5,062,242 )	\$(2,553,145 )	\$(18,320,845 )	\$(6,061,011 )
Net Loss Per Common Share – Basic and Diluted	\$(0.23 )	\$(0.18 )	\$(0.87 )	\$(0.46 )
Weighted Average Common Shares Outstanding – Basic and Diluted	22,080,673	14,430,374	21,161,532	13,037,814

See Notes to Unaudited Condensed Consolidated Financial Statements.

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

For the Nine Months Ended September 30, 2014

	Common Stock		Non Voting Preferred Stock – Series A, Series B, Series C-1, Series C-2, Series C-3, Series D and Series E		Deferred Stock Issuances	Accumulated Other Comprehensive Income (Loss)	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount					
Balance at December 31, 2013	16,606,695	\$ 16,606	857,160	\$ 857	\$(146)	\$(9,323 )	\$ 51,720,302	\$(55,750,639)	\$(4,022,343)
Series C-3 non-voting preferred stock issued in January 2014 financing at \$10 per share, net			200,000	200					200
Conversion of Series C-1 non-voting preferred stock to common stock	1,400,000	1,400	(140,000)	(140)			2,446,124		2,447,384
Stock issued in connection with March 2014 public offering at \$2.50 per unit, net	2,960,000	2,960					4,991,838		4,994,798
Reclassification of Series C-2 and C-3 preferred stock conversion option derivative liability to equity							6,235,398		6,235,398
Reclassification of derivative liabilities to equity from modification of various equity instruments			53,788	54			11,740,809		11,740,863
Stock issued in connection with	751,689	752					(752 )		-

warrants exercised									
Conversion of Series C-3 non-voting preferred stock to common stock	160,000	160	(16,000 )	(16 )		(144 )			-
Stock issued in connection with stock options exercised	425,000	425				309,025			309,450
Conversion of wages to common stock	22,225	22				42,478			42,500
Stock-based compensation						1,942,192			1,942,192
Other comprehensive income						126,302			126,302
Net loss								(18,239,118)	(18,239,118)
Balance at September 30, 2014	22,325,609	\$22,325	954,948	\$955	\$(146)	\$116,979	\$79,427,270	\$(73,989,757)	\$5,577,626

See Notes to Unaudited Condensed Consolidated Financial Statements.



## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	For the Nine Months Ended September 30,	
	2014	2013
Cash Flows From Operating Activities:		
Net loss	\$(18,239,118)	\$(5,697,821)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,942,192	753,476
Warrants issued in connection with license agreements	-	76,574
Amortization of deferred financing costs	-	269,156
Amortization of debt discount	-	1,050,240
Loss on foreign currency transactions	150,803	-
Loss on issuance of preferred stock, convertible notes and warrants	89,590	945,892
Loss on modification of equity instruments and extinguishment of derivative liabilities	2,462,588	33,626
Revaluation of derivative liabilities	8,848,953	(45,934 )
Non-cash interest expense	-	28,855
Depreciation	11,467	1,628
Changes in operating assets and liabilities:		
Restricted cash	220,586	(220,500 )
Trade receivables	(47,353 )	-
Inventories	(597,396 )	(270,506 )
Prepaid expenses and other current assets	95,611	9,310
Accounts payable	(170,898 )	(121,785 )
Accrued expenses and accrued interest	441,469	493,102
Accrued interest, related parties	-	3,087
Deferred revenue	48,529	-
Deferred rent	(3,699 )	(3,695 )
Net cash used in operating activities	(4,746,676 )	(2,695,295)
Cash Flows From Investing Activities:		
Purchase of equipment	(25,898 )	-
Net cash used in investing activities	(25,898 )	-
Cash Flows From Financing Activities:		
Proceeds from Series C-3 preferred stock, net	743,884	-
Proceeds from Series C-3 preferred stock, related party	575,000	-
Proceeds from exercise of warrants	-	60,000
Proceeds from exercise of stock options	309,450	-
Payments for deferred financing costs and private placement expenses	(2,366 )	(89,624 )
Proceeds from sale of equity securities	6,723,248	1,033,000
Proceeds from senior convertible notes, net	-	686,250
Proceeds from senior convertible notes, related party, net	-	686,250
Repurchase of outstanding warrants	-	(33,000 )
Net cash provided by financing activities	8,349,216	2,342,876
Foreign exchange effect on cash	(30,515 )	-
Net Increase (Decrease) In Cash	3,546,127	(352,419 )
Cash – Beginning of Period	2,373,893	835,471
Cash – End of Period	\$5,920,020	\$483,052

Cash Paid for Interest	\$1,531	\$93,451
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See Notes to Unaudited Condensed Consolidated Financial Statements.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS  
(Unaudited)

	For the Nine Months Ended September 30,	
	2014	2013
Supplemental Disclosure of Non-Cash Financing Activities:		
Conversion of notes payable and accrued interest to common stock, fair value	\$-	\$1,416,321
Conversion of preferred stock to common stock	\$2,447,384	\$533,000
Conversion of accounts payable and accrued expenses to preferred stock	\$645,458	\$-
Reclassification of derivative liabilities to equity	\$17,955,143	\$-
Conversion of wages to common stock	\$42,500	\$-
Dividends, including beneficial conversion feature	\$81,727	\$363,190
Accrued and unpaid deferred financing costs	\$-	\$48,534
Accrued private placement expenses	\$-	\$19,538

See Notes to Unaudited Condensed Consolidated Financial Statements.

Note 1 — Business and Basis of Presentation:

Business and Nature of Operations:

CorMedix Inc. (“CorMedix” or the “Company”) was incorporated in the State of Delaware on July 28, 2006. The Company in-licenses, develops and commercializes prophylactic and therapeutic products for the prevention and treatment of infectious diseases in cardiac, renal and oncology patients. The Company formed a wholly-owned subsidiary, CorMedix Europe GmbH, in 2013. CorMedix’s product Neutrolin® received its CE Mark in Europe in July 2013 and product shipments to dialysis centers began in December 2013. The Company expects to incur additional expenses as it continues to commercialize Neutrolin in Europe and other foreign markets and seeks U.S. Food and Drug Administration (“FDA”) approval of Neutrolin in the U.S.

The Company expects to conduct one Phase III clinical trial in hemodialysis catheters and one Phase III clinical trial in oncology/total parenteral nutrition. A protocol was designed for the planned Phase III trial in hemodialysis patients with a central venous catheter; this protocol was accepted by the FDA in August 2014 and the Company filed an IND in September 2014. In October 2014, the FDA informed the Company that it had determined that the IND is not subject to a clinical hold, and that the Phase III clinical trial in hemodialysis patients can be initiated in the U.S.

Basis of Presentation and Liquidity:

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 pursuant to the rules and regulations of the Securities and Exchange Commission (“SEC”). Accordingly, the unaudited condensed consolidated financial statements do not include all information and footnotes required by U.S. GAAP for complete 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, 2014 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 on March 31, 2014. The accompanying condensed balance sheet as of December 31, 2013 has been derived from the audited financial statements included in such Form 10-K.

To date, the Company has not generated significant revenues. For the nine months ended September 30, 2014, the Company incurred an operating loss of \$6.7 million and a net loss of \$18.2 million. Based on current assumptions about sales of Neutrolin and the development plans for Neutrolin, management believes that the Company’s existing cash will be sufficient to fund its operations through the third quarter of 2015. However, the Company’s continued operations beyond the third quarter of 2015, including the commencement of its planned Phase III trial for Neutrolin in hemodialysis patients in the U.S., will depend on its ability to generate substantial revenue from the sale of Neutrolin and on its ability to raise additional capital 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 on future sales of Neutrolin or that financing or strategic relationships will be available on acceptable terms, or at all. If the Company is unable to raise sufficient capital, find strategic partners or generate substantial revenue from the sale of Neutrolin, there would be a material adverse effect on its business. Further, the Company expects in the future to incur additional expenses as it continues to commercialize Neutrolin in Europe and other foreign markets, protects its intellectual property and seeks FDA approval of Neutrolin in the U.S.



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 the Company and CorMedix Europe GmbH, its wholly owned subsidiary. All significant intercompany accounts and transactions have been eliminated in consolidation.

Recently Adopted Accounting Standards:

In June 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update No. 2014-10, Development Stage Entities (Topic 915) – Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation (“ASU 2014-10”). ASU 2014-10 eliminates the concept of a development stage entity in its entirety from current accounting guidance. The new guidance eliminates the requirements for development stage entities to (i) present inception-to-date information in the statement of operations, stockholders’ equity and cash flows, (ii) label the financial statements as those of a development stage entity, (iii) disclose a description of the development stage activities in which the entity is engaged, and (iv) disclose in the first year in which the entity is no longer a development stage entity that in prior years it had been in the development stage. ASU 2014-10 is effective prospectively for public entities for annual reporting periods beginning after December 15, 2015, and interim periods within those annual periods. However early adoption is permitted. The Company elected to adopt ASU 2014-10 beginning with the quarter ended June 30, 2014 and, accordingly, has not included the inception-to-date disclosures and other previously required disclosures for development stage entities.

Recent Authoritative Pronouncements:

In May 2014, the FASB issued new guidance related to how an entity should recognize revenue. The guidance specifies that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods and services. In addition, the guidance expands the required disclosures related to revenue and cash flows from contracts with customers. The guidance is effective for the Company beginning in the first quarter of 2017. Early adoption is not permitted and retrospective application is required. The Company is currently evaluating the impact of adopting this guidance on its consolidated financial condition, results of operations and cash flows.

In June 2014, the FASB issued an accounting standard that clarifies the accounting for share-based payments when the terms of an award provide that a performance target could be achieved after the requisite service period. The standard requires that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. The amendments are effective for interim and annual reporting periods beginning after December 15, 2015. Earlier adoption is permitted. The standard may be applied prospectively to all awards granted or modified after the effective date; or retrospectively to all awards with performance targets that are outstanding as of the beginning of the earliest annual period presented in the financial statements and to all new or modified awards thereafter. The Company is currently evaluating the impact of adopting this guidance on its consolidated financial condition, results of operations and cash flows.



Cash and Cash Equivalents:

Cash and cash equivalents include cash accounts and all investments purchased with initial maturities of three months or less. The Company attempts to mitigate its exposure to liquidity, credit and other relevant risks by placing its cash and cash equivalents with financial institutions it believes are structurally sound. The Company maintains its cash and cash equivalents in bank deposit and other interest bearing accounts, the balances of which, at times, may exceed federally insured limits.

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 Euro, foreign currency asset and liability amounts are translated into USD at end-of-period exchange rates. Foreign currency income and expenses are translated at average exchange rates in effect during the period. Translation gains and losses resulting from this process are included in other comprehensive income (loss). Transaction gains and losses that arise from the exchange rate fluctuations on transactions are included in other income (expense).

Geographic Information:

The Company reported revenues for the three-month period ended September 30, 2014 of \$52,441 of which \$50,970 was attributable to its European operations which are based in Germany and \$1,471 was attributable to the amortization of deferred revenue received as a result of distribution agreement with a Korean company (See Deferred Revenue below). The Company reported revenues for the nine-month period ended September 30, 2014 of \$104,373 of which \$102,902 was attributable to its European operations and \$1,471 was attributable to the amortization of deferred revenue received as a result of distribution agreement with a Korean company. Of the Company's total assets of \$6.8 million at September 30, 2014, \$6 million was located in the U.S., with the remainder located in Germany.

Restricted Cash:

Pursuant to a supply agreement, the Company had invested in a twelve-month 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 was recorded on the consolidated balance sheets at December 31, 2013 as restricted cash. As of September 30, 2014, the transaction which covered the letter of credit was completed, which resulted in the release of the restriction in the cash.

Prepaid Expenses:

Prepaid expenses consist of payments made in advance to vendors relating to service contracts for clinical trial development, manufacturing, preclinical development and insurance policies. These advanced payments are amortized to expense either as services are performed or over the relevant service period using the straight-line method.



## Inventories:

Inventories are valued at the lower of 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:

	September 30, 2014	December 31, 2013
Raw materials	\$304,282	\$77,103
Work in process	368,955	-
Finished goods	4,180	2,918
Total	\$677,417	\$80,021

## Accrued Expenses:

Accrued expenses consist of the following:

	September 30, 2014	December 31, 2013
Licensing fee	\$-	\$500,000
Royalty fee	30,000	-
Accrued payroll and related taxes	2,153	197,969
Professional and consulting fees	382,201	12,000
Raw material purchases	54,000	-
Other	6,649	3,210
Total	\$475,003	\$713,179

## Deferred Revenue:

In August 2014, the Company entered into an exclusive distribution agreement (the "Agreement") with Wonik Corporation, a South Korean company, to market, sell and distribute Neutrolin for hemodialysis and oncolytic patients upon receipt of regulatory approval in Korea. Upon execution of the Agreement, Wonik paid the Company a non-refundable \$50,000 payment and will pay an additional \$50,000 upon receipt of the product registration necessary to sell Neutrolin in the Republic of Korea (the "Territory"). The term of the agreement commenced on August 8, 2014 and will continue for three years after the first commercial sale of Neutrolin in the Territory. The non-refundable up-front payment has been recorded as deferred revenue and will be recognized as revenue on a straight-line basis over the contractual term of the Agreement.

## Revenue Recognition:

CorMedix recognizes revenue in accordance with SEC Staff Accounting Bulletin ("SAB") No. 101, Revenue Recognition in Financial Statements ("SAB 101"), as amended by SAB No. 104, Revenue Recognition ("SAB 104") and FASB Accounting Standards Codification ("ASC") 605, Revenue Recognition ("ASC 605"). This guidance requires that revenue is recognized from product sales when the following four revenue recognition criteria are met: persuasive evidence of an arrangement exists, delivery has occurred, the selling price is fixed or determinable, and collectability is reasonably assured.

CorMedix's product Neutrolin received its CE Mark in Europe in July 2013 and product shipments to dialysis centers began in December 2013. Orders are processed through a distributor; however, Neutrolin is drop-shipped via a pharmacy directly to the Company's customer, the dialysis center. The Company recognizes net sales upon shipment of product to the dialysis centers.

## Income (loss) per common share:

Basic income (loss) per common share excludes any potential dilution and is computed by dividing net income (loss) available to common shareholders by the weighted average number of common shares outstanding during the period. Diluted earnings (loss) 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,	
	2014	2013
Convertible notes	-	2,035,628
Series B non-voting preferred stock	454,546	454,546
Series C non-voting preferred stock	3,340,000	-
Series D non-voting preferred stock	1,479,240	-
Series E non-voting preferred stock	2,021,358	-
Shares underlying outstanding warrants	11,571,233	8,985,025
Shares underlying outstanding stock options	3,653,500	3,179,630
Total	22,519,877	14,654,829

## Stock-Based Compensation:

The Company measures and recognizes compensation expense for all stock-based payments granted to employees, officers and directors at fair value, net of estimated forfeitures, over the vesting period of the underlying stock-based awards.

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 based on the revalued amount of the options at the end of each reporting period which is amortized to 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.

## Embedded Derivative Liabilities and Warrant Liabilities:

The Company does not use derivative instruments to hedge exposures to cash flow, market or foreign currency risks; however, the Company has several series of preferred stock and warrants that contain embedded derivatives. The Company evaluates all its financial instruments to determine if those instruments or any potential embedded components of those instruments qualify as derivatives that need to be separately accounted for in accordance with FASB ASC 815, "Derivatives and Hedging". Embedded derivatives satisfying certain criteria are recorded at fair value at issuance and marked-to-market at each balance sheet date with the change in the fair value recorded as income or expense. In addition, upon the occurrence of an event that requires the derivative liability to be reclassified to equity, the derivative liability is revalued to fair value at that date.



The Company accounts for stock warrants as either equity instruments or derivative liabilities depending on the specific terms of the warrant agreement. Stock warrants that allow for cash settlement or provide for certain modifications of the warrant exercise price were accounted for as derivative liabilities. For those liability-classified warrants that have down-round provisions which allow the exercise price to be adjusted as a result of certain future financing transactions, the Company uses level 3 inputs to value those warrants. The estimated fair values of the warrant liabilities with downround protection were determined using a Monte Carlo option pricing model which takes into account the probabilities of certain events occurring over the life of the warrants. The derivative liabilities were adjusted to their estimated fair values at each reporting period, with any decrease or increase in the estimated fair value being recorded in other income (expense). The significant inputs and assumptions are as follows:

**Stock price** – Due to the historical volatility of the Company's common stock price, a one month 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 (wherever applicable) 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** – The Company used a weighted average of (i) the historical volatility of the Company's common stock for approximately five years, (ii) the volatility used for prior period valuations, and (iii) the volatilities of comparable companies (provided by the Company's management) from the date product approval is received to the various valuation dates. Then, appropriate weights were applied to these data points to arrive at the weighted average historical volatility.

**Term** – Although the Series C, D and E preferred stocks do not have a specified contracted life, the Company has assumed a five year life from the date of inception for the purpose of the valuations.

**Risk-free Rate** – The U.S. 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.

As discussed in Note 4, the warrants issued in March 2014, which do not have downround protection, were valued using a Black Scholes option pricing model.

## Note 3 — Stockholders' Equity:

## Common Stock and Warrants

In March 2014, the Company sold an aggregate of 2,960,000 units in a registered direct offering at a purchase price of \$2.50 per unit. Each unit consisted of one share of the Company's common stock and 0.35 of a warrant, each to purchase one share of the Company's common stock. Upon issuance, the warrants had an exercise price of \$3.10 per share, are exercisable commencing six months from the date of issuance, and have a term of five years from the date of exercisability. A holder is prohibited from exercising a warrant if, as a result of such exercise, the holder, together with its affiliates, would own more than 3.99% or 4.99%, at the holder's election, of the total number of shares of the Company's common stock then issued and outstanding. The Company received net proceeds of \$6,723,248. Under certain circumstances, the warrants may be settled in cash and were therefore classified as derivative liabilities. The Company used the Black Scholes option pricing model to value the warrants, of which \$1,728,450 was the ascribed value calculated at the issuance date. These warrants were revalued at each balance sheet date and the resulting changes were recorded in other income (expense) in the statement of operations. On September 15, 2014, the exercise price of these warrants was decreased to \$2.50 in exchange for the removal of the cash settlement provisions of the warrant. The Company revalued the warrants on September 15, 2014 immediately prior to the modification which resulted in a change in fair value recorded in other income (expense) in the statement of operations, and immediately subsequent to the modification which resulted in a loss on modification of equity instruments and extinguishment of derivative liabilities recorded in other income (expense) in the statement of operations. Refer to Note 4 for further details of this transaction. During 2014, the Company used the following assumptions in calculating the Black Scholes values of these warrants:

	At Issuance Date		September 15, 2014	
Expected term (years)	5.5		5	
Volatility	75	%	75	%
Dividend yield	0.0	%	0.0	%
Risk-free interest rate	1.63	%	1.8	%

During the nine months ended September 30, 2014, stock options to purchase 425,000 shares of the Company's common stock were exercised resulting in gross proceeds of \$309,450 to the Company.

During the nine months ended September 30, 2014, an aggregate of 140,000 shares of the Series C-1 non-voting preferred stock were converted into 1,400,000 shares of the Company's common stock.

During the nine months ended September 30, 2014, 16,000 shares of the Series C-3 non-voting preferred stock were converted into 160,000 shares of the Company's common stock.

During the nine months ended September 30, 2014, warrants to purchase 887,292 shares of the Company's common stock were exercised on a cashless basis resulting in the issuance of 751,689 shares of the Company's common stock.

During the nine months ended September 30, 2014, wages in the amount of \$42,500 were converted into 22,225 shares of common stock by an officer at prices of \$1.71 - \$2.00 per share.

## Preferred Stock and Warrants

In January 2014, the Company sold to various investors 200,000 shares of Series C-3 preferred stock, together with warrants to purchase up to an aggregate of 1,000,000 shares of common stock, for aggregate gross proceeds of \$2,000,000. The Series C-3 preferred stock and the related warrants were sold together at a price of \$10.00 per share for each share of Series C-3 preferred stock. The Series C-3 preferred stock has rights, privileges and terms that are identical to the Company's Series C-1 and C-2 non-voting convertible preferred stock. Each share of Series C-3 preferred stock is convertible into 10 shares of common stock at any time at the holder's option. However, the holder is prohibited from converting Series C-3 preferred stock into shares of common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 9.99% of the total number of shares of the Company's common stock then issued and outstanding. The warrants are exercisable one year after issuance, had an exercise price of \$1.25 per share (decreased to \$0.90 per share in September 2014 – See Note 4), subject to adjustment, and a term of five years from the date they are first exercisable. However, a holder is prohibited from exercising a warrant if, as a result of such exercise, the holder, together with its affiliates, would own more than 4.99% or 9.99%, at the holder's election, of the total number of shares of the Company's common stock then issued and outstanding. Included in this financing was the settlement of an aggregate amount of \$645,458 in accruals and payables owed to ND Partners, the Company's CEO for his 2013 salary, and a consultant. The Company received net proceeds of \$1,318,884.

Due to the existence of downround provisions, the conversion features of the Series C-3 stock and the associated warrants were classified as derivative liabilities upon issuance and were valued using a Monte Carlo simulation model. On the issuance date, the estimated value of the conversion features and warrants was \$1,398,158 and \$655,574, respectively.

In January 2014, all 140,000 outstanding shares of Series C-1 preferred stock were converted into 1,400,000 shares of the Company's common stock which resulted in the reclassification of the derivative liability to equity in the amount of \$2,447,384.

In February 2014, the downround protection of Series C-2 and Series C-3 preferred stock was eliminated as, pursuant to its terms, the closing price of the Company's common stock was greater than \$2.00 for a period of twenty trading days for a consecutive thirty trading day period subsequent to the closing, resulting in the reclassification of the related derivative liability to equity in the amount of \$6,235,398.

On September 15, 2014 the Company entered into consent and exchange agreements with investors holding its outstanding Series C-2, Series C-3, Series D, and Series E preferred stock. The Company modified certain terms within the preferred stock, as described in Note 4, which resulted in the reclassification of the remaining derivative liability to equity.

The Company used a Monte Carlo simulation model to separately value the conversion options associated with the preferred stock instruments and the warrants issued in connection with the preferred stock. A summary of the assumptions used in the Monte Carlo models are as follows:

	At September 15, 2014		At Issuance Date	
Expected term (months)	49 - 64		56 - 60	
Volatility	75	%	75	%
Dividend yield	0.0	%	0.0	%
Risk-free interest rate	1.63 - 1.8 %		1.3 - 1.5 %	

### Stock Options

During the nine months ended September 30, 2014, the Company granted to its officers, directors and employees, ten-year non-qualified stock options under the 2013 Stock Incentive Plan, covering an aggregate of 1,185,000 shares, respectively, of the Company's common stock with exercise prices ranging from \$1.80 to \$2.79 per share. Of these options, 896,000 vested on the date of grant, 204,000 options vest one year after the grant date, 45,000 options vest two years after the grant date, 25,000 options vest three years after the grant date. The remaining 15,000 options are subject to certain performance milestones which were achieved during the nine months ended September 30, 2014, resulting in the vesting of 15,000 options in addition to the 896,000 options that vested on the date of grant.

During the nine months ended September 30, 2014, the Company granted to its consultants ten-year non-qualified stock options under the 2013 Plan, covering an aggregate of 180,000 shares, respectively, of the Company's common stock with exercise prices ranging from \$1.77 to \$2.24 per share. Of these options, 13,000 vested on the grant date, 40,000 options vest quarterly for two years from grant date and the remaining 127,000 options are subject to performance milestones. Some of these milestones were achieved as of September 30, 2014 which resulted in the vesting of 30,000 options in addition to the 13,000 options that vested on the date of grant.

During the three and nine months ended September 30, 2014, total compensation expense for stock options issued to employees, directors, officers and consultants was \$166,439 and \$1,942,192, respectively. For the nine months ended September 30, 2013, compensation expense was \$321,627 and \$753,476, respectively.

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

	Nine Months Ended September 30,	
	2014	2013
Expected term (years)	5 - 10	2 - 10
Volatility	74% - 113%	86% - 131%
Dividend yield	0.0 %	0.0 % 0.34% -
Risk-free interest rate	1.5% - 2.9%	2.78 %

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 full term of the respective option agreements. Given the Company's short period of publicly-traded stock history, management's estimate of expected volatility is based on the average historical 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 estimation of the number of stock awards that will ultimately vest requires judgment, and to the extent actual results or updated estimates differ from the Company's current estimates, compensation expense may need to be revised. The Company considers many factors when estimating expected forfeitures for stock awards granted to employees, officers and directors, including types of awards, employee class, and an analysis of the Company's historical forfeitures.

A summary of the Company's stock option activity and related information for the nine months ended September 30, 2014 is as follows:

	Shares	Weighted Average Exercise Price
Outstanding at beginning of period	3,453,630	\$ 1.06
Exercised	(425,000 )	\$0.73
Forfeited	(215,500 )	\$ 1.22
Expired	(524,630 )	\$ 1.89
Granted	1,365,000	\$ 2.04
Outstanding at end of period	3,653,500	\$ 1.22
Options exercisable	2,925,000	\$ 1.17
Weighted-average fair value of options granted during the period		\$ 1.52

The weighted average remaining contractual life of stock options outstanding at September 30, 2014 is 8.17 years. The weighted average remaining contractual life of stock options exercisable at September 30, 2014 is 7.94 years. The aggregate intrinsic value is calculated as the difference between the exercise prices of the underlying options and the quoted closing price of the common stock of the Company at September 30, 2014 for those options that have an exercise price below the quoted closing price. As of September 30, 2014, the aggregate intrinsic value of stock options outstanding was \$2,683,650 and the aggregate intrinsic value of stock options exercised during the nine months ended September 30, 2014 was \$600,550.

As of September 30, 2014, the total compensation expense related to non-vested options not yet recognized totaled \$443,556. The weighted-average remaining vesting period related to these non-vested options at September 30, 2014 was approximately 0.58 years.

#### Warrants

The following table is the summary of warrant activity for the nine months ended September 30, 2014:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life
Outstanding at beginning of period	10,422,525	\$ 2.00	3.12
Granted	2,036,000	\$ 2.19	5.11
Exercised	(887,292 )	\$ 1.18	-
Outstanding at end of period	11,571,233	\$ 2.00	* 2.80

\* Reflects reduced exercise prices of warrants as per September 15, 2014 amendment, see Note 4.

#### Stock-based Deferred Compensation Plan for Non-Employee Directors

During the third quarter of 2014, the Company established an unfunded stock-based deferred compensation plan, providing non-employee directors the opportunity to defer up to one hundred percent of fees and compensation, including restricted stock units. The amount of fees and compensation deferred by a non-employee director is

converted into stock units, the number of which is determined based on the closing price of the Company's common stock on the date such compensation would have otherwise been payable. At all times, the plan participants are one hundred percent vested in their respective deferred compensation accounts. On the tenth business day of January in the year following a director's termination of service, the director will receive a number of common shares equal to the number of stock units accumulated in the director's deferred compensation account. The Company accounts for this plan as stock based compensation under ASC 718. During the three months ended September 30, 2014, the amount of compensation that was deferred under this plan was not material.

## Note 4 — Equity Instruments Modification and Fair Value Measurements:

The fair value of the Company's cash, accounts receivable and accounts payable at September 30, 2014 approximate their carrying values due to the relative liquidity and/or short-term nature of these instruments. As defined by ASC Topic 820, "Fair Value Measurements and Disclosures" ("ASC 820"), fair value measurements and disclosures establish a fair value hierarchy that prioritizes fair value measurements based on the type of inputs used for the various valuation techniques (market approach, income approach and cost approach). The three levels of the fair value hierarchy under ASC 820 are described below:

Level 1 - observable inputs such as quoted prices in active markets for identical assets or liabilities;

Level 2 - inputs other than quoted market prices that are observable for the asset or liability, either directly or indirectly; these include quoted prices for similar assets or liabilities in active markets, such as interest rates and yield curves that are observable at commonly-quoted intervals; and

Level 3 - unobservable inputs that reflect the Company's own assumptions, as there is little, if any, related market activity.

The following table presents the fair value hierarchy and the change in fair values of the Company's derivative liabilities measured at fair value on a recurring basis.

	Fair Value Hierarchy Level	Fair Value December 31, 2013	Change in Fair Value From July 1 to Sept. 15, 2014 (Modification Date)	Change in Fair Value From Jan. 1 to Sept. 15, 2014 (Modification Date)
Series C-1, C-2 and C-3 non-voting preferred stock conversion option issued in October 2013 and January 2014	3	\$2,027,330	\$-	\$ 599,814
Series D non-voting preferred stock conversion option issued in October 2013	3	901,625	204,102	2,017,960
Series E non-voting preferred stock conversion option issued in October 2013	3	735,619	176,437	1,786,902
Warrants issued in connection with convertible debt issued in May 2013	3	660,869	105,471	1,566,444
Warrants issued in connection with Series C-1, C-2 and C-3 non-voting preferred stock issued in October 2013 and January 2014	3	983,361	193,984	3,732,962
Warrants issued in March 2014 in connection with the private placement of common stock and warrants	3	-	(93,554 )	(855,129 )
<b>Total</b>		<b>\$5,308,804</b>	<b>\$586,440</b>	<b>\$ 8,848,953</b>

The Company's derivative liabilities are classified as Level 3. Changes in the unobservable input values would likely cause material changes in the fair value of the Company's Level 3 derivative liabilities. Significant unobservable inputs are implied volatilities. Significant increases (decreases) in implied volatilities in isolation would result in a significantly higher (lower) fair value measurement. The Company reviews these valuations and the changes in the fair value measurements for reasonableness.

On September 15, 2014, the Company entered into consent and exchange agreements with the investors holding its outstanding Series C-2 preferred stock and related warrants, Series C-3 preferred stock and related warrants, Series D preferred stock and Series E preferred stock, and the investors holding warrants issued in March 2014. Pursuant to those agreements, the Company and the investors agreed to amend and restate the Series C-2 preferred stock and related warrants, Series C-3 preferred stock and related warrants, Series D preferred stock and Series E preferred stock and the warrants issued in May 2013, October 2013 and March 2014, to remove anti-dilution, price reset, cash settlement features and certain change of control provisions that caused those instruments to be classified as derivative liabilities. The Company also eliminated the preferred dividends on the Series D preferred stock and Series E preferred stock.

In exchange for the removal of the anti-dilution, price reset, cash settlement, change of control and dividend provisions from the Series C-2 preferred stock, Series C-3 preferred stock, Series D preferred stock and Series E preferred stock and the related warrants, as applicable, the Company agreed to the following:

1. Decrease the exercise price of the warrants issued in May 2013 from \$1.00 to \$0.65, decrease the exercise price of the warrants issued in October 2013 from \$1.25 to \$0.90, decrease the exercise price of the warrants issued in January 2014 from \$1.25 to \$0.90, and decrease the exercise price of the warrants issued in March 2014 from \$3.10 to \$2.50;
2. Extend the existing right of the two institutional investors in our May and October 2013 financings to participate in future financings to the later of two years after September 15, 2014 or the date on which the respective holder holds less than 5% of the Company's common stock on a fully diluted basis;
3. Increase the conversion ratio of the Series E preferred stock from 20 shares to 21.8667 shares of common stock for every share of Series E preferred stock;
4. Issue 16,562 shares of the Company's Series D preferred stock to the investor holding all of the outstanding shares of the Series D preferred stock in satisfaction of the 9.0% payment-in-kind dividend on that stock; and
5. Issue an aggregate of 37,226 shares of Series E preferred stock to the two investors holding all of the outstanding shares of Series E preferred stock in satisfaction of the 8.0% payment-in-kind dividend on that stock.

As a result of these modifications, all of the outstanding derivative liabilities were reclassified to equity. The Company applied the accounting treatment prescribed for the modification of stock options under ASC 718 to the modification of the preferred stock and warrant instruments by analogy. The outstanding warrants and the preferred stock Series E and Series D hybrid instruments were re-measured immediately prior to the modification date with the original terms and immediately after the modification date with the amended terms. The change in fair value resulting from the modifications made to those instruments on September 15, 2014 was recorded as loss on modification of equity instruments and extinguishment of derivative liabilities in the amount of approximately \$2,463,000.

The table below sets forth a summary of changes in the fair value of the Company's Level 3 derivative liabilities related to the non-voting preferred stock embedded derivatives and the liability classified warrants.

	September 30, 2014	
	Three	Nine Months
	Months	
Balance at beginning of period	\$8,670,717	\$5,308,804
Additions to derivative liabilities	-	3,782,182
Conversion of convertible preferred stock to common stock	-	(2,447,384 )
Loss from modification of preferred stock and warrant instruments	2,462,588	2,462,588
Change in fair value of derivative liabilities	586,440	8,848,953
Reclassification of derivative liabilities to equity (excluding \$21,117 dividends issued in 2013)	(11,719,745)	(17,955,143)
Balance at end of period	\$-	\$-

## Note 5 — Commitments and Contingencies:

In February 2007, Geistlich Söhne AG für Chemische Industrie, Switzerland, (Geistlich), filed an opposition against the Sodemann patent covering our 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 opposition against the Sodemann patent that was filed at the head office of the European Patent Office in Munich, Germany, 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. In June 2008 the opposition division at the European Patent Office held oral proceedings and rejected the opposition by Geistlich and maintained the patent as granted. 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 it requested a dismissal of the appeal and to maintain the patent as granted. 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 opposition division as 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 filed its response on February 3, 2014 to request that the patent be maintained as amended during the appeal proceedings. Geistlich did not provide any filing by February 10, 2014; however, the Board of the European Patent Office opposition division granted Geistlich an extension to respond by the end of July 2014 because its representative did not receive the September 30, 2013 letter due to a change of address. Geistlich did not file a further statement within the required timeline. As a result, the case is open for a final decision by the Board of the European Patent Office opposition division. The Company intends to continue to vigorously defend the patent in a restricted form. However, the Company can provide no assurances regarding the timing or 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 Neutrolin) 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, purchases a minimum of \$2,250,000 of product on an annual basis for five years. The Company will not purchase the required amount in 2014. 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 over five years. The Navinta Agreement has a term of five years, but may be terminated by either party upon 30 days written notice.

In January 2008, the Company entered into a License and Assignment Agreement (the “NDP License Agreement”) with ND Partners, LLC (“NDP”). Pursuant to the NDP License Agreement, NDP granted us exclusive, worldwide licenses for certain antimicrobial catheter lock solutions, processes for treating and inhibiting infections, a biocidal lock system and a taurolidine delivery apparatus, and the corresponding United States and foreign patents and applications (the “NDP Technology”). As consideration in part for the rights to the NDP Technology, the Company paid NDP an initial licensing fee of \$325,000 and granted NDP an equity interest in us consisting of 365,534 shares of the Company’s

common stock as of December 31, 2010. In addition, the Company is required to make payments to NDP upon the achievement of certain regulatory and sales-based milestones. Certain of the milestone payments are to be made in the form of shares of common stock currently held in escrow for NDP, and other milestone payments are to be paid in cash. The maximum aggregate number of shares issuable upon achievement of milestones and the number of shares held in escrow was 145,543 shares of common stock as of September 30, 2014, which are reflected as deferred stock issuances on the condensed consolidated balance sheets. The maximum aggregate amount of cash payments of \$2.5 million is based upon achievement of milestones related to U.S. regulatory development and attainment of designated worldwide net sales levels from licensed products, none of which are expected to be met in 2014 or 2015.



In April 2013, the Company entered into an amendment to the NDP License Agreement. Under the NDP License Agreement, the Company was obligated to make a milestone payment of \$500,000 to NDP upon the first issuance of a CE Mark for a licensed product. Pursuant to the terms of the amendment, the Company and NDP agreed to delay such milestone payment to a time, to be chosen by the Company, within 12 months after the achievement of such issuance. In July 2013, a milestone payment of \$500,000 was earned by NDP upon the first issuance of the CE Mark for Neutrolin and was settled upon issuance of 50,000 shares of Series C-3 preferred stock in January 2014 (See Note 3 – Stockholders' Equity).

In January 2008, the Company also entered into an Exclusive License and Consulting Agreement with Dr. Polaschegg (the "Polaschegg License Agreement"). The Polaschegg License Agreement replaced the original license agreement between NDP and Dr. Polaschegg that the Company was assigned and the Company assumed under the NDP License Agreement. Pursuant to the Polaschegg License Agreement, Dr. Polaschegg granted the Company an exclusive, worldwide license for a certain antimicrobial solution and certain taurolidine treatments and the corresponding United States patent applications (the "Polaschegg Technology"), and agreed to provide the Company with certain consulting services. As consideration for the rights to the Polaschegg Technology, the Company paid Dr. Polaschegg an initial payment of \$5,000 and agreed to pay Dr. Polaschegg certain royalty payments ranging from 1% to 3% of the net sales of the Polaschegg Technology. The Polaschegg License Agreement also sets forth certain minimum royalty payments (on an annual basis) to be made to Dr. Polaschegg in connection with the Polaschegg Technology, which payments range from \$10,000 to \$45,000. The Company may terminate the Polaschegg License Agreement with respect to any piece of the Polaschegg Technology upon 60 days notice. If the Polaschegg License Agreement is terminated with respect to any piece of the Polaschegg Technology by either party, all rights with respect to such portion of the Polaschegg Technology will revert to Dr. Polaschegg. The Company expensed \$10,000 and \$30,000 during the three and nine months ended September 30, 2014, respectively, and \$11,250 and \$33,750 for the three and nine months ended September 30, 2013, respectively.

On July 21, 2014, the Company appointed Harry O'Grady as its Chief Financial Officer and Dr. Antony Pfaffle as its Chief Scientific Officer and entered into an employment agreement with each officer. Pursuant to their respective employment agreements, the Company will pay a base salary of \$230,000 to Mr. O'Grady and \$200,000 to Dr. Pfaffle. Mr. O'Grady will be eligible to participate in the Company's Short Term Incentive Plan ("STIP") beginning January 1, 2015, with a target award opportunity equal to 40% of his base salary. Dr. Pfaffle is eligible to participate in the STIP beginning on his employment date. His 2015 target award opportunity is equal to 30% of his base salary. Pursuant to his employment agreement, the Company also granted Mr. O'Grady an option to purchase 100,000 shares of the Company's common stock. If either officer's employment is terminated as a result of his death or disability, the Company will pay him or his estate, as applicable (i) his base salary for 180 days after the termination of his employment, and (ii) additional benefits, if any, as may be provided under applicable employee benefit plans, programs and arrangements of the Company. If the Company terminates either officer's employment without "cause" (as defined in the employment agreement) or the officer terminates his employment for "good reason" (as defined in the employment agreement), then the Company will (i) pay the officer his then-current salary for 12 months, and (ii) provide the officer such other benefits, if any, as may be provided under applicable employee benefit plans, programs and arrangements of the Company.

#### Note 6 — Related Party Transactions:

In January 2014, the following related parties participated in the private placement of Series C-3 preferred stock and warrants to purchase the Company's common stock at an exercise price of \$1.25 per share, which was reduced to \$0.90 in September 2014. Each share of Series C-3 preferred stock is convertible into 10 shares of common stock. All terms were the same as the Series C-1 and C-2 preferred stock issued in the October 2013 private placement (see Note 3 – Stockholders' Equity):

		Amount	Number of Series C-3 Preferred Stock	Number of Warrants
Gary A. Gelbfish (1)	Former Chairman of the Board	\$ 500,000	50,000	250,000
Randy Milby	CEO and Director	\$ 237,000	23,700	118,500
MW Bridges LLC, an entity for which Randy Milby is Managing Partner		\$ 13,000	1,300	6,500
Steven W. Lefkowitz	Director and Former Interim CFO	\$ 45,000	4,500	22,500
Wade Capital Corporation Money Purchase Plan, an entity for which Steven W. Lefkowitz has voting and investment control		\$ 30,000	3,000	15,000

(1) Gary A. Gelbfish resigned effective June 13, 2014 and ceased to be a related party 90 days thereafter.

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 2013 Annual Report on Form 10-K, filed with the Securities and Exchange Commission, or the SEC, on March 31, 2014.

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," "solicit," "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" in our most recent annual report on Form 10-K, as well as any amendments thereto, and our quarterly reports on Form 10-Q, as filed with the SEC. 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 transitioning to a commercial pharmaceutical and medical device company. We in-license, develop and commercialize prophylactic and therapeutic products for the prevention and treatment of infectious diseases in cardiac, renal and oncology patients. As of the date of this report, we have in-licensed all of the product candidates in our pipeline. We formed a wholly-owned subsidiary, CorMedix Europe GmbH, in 2013.

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 are initially marketing for use in hemodialysis catheters.

During the third quarter of 2011, we received a notice from the U.S. Food and Drug Administration ("FDA") that Neutrolin had been assigned to the 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 that time.

In July 2013, we received CE Mark approval for Neutrolin. We began the commercial launch of Neutrolin for the prevention of catheter-related bloodstream infections (“CRBI”) and maintenance of catheter patency in hemodialysis patients in Europe in the fourth quarter of 2013.

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 late 2013, we met with the FDA to determine the pathway for U.S. approval of Neutrolin, which we expect to entail at least one Phase III clinical trial in hemodialysis catheters and one Phase III clinical trial in oncology/total parenteral nutrition. We have worked with the FDA to design the protocol for a planned Phase III trial in hemodialysis patients with a central venous catheter; this protocol was accepted in August 2014 and we filed an IND in September 2014. In October 2014, the FDA informed us that it had determined that the IND is not subject to a clinical hold, and that the Phase III clinical trial in hemodialysis patients can be initiated in the U.S. We are seeking one or more strategic partners or other sources of capital to complete the development of Neutrolin in the U.S.

In August 2014, we entered into an exclusive distribution agreement (the “Agreement”) with Wonik Corporation, a South Korean company, to market, sell and distribute Neutrolin for hemodialysis and oncolytic patients upon receipt of regulatory approval in Korea. Upon execution of the Agreement, Wonik paid us a non-refundable \$50,000 payment and will pay an additional \$50,000 upon receipt of the product registration necessary to sell Neutrolin in the Republic of Korea (the “Territory”). The term of the agreement commenced on August 8, 2014 and will continue for three years after the first commercial sale of Neutrolin in the Territory. There have been no sales to this distributor as of the reporting date.

Our other product candidate is CRMD004, which is the gel formulation of Neutrolin that we may develop for a variety of indications that include but are not limited to the treatment of wounds, skin infections, the prevention of catheter exit site infections and, based on the gel’s thixotropic properties which cause it to liquefy under pressure/kinetic energy, as a follow-on to our Neutrolin catheter lock solution. CRMD004 is currently in the pre-clinical stage of development.

Since our inception, we have had no substantial 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, performing business and financial planning, performing research and development, seeking regulatory approval for our products 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 incur increases in our cash used in operations as we continue to commercialize Neutrolin in Europe and other foreign markets and seek FDA approval of Neutrolin in the U.S. We are unable to predict the extent of any future losses or when we will become profitable, if at all.

## Financial Operations Overview

### Revenue

We have not generated substantial 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.

We recognize revenue in accordance with SEC Staff Accounting Bulletin (“SAB”) No. 101, Revenue Recognition in Financial Statements (“SAB 101”), as amended by SAB No. 104, Revenue Recognition (“SAB 104”) and Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) 605, Revenue Recognition (“ASC 605”).

Our product Neutrolin received CE Mark in Europe in July 2013 and product shipments to dialysis centers began in December 2013. Orders are processed through a distributor; however, Neutrolin is drop-shipped via a pharmacy directly to our customer, the dialysis center. We recognize net sales upon shipment of product to the dialysis centers.

### Cost of Sales

Cost of sales includes all costs incurred in bringing our product to their final selling destination, which primarily include direct raw materials, direct labor, third-party manufacturing, indirect overhead and stability testing costs. During the first nine months of 2014, the majority of the costs of raw materials and the cost to manufacture the product sold were previously charged to research and development expense because it had been purchased and manufactured prior to the receipt of the CE Mark.



## 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 development is central to our business model. 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 plan to increase our R&D expenses for the foreseeable future in order to complete development of Neutrolin in the U.S.

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,			
	2014		2013	
CRMD003	97	%	96	%
CRMD004	3	%	4	%

The process of conducting pre-clinical studies and clinical trials necessary to obtain FDA and foreign 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. We intend to seek U.S. approval of Neutrolin for the prevention of CRBI and maintenance of catheter patency in the United States which we expect to entail at least one Phase III trial in hemodialysis catheters and one Phase III trial in oncology/total parenteral nutrition, based on guidance from the FDA. We submitted to the FDA an IND in September 2014 and in October 2014 the FDA informed us that it had determined that the IND is not subject to a clinical hold, and that the Phase III clinical trial in hemodialysis patients can be initiated in the U.S. We are seeking one or more strategic partners or other sources of capital to complete the development of Neutrolin in the U.S.

#### Selling, General and Administrative Expense

Selling, general and administrative, or SG&A, expense includes costs related to commercial personnel, medical education professionals, marketing and advertising, salaries and other related costs, including stock-based compensation expense, for persons serving in our executive, sales, finance and accounting functions. Other SG&A expense includes facility-related costs not 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 SG&A expenses will increase due to marketing of our Neutrolin product in Europe.

#### Loss on Issuance of Preferred Stock, Convertible Notes and Warrants

As discussed in Note 3, we issued preferred stock and related warrants during the nine months ended September 30, 2014. The loss on the issuance of preferred stock and related warrants represents the difference on the issuance date between the combined fair value of the conversion option and the warrants, and the proceeds that were received net of all fees and expenses related to the issuance.

#### Change in Fair Value of Conversion Options and Warrants

The change in the fair value of conversion option and warrants represents the change in the fair value of the Series C, D and E preferred stock conversion options and the change in the fair value of warrants that are recorded at fair value on a recurring basis under generally accepted accounting principles. This includes any changes in fair value resulting from the re-measurement of the derivative liabilities in connection with the redemption or conversion of the preferred stock and the exercise of warrants.

#### Loss on Modification of Equity Instruments and Extinguishment of Derivative Liabilities

The loss on modification of equity instruments and extinguishment of derivative liabilities represents the change in the fair value of the preferred stock hybrid instruments and liability classified warrants resulting from the modifications made to those instruments on September 15, 2014.

#### Foreign Exchange Transaction Gain (Loss)

Foreign exchange transaction gain (loss) consists of intercompany foreign exchange transaction gains and losses.

#### Interest Income

Interest income consists of interest earned on our cash and cash equivalents.

#### Results of Operations

Three months ended September 30, 2014 compared to three months ended September 30, 2013

Revenue. Revenue was approximately \$52,000 for the three months ended September 30, 2014 compared to zero in the same period last year, primarily due to sales of Neutrolin following the receipt in July 2013 of the CE Mark in Europe of approximately \$51,000 and amortization of deferred revenue of non-refundable payment received from a distribution agreement of approximately \$1,000.





**Cost of Sales.** Cost of sales was approximately \$37,000 for the three months ended September 30, 2014 compared to zero in the same period last year. Cost of sales for the three months ended September 30, 2014 are primarily comprised of costs related to the management of our manufacturing and on-going stability studies of approximately \$33,000, and direct cost of materials of approximately \$3,000. The costs associated with on-going stability studies are expected to continue into 2015, while the costs associated with transitioning Neutrolin to new labels and packaging are not expected to repeat in subsequent periods. During the three months ended September 30, 2014, the majority of the costs of raw materials and the cost to manufacture the product sold were previously charged to research and development expense because it had been purchased and manufactured prior to the receipt of the CE Mark.

**Research and Development Expense.** R&D expense, which is primarily focused on the development of Neutrolin in the U.S., was approximately \$293,000 for the three months ended September 30, 2014, a decrease of approximately \$458,000, from approximately \$751,000 for the three months ended September 30, 2013. The decrease was primarily attributable to the \$500,000 license fee last year as a result of the CE Mark approval for Neutrolin in the European Union, or EU, and decrease in stock based compensation of approximately \$65,000, offset by an increase in costs related to development of Neutrolin in the U.S. of approximately \$120,000.

**Selling, General and Administrative Expense.** SG&A expense was approximately \$1,587,000 for the three months ended September 30, 2014, an increase of approximately \$1,082,000 from approximately \$505,000 for the three months ended September 30, 2013. The increase was primarily attributable to increase in costs related to the commercialization of Neutrolin in the EU of approximately \$400,000, increase in legal fees of approximately \$348,000, due mainly to the patent infringement lawsuit, increase in accounting and consulting fees of \$140,000, increase in expenses related to investor relations, filing fees, travel, insurance and business development of \$114,000 and increased personnel cost of approximately \$97,000, offset by decreased non-cash stock-based compensation expense of approximately \$90,000.

**Change in Fair Value of Derivative Liabilities.** The change in the fair value of derivative liabilities for the three months ended September 30, 2014 of approximately \$586,000 consists of decreases in the fair value of preferred stock conversion options and warrants between June 30, 2014 and September 15, 2014 (date of equity instrument modification and discontinuance of derivative instruments) of approximately \$380,000 and approximately \$206,000, respectively. The change in the fair value of the preferred stock conversion options is the change in fair value of the preferred stock conversion options not converted between June 30, 2014 and September 15, 2014. The change in fair value of the warrants is the difference between the fair values at June 30, 2014 and September 15, 2014. On September 15, 2014, the downround protection of these derivative liabilities was eliminated resulting in the reclassification of derivative liabilities to equity amounting to approximately \$11,720,000.

**Loss on Modification of Equity Instruments and Extinguishment of Derivative Liabilities.** The loss on extinguishment of derivative liabilities for the three months ended September 30, 2014 of approximately \$2,463,000 represents the change in the fair value of the preferred stock hybrid instruments of approximately \$2,119,000 and liability classified warrants of approximately \$344,000 resulting from the modifications made to those instruments on September 15, 2014 for the purpose of changing the balance sheet classification from liability to equity.

**Foreign Exchange Transaction Gain (Loss).** Foreign exchange transaction gain (loss) was approximately \$123,000 for the three months ended September 30, 2014 as compared to approximately \$1,000 for the three months ended September 30, 2013. The increase was due to increased foreign exchange transactions.

**Interest Income.** Interest income was approximately \$600 for the three months ended September 30, 2014, an increase of approximately \$500 from approximately \$100 for the three months ended September 30, 2013. The increase was attributable to having a higher interest-bearing cash balance during the third quarter of 2014 compared to the same quarter in 2013.

**Interest Expense.** Interest expense was approximately \$500 for the three months ended September 30, 2014 as compared to approximately \$312,000 for the same period last year. The interest expense for the three months ended September 30, 2013 consisted primarily of a beneficial conversion feature charge of approximately \$167,000 related to the senior convertible notes and warrants issued in 2012 and 2013, amortization of deferred financing fees of approximately \$109,000 and accrued interest of approximately \$36,000 related to the senior convertible notes.

Nine months ended September 30, 2014 compared to nine months ended September 30, 2013

**Revenue.** Revenue was approximately \$104,000 for the nine months ended September 30, 2014 compared to zero in the same period last year, primarily due to sales of Neutrolin following the receipt of the CE Mark in July 2013 in Europe of approximately \$103,000 and amortization of deferred revenue of non-refundable payment received from a distribution agreement of approximately \$1,000.

**Cost of Sales.** Cost of sales was approximately \$172,000 for the nine months ended September 30, 2014 compared to zero in the same period last year. Cost of sales for the nine months ended September 30, 2014 are primarily comprised of costs related to the management of our manufacturing and on-going stability studies of approximately \$105,000, costs in transitioning Neutrolin to new labels and packaging of approximately \$47,000, and direct cost of materials of approximately \$15,000. The costs associated with on-going stability studies are expected to continue into 2015, while the costs associated with transitioning Neutrolin to new labels and packaging are not expected to repeat in subsequent periods. During the nine months ended September 30, 2014, the majority of the costs of raw materials and the cost to manufacture the product sold were previously charged to research and development expense because it had been purchased and manufactured prior to the receipt of the CE Mark.

**Research and Development Expense.** R&D expense, which is primarily focused on the development of Neutrolin in the U.S., was approximately \$818,000 for the nine months ended September 30, 2014, a decrease of approximately \$568,000, from approximately \$1,386,000 for the nine months ended September 30, 2013. The decrease was primarily attributable to the \$500,000 license fee as a result of the CE Mark approval for Neutrolin in the EU and approximately \$76,000 non-cash value of the warrants issued as a result of the amendment to the License and Assignment Agreement between the Company and ND Partners, LLC for the same period last year.

**Selling, General and Administrative Expense.** SG&A expense was approximately \$5,802,000 for the nine months ended September 30, 2014, an increase of approximately \$3,837,000 from approximately \$1,965,000 for the nine months ended September 30, 2013. The increase was primarily attributable to costs related to commercialization of Neutrolin in the EU of approximately \$1,433,000, non-cash stock-based compensation expense of approximately \$1,033,000, increase in legal fees of approximately \$508,000, increase in accounting and consulting fees of approximately \$389,000, increased personnel cost of approximately \$205,000, and increase in expenses related to investor relations, filing fees, travel, insurance and business development of \$159,000.

**Loss on Issuance of Preferred Stock, Convertible Notes and Warrants.** The loss on the issuance of preferred stock, convertible notes and warrants of approximately \$90,000 for the nine months ended September 30, 2014 represents the difference on the issuance date between the combined fair value of the conversion option and the warrants of approximately \$2,054,000, and the combined proceeds received and liabilities settled, net of all issuance-related fees and expenses of approximately \$1,964,000. For the nine months ended September 30, 2013, the loss on the issuance of preferred stock, convertible notes and warrants of approximately \$946,000 represents the difference on the issuance

date between the combined fair value of the convertible notes and the warrants of \$2,231,000, and the proceeds received, net of all issuance-related fees and expenses, of \$1,285,000.

**Change in Fair Value of Derivative Liabilities.** The change in the value of derivative liabilities for the nine months ended September 30, 2014 of approximately \$8,849,000 consists of increases in the fair value of preferred stock conversion options and warrants between December 31, 2013 and September 15, 2014 of approximately \$7,138,000 and approximately \$1,711,000, respectively. The change in the fair value of the preferred stock conversion options includes the combined changes in (i) the fair value of the converted and redeemed amounts between December 31, 2013 and the relevant conversion and redemption dates and (ii) the change in fair value of the preferred stock conversion options between December 31, 2013 and September 15, 2014. The change in fair value of the warrants is the difference between the fair value at December 31, 2013 and September 15, 2014. On September 15, 2014, the downround protection of these derivative liabilities was eliminated resulting in the reclassification of derivative liabilities to equity amounting to approximately \$17,955,000.

**Loss on Modification of Equity Instruments and Extinguishment of Derivative Liabilities.** The loss on extinguishment of derivative liabilities for the nine months ended September 30, 2014 of approximately \$2,463,000 represents the change in the fair value of the preferred stock hybrid instruments of approximately \$2,119,000 and liability classified warrants of approximately \$344,000 resulting from the modifications made to those instruments on September 15, 2014 for the purpose of changing the balance sheet classification from liability to equity.

**Foreign Exchange Transaction Gain (Loss).** Foreign exchange transaction gain (loss) was approximately \$151,000 for the nine months ended September 30, 2014, an increase of approximately \$151,000 from approximately \$400 for the nine months ended September 30, 2013. The increase was due to increased foreign exchange transactions.

**Interest Income.** Interest income was approximately \$2,100 for the nine months ended September 30, 2014, an increase of approximately \$1,800 from approximately \$300 for the three months ended September 30, 2013. The increase was attributable to having higher average interest-bearing cash balances during the nine months ended September 30, 2014 as compared to the same period last year.

**Interest Expense.** Interest expense was approximately \$1,000 for the nine months ended September 30, 2014 as compared to approximately \$1,414,000 for the same period last year. The interest expense for the nine months ended September 30, 2013 consisted primarily of a beneficial conversion feature charge of approximately \$1,050,000 related to the senior convertible notes and warrants issued in 2012 and 2013, amortization of deferred financing fees of approximately \$269,000 and accrued interest of approximately \$94,000 related to the senior convertible notes.

## Liquidity and Capital Resources

### Sources of Liquidity

As a result of our cost of sales, R&D and SG&A expenditures and the lack of substantial product sales revenue, we have not been profitable and have generated operating losses since we were incorporated in July 2006. We received CE Mark approval for our Neutrolin product in July 2013 and launched our product in the EU in December 2013. Prior to our initial public offering, or IPO, we had funded our operations principally with convertible notes of approximately \$14,365,000 and \$625,000 sold in private placements to third parties and private placements to related parties, respectively. Upon the closing of the IPO in March 2010, we received net proceeds of approximately \$10,457,000. 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.



Since the IPO, we have completed the following financings:

In 2012, we sold 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 \$1,096,000 from the private placement. The notes issued matured in 2013 and an aggregate of \$924,000 of the notes was converted to common stock and \$400,000 of the notes was exchanged for Series D convertible preferred stock during the year ended December 31, 2013.

In 2013, we sold 761,429 shares of our 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 in February; we sold \$1,500,000 of convertible notes and warrants to purchase up to 750,000 shares of our common stock in May; we sold 454,546 shares of Series B non-voting convertible preferred stock and a warrant to purchase up to 227,273 shares of our common stock for gross proceeds of \$500,000 in July; and we sold 150,000 shares of our Series C-1 and 150,000 shares of our Series C-2 non-voting convertible preferred stock and warrants to purchase up to 1,500,000 shares of our common stock for gross proceeds of \$3,000,000 in October. Also in October 2013, as noted above, we exchanged \$400,000 in principal amount of September 2012 convertible notes for 57,400 shares of our Series D non-voting convertible preferred stock and also exchanged \$750,000 in principal amount of May 2013 convertible notes for 53,537 shares of our Series E non-voting convertible preferred stock. All of the Series A and Series C-1 non-voting convertible preferred stock have converted to common stock.

In January 2014, we sold 200,000 shares of our Series C-3 non-voting convertible preferred stock and warrants to purchase up to 1,000,000 shares of our common stock for net cash proceeds of \$1,319,000 and accounts payable and accrued expenses of \$645,000.

In March 2014, we sold 2,960,000 units, each unit consisted of one share of our common stock and 0.35 of a warrant to purchase one share of our common stock, for gross proceeds of \$7,400,000. We received net proceeds of approximately \$6,723,000.

#### Net Cash Used in Operating Activities

Net cash used in operating activities was approximately \$4,747,000 for the nine months ended September 30, 2014. The net loss of approximately \$18,239,000 for the nine months ended September 30, 2014 was higher than cash used in operating activities by approximately \$13,492,000. The difference is attributable primarily to revaluation of derivative liabilities of approximately \$8,849,000, non-cash loss on extinguishment of derivative liabilities of approximately \$2,463,000, non-cash stock-based compensation of approximately \$1,942,000 and losses on foreign currency transactions and issuance of preferred stock of approximately \$151,000 and \$90,000, respectively.

#### Net Cash Used in Investing Activities

Net cash used in investing activities was approximately \$26,000 for the nine months ended September 30, 2014 as compared to \$0 for the same period last year primarily due to the purchase of software for our German subsidiary, which was established in 2013.

#### Net Cash Provided by Financing Activities

Net cash provided by financing activities was approximately \$8,349,000 for the nine months ended September 30, 2014 as compared to approximately \$2,343,000 for the same period last year. The increase was attributable to the net

proceeds from the sale of common stock of approximately \$6,723,000 and Series C-3 preferred stock of approximately \$1,319,000, and exercise of stock options of approximately \$309,000. In comparison, for the same period last year, we received gross proceeds from the sale of 8% senior convertible notes of approximately \$1,373,000, proceeds from the sale of Series A and Series B preferred stock of \$1,033,000, proceeds from exercise of warrants of \$60,000, offset by repurchase of outstanding warrants of \$33,000 and payment of deferred financing costs of \$90,000.

#### Funding Requirements

Our total cash on hand as of September 30, 2014 was approximately \$5,920,000 compared to approximately \$2,374,000 at December 31, 2013. Because our business does not generate positive operating cash flow, we may need to raise additional capital before we exhaust our current cash resources in order to continue to fund our planned commercialization of Neutrolin and our research and development, as well as to fund operations generally. Our continued operations will depend on whether we are able to generate substantial revenue from the sale of Neutrolin or raise additional funds through various potential sources, such as equity and/or debt financings, strategic relationships, out-licensing or distribution arrangements of our products. Through September 30, 2014, all of our financing has been through equity financing of common stock and warrants, issuance of convertible notes and issuance of preferred stock.



Based on current assumptions about sales of Neutrolin and the development plans for Neutrolin, we believe that our existing cash at September 30, 2014 will be sufficient to fund our operations through the third quarter of 2015. However, our continued operations beyond the third quarter of 2015, including the commencement of our planned Phase III trial for Neutrolin in hemodialysis patients in the U.S., will depend on our ability to generate substantial revenue from the sale of Neutrolin and on our ability to raise additional capital through various potential sources, such as equity and/or debt financings, strategic relationships, or out-licensing of our products. However, we can provide no assurances on future sales of Neutrolin or that financing or strategic relationships will be available on acceptable terms, or at all. If we are unable to raise sufficient capital, find strategic partners or generate substantial revenue from the sale of Neutrolin, there would be a material adverse effect on our business. Further, we expect in the future to incur additional expenses as we continue to commercialize Neutrolin in Europe and other foreign markets, protect our intellectual property and seek FDA approval of Neutrolin in the U.S.

We expect to continue to fund operations from cash on hand and through either capital raising sources as previously described, which may be dilutive to existing stockholders, or through generating revenues from the licensing of our products or strategic alliances. We plan to seek additional debt and/or equity financing, but can provide no assurances that such financing will be available on acceptable terms, or at all. Moreover, the incurrence of indebtedness in connection with a debt financing would result in increased fixed obligations and could also result in covenants that would restrict our operations. Our actual cash requirements may vary materially from those now planned, however, because of a number of factors including the changes in the focus and direction of our research and development programs, the acquisition and pursuit of development of new product candidates, competitive and technical advances, costs of commercializing any of our product candidates, and costs of filing, prosecuting, defending and enforcing any patent claims and any other intellectual property rights.

While we expect to grow product sales substantially, we may not be able to do so and may not generate significant product sales revenue for 2014. In the absence of such revenue, we would experience continuing operating cash flow losses. We expect to incur increases in our cash used in operations over the next several quarters as we continue to commercialize Neutrolin and seek FDA approval of Neutrolin in the U.S.

#### 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 ("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 31, 2014, we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our reported financial results and affect the more significant judgments and estimates that we use in the preparation of our financial statements.

#### Stock-Based Compensation

We account for stock options according to the FASB ASC No. 718, "Compensation — Stock Compensation" ("ASC 718"). Under ASC 718, share-based compensation cost is measured at grant date, based on the estimated fair value of the award, and is recognized as expense net of expected forfeitures, 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 in accordance with ASC 718. The non-cash charge to operations for non-employee options with vesting is based upon the change in the fair value of the options and amortized to expense over the related vesting period.

For the purpose of valuing options and warrants granted to our directors, officers, employees and consultants, we used the Black-Scholes option pricing model. For the purpose of valuing performance based options granted to non-employees, we use the guidelines in accordance with FASB ASC No. 505-50 (“ASC 505”), “Equity-Based Payments to Non-Employees”, of which if the performance condition is 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 we believe it is probable that the performance condition will be achieved. To determine the risk-free interest rate, we utilize 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 estimate 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 is 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. The estimation of the number of stock awards that will ultimately vest requires judgment, and to the extent actual results or updated estimates differ from our current estimates, compensation expense may need to be revised. We consider many factors when estimating expected forfeitures for stock awards granted to employees, officers and directors, including types of awards, employee class, and an analysis of our historical forfeitures.

## Revenue Recognition

We recognize revenue in accordance with SEC SAB No. 101, “Revenue Recognition in Financial Statements” (“SAB 101”), as amended by SAB No. 104, “Revenue Recognition” (“SAB 104”) and FASB ASC 605, “Revenue Recognition” (“ASC 605”). Our product Neutrolin received its CE Mark in Europe in July 2013 and shipment of product to the dialysis centers began in December 2013. In accordance with SAB 101 and SAB 104, we recognize revenue from product sales when the following four revenue recognition criteria are met: persuasive evidence of an arrangement exists, delivery has occurred, the selling price is fixed or determinable, and collectability is reasonably assured. We recognize revenue upon shipment of product to the dialysis centers because the four revenue recognition criteria are met at that time.

In August, 2014, we entered into a distribution agreement with Wonik Corporation, a South Korean company, to market, sell and distribute Neutrolin for hemodialysis and oncolytic patients upon receipt of regulatory approval in Korea. Upon execution of the agreement, Wonik paid to us a non-refundable \$50,000 payment and will pay an additional \$50,000 upon receipt of the product registration necessary to sell Neutrolin in the Republic of Korea. Revenue associated with the non-refundable up-front payment under this arrangement is deferred and recognized as revenue on a straight-line basis over the contractual term of our agreement.

## Embedded Derivative Liabilities and Warrant Liabilities:

We do not use derivative instruments to hedge exposures to cash flow, market or foreign currency risks; however, we have several series of preferred stock and warrants that contain embedded derivatives. We evaluate all our financial instruments to determine if those instruments or any potential embedded components of those instruments qualify as derivatives that need to be separately accounted for in accordance with FASB ASC 815, “Derivatives and Hedging”. Embedded derivatives satisfying certain criteria are recorded at fair value at issuance and marked-to-market at each balance sheet date with the change in the fair value recorded as income or expense. In addition, upon the occurrence of an event that requires the derivative liability to be reclassified to equity, the derivative liability is revalued to fair value at that date.

We account for stock warrants as either equity instruments or derivative liabilities depending on the specific terms of the warrant agreement. Stock warrants that allow for cash settlement or provide for certain modifications of the warrant exercise price are accounted for as derivative liabilities. For those liability-classified warrants that have down-round provisions which allow the exercise price to be adjusted as a result of certain future financing transactions, we use level 3 inputs to value those warrants. The estimated fair values of the warrant liabilities with downround protection were determined using a Monte Carlo option pricing model which takes into account the probabilities of certain events occurring over the life of the warrants. The derivative liabilities are adjusted to their estimated fair values at each reporting period, with any decrease or increase in the estimated fair value being recorded in other income (expense). The warrants issued in March 2014, which do not have downround protection, were valued using a Black Scholes option pricing model.

## Recently Adopted Accounting Standards

In June 2014, the FASB issued Accounting Standards Update No. 2014-10, Development Stage Entities (Topic 915) – Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation (ASU 2014-10). ASU 2014-10 eliminates the concept of a development stage entity in its entirety from current accounting guidance. The new guidance eliminates the requirements for development stage entities to (i) present inception-to-date information in the statement of operations, stockholders’ equity and cash flows, (ii) label the financial statements as those of a development stage entity, (iii) disclose a description of the development stage activities in which the entity is engaged, and (iv) disclose in the first year in

which the entity is no longer a development stage entity that in prior years it had been in the development stage. ASU 2014-10 is effective prospectively for public entities for annual reporting periods beginning after December 15, 2015, and interim periods within those annual periods, however early adoption is permitted. We evaluated and elected to adopt ASU 2014-10 as permitted, beginning with the quarter ended June 30, 2014 and, accordingly, have not included the inception-to-date disclosures and other previously required disclosures for development stage entities.

Recent Authoritative Pronouncements:

In May 2014, the FASB issued new guidance related to how an entity should recognize revenue. The guidance specifies that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods and services. In addition, the guidance expands the required disclosures related to revenue and cash flows from contracts with customers. The guidance is effective for us beginning in the first quarter of 2017. Early adoption is not permitted and retrospective application is required. We are currently evaluating the impact of adopting this guidance on our consolidated financial condition, results of operations and cash flows.

In June 2014, the FASB issued an accounting standard that clarifies the accounting for share-based payments when the terms of an award provide that a performance target could be achieved after the requisite service period. The standard requires that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. The amendments are effective for interim and annual reporting periods beginning after December 15, 2015. Earlier adoption is permitted. The standard may be applied prospectively to all awards granted or modified after the effective date; or retrospectively to all awards with performance targets that are outstanding as of the beginning of the earliest annual period presented in the financial statements and to all new or modified awards thereafter. We are currently evaluating the impact of adopting this guidance on our consolidated financial condition, results of operations and cash flows.

#### Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

#### Item 4. Controls and Procedures.

As previously reported in our Annual Report on Form 10-K for the year ended December 31, 2013, we have 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, or the Exchange Act) related to our limited finance staff and the resulting ineffective management review over financial reporting, coupled with increasingly complex accounting treatments associated with our financing activities and European expansion. We have taken initial measures to remediate this weakness by increasing internal review processes, in addition to the previously established accounting oversight committee, which is comprised of members of our senior management and third party GAAP advisor. The hiring of our full-time Chief Financial Officer was a key step in bolstering our financial infrastructure. We continue to build on our infrastructure to address this weakness. However, we cannot be assured that this weakness will be remediated or that other material weaknesses will not be discovered.

#### Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures are designed only to provide reasonable assurance that information to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. As of the end of the period covered by this report, our management, including our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures. Based on their evaluation of our disclosure controls and procedures, and as a result of the material weakness described above, our management, including our principal executive officer and principal financial officer, have concluded that our disclosure controls and procedures were not effective as of September 30, 2014 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. As noted above, management is taking steps to improve the internal review process, to add accounting support, and is committed to the remediation of the material weakness.

#### Changes in Internal Control Over Financial Reporting

During the three months ended September 30, 2014, 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.

On September 9, 2014, we filed in the Mannheim, Germany District Court a patent infringement action against TauroPharm GmbH and Tauro-Implant GmbH as well as their respective CEOs (the "Defendants") claiming infringement of our European Patent EP 1 814 562 B1, which was granted by the European Patent Office on January 8, 2014 (the "Prosl Patent"). The Prosl patent covers a low heparin catheter lock solution for maintaining patency and preventing infection in a hemodialysis catheter. In this action, we claim that the Defendants infringe on the Prosl Patent by manufacturing and distributing catheter locking solutions to the extent they are covered by the claims of the Prosl Patent. We believe that our patent is sound, and we are seeking injunctive relief and raising claims for information, rendering of accounts, calling back, destruction, compensation and damages. An oral hearing in this action has been scheduled for 30 January 2015. Separately, TauroPharm has filed an opposition with the European Patent Office against the Prosl Patent alleging that it lacks novelty and inventive step. We cannot predict what other defenses the Defendants may raise, or the ultimate outcome of either of these related matters.

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

During the quarter ended September 30, 2014, Randy Milby, our CEO, converted \$42,500 of his wages into 22,225 shares of the Company's common stock at per share prices of \$1.71 to \$2.00, which were the closing prices of our common stock as reported on the NYSE MKT on its respective payroll dates. The shares of common stock were sold in a transaction exempt from registration under the Securities Act of 1933, as amended, in reliance on Section 4(a)(2) thereof.

Item 6. Exhibits.

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

E x h i b i t Number	Description
<u>31.1</u>	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
<u>31.2</u>	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
<u>32.1</u>	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.*
<u>32.2</u>	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, 2014, formatted in Extensible Business Reporting Language (XBRL): (i) Condensed Consolidated Balance Sheets at September 30, 2014 and December 31, 2013, (ii) Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2014 and 2013, (iii) Condensed Consolidated Statements of Changes in Stockholders' Equity (Deficit) for the nine months ended September 30, 2014, (iv) Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2014 and 2013, and (v) Notes to the Unaudited Condensed Consolidated Financial Statements.**

\*

Filed herewith.

\*\*

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



SIGNATURES

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

CORMEDIX INC.

Date: November 13, 2014                      By: /s/ Randy Milby  
Name: Randy Milby  
Title: Chief Executive Officer  
(Principal Executive Officer)

Date: November 13, 2014                      By: /s/ Harry O'Grady  
Name: Harry O'Grady  
Title: Chief Financial Officer  
(Principal Financial and Accounting  
Officer)

EXHIBIT INDEX

Exhibit Description

Number

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