

CorMedix Inc.  
Form 10-Q  
August 06, 2015

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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 June 30, 2015

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 001-34673

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

Delaware  
(State or Other  
Jurisdiction of  
Incorporation or  
Organization)

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

1430 US 07921  
Highway 206,  
Suite 200,  
Bedminster, 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 August 3, 2015 was 34,232,044.

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## CORMEDIX INC.

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## PART I

## FINANCIAL INFORMATION

## Item 1. Consolidated Financial Statements.

## CORMEDIX INC. AND SUBSIDIARY

## CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

	June 30, 2015	December 31, 2014
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$24,110,836	\$4,339,540
Restricted cash	131,994	-
Short-term investments	13,377,077	-
Trade receivables	112,872	80,183
Inventories, net	715,049	463,029
Other prepaid expenses and current assets	298,546	155,210
Total current assets	38,746,374	5,037,962
Property and equipment, net	44,652	41,458
Security deposit	5,000	18,342
<b>TOTAL ASSETS</b>	<b>\$38,796,026</b>	<b>\$5,097,762</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities		
Accounts payable	\$1,141,629	\$893,385
Accrued expenses	761,121	521,525
Deferred revenue	9,025	10,477
Total current liabilities	1,911,775	1,425,387
Deferred revenue, long term	33,391	37,903
<b>TOTAL LIABILITIES</b>	<b>1,945,166</b>	<b>1,463,290</b>
<b>COMMITMENTS AND CONTINGENCIES</b>		
<b>STOCKHOLDERS' EQUITY</b>		
Preferred stock - \$0.001 par value: 2,000,000 shares authorized; 450,085 and 949,948 shares issued and outstanding at June 30, 2015 and December 31, 2014, respectively	450	950
Common stock - \$0.001 par value: 80,000,000 shares authorized; 34,212,044 and 22,461,668 shares issued and outstanding at June 30, 2015 and December 31, 2014, respectively	34,212	22,461
Deferred stock issuances	(110 )	(110 )
Accumulated other comprehensive income	92,704	98,972
Additional paid-in capital	122,560,439	79,716,265
Accumulated deficit	(85,836,835 )	(76,204,066)

TOTAL STOCKHOLDERS' EQUITY	36,850,860	3,634,472
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$38,796,026	\$5,097,762

See Notes to Unaudited Condensed Consolidated Financial Statements.

CORMEDIX INC. AND SUBSIDIARY  
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS  
AND COMPREHENSIVE INCOME (LOSS)  
(Unaudited)

	For the Three Months Ended June 30, 2015	For the Three Months Ended June 30, 2014	For the Six Months Ended June 30, 2015	For the Six Months Ended June 30, 2014
<b>Revenue:</b>				
Net sales	\$ 119,973	\$ 39,729	\$ 151,237	\$ 51,932
Cost of sales	(101,798 )	(54,479 )	(119,117 )	(135,505 )
Gross profit (loss)	18,175	(14,750 )	32,120	(83,573 )
<b>Operating Expenses:</b>				
Research and development	(1,797,588 )	(171,929 )	(3,032,103 )	(524,947 )
Selling, general and administrative	(2,355,176 )	(1,703,041 )	(6,631,531 )	(4,215,750 )
Total Operating Expenses	(4,152,764 )	(1,874,970 )	(9,663,634 )	(4,740,697 )
Loss From Operations	(4,134,589 )	(1,889,720 )	(9,631,514 )	(4,824,270 )
<b>Other Income (Expense):</b>				
Interest income	8,778	987	9,321	1,508
Foreign exchange transaction loss	(5,597 )	(20,520 )	(6,026 )	(28,158 )
Loss on issuance of preferred stock, convertible notes and warrants	-	-	-	(89,590 )
Change in fair value of derivative liabilities	-	5,419,056	-	(8,262,513 )
Interest expense	(3,692 )	(513 )	(4,550 )	(978 )
Net Income (Loss)	(4,135,100 )	3,509,290	(9,632,769 )	(13,204,001 )
<b>Other Comprehensive Income (Loss):</b>				
Unrealized loss from investments	(5,504 )	-	(5,504 )	-
Foreign currency translation gain (loss)	(3,574 )	9,344	(764 )	7,983
Comprehensive Income (Loss)	(4,144,178 )	3,518,634	(9,639,037 )	(13,196,018 )
Net income (loss)	(4,135,100 )	3,509,290	(9,632,769 )	(13,204,001 )
Dividends, including beneficial conversion feature	-	(27,453 )	(33,121 )	(54,602 )
Net Income (Loss) Attributable To Common Shareholders	\$(4,135,100 )	\$3,481,837	\$(9,665,890 )	\$(13,258,603 )
Net Income (Loss) Per Common Share – Basic	\$(0.13 )	\$0.12	\$(0.35 )	\$(0.64 )
Weighted Average Common Shares Outstanding – Basic	31,623,100	21,993,384	27,793,627	20,636,671
Net Loss Per Common Share – Diluted	\$(0.13 )	\$(0.05 )	\$(0.35 )	\$(0.64 )
Weighted Average Common Shares Outstanding – Diluted	31,623,100	25,439,799	27,793,627	20,636,671

See Notes to Unaudited Condensed Consolidated Financial Statements.

## CORMEDIX INC. AND SUBSIDIARY

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

For the Six Months Ended June 30, 2015

	Common Shares	Stock Amount	Non-Voting Preferred Stock – Series C-2, Series C-3, Series D and Series E Shares	Deferred Stock Amount	Accumulated Other Comprehensive Income	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity	
Balance at January 1, 2015	22,461,668	\$22,461	949,948	\$950	\$(110)	\$98,972	\$79,716,265	\$(76,204,066)	\$3,634,472
Conversion of Series B non-voting preferred stock to common stock	454,546	455	(454,546)	(455)		-		-	
Conversion of Series C-3 non-voting preferred stock to common stock	425,000	425	(42,500)	(42)		(383)		-	
Conversion of Series E non-voting preferred stock to common stock	61,598	62	(2,817)	(3)		(59)		-	
Stock issued in connection with warrants exercised	4,581,783	4,581				14,653,579		14,658,160	
Stock issued in connection with warrants cashless exercised	2,158,033	2,158				(2,158)		-	
Stock issued in connection with stock options exercised	454,955	455				452,005		452,460	



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Stock issued in connection with sale of common stock	3,603,733	3,604					23,978,671		23,982,275
Stock issued in connection with conversion of wages	10,728	11					49,989		50,000
Value of warrants issued in connection with backstop financing							1,583,252		1,583,252
Modification of warrant agreement							112,982		112,982
Short swing profit recovery							28,594		28,594
Stock-based compensation							1,987,702		1,987,702
Other comprehensive income (loss)							(6,268 )		(6,268 )
Net loss								(9,632,769 )	(9,632,769 )
Balance at June 30, 2015	34,212,044	\$34,212	450,085	\$450	\$(110)	\$92,704	\$122,560,439	\$(85,836,835)	\$36,850,860

See Notes to Unaudited Condensed Consolidated Financial Statements.

CORMEDIX INC. AND SUBSIDIARY  
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS  
(Unaudited)

	For the Six Months Ended June 30, 2015	For the Six Months Ended June 30, 2014
<b>Cash Flows From Operating Activities:</b>		
Net loss	\$(9,632,769 )	\$(13,204,001)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,987,702	1,775,753
Value of warrants issued in connection with backstop financing	1,583,252	-
Modification of warrant agreement	112,982	-
Loss on foreign currency transactions	-	28,158
Loss on issuance of warrants and preferred stock	-	89,590
Revaluation of derivative liabilities	-	8,262,513
Depreciation	7,115	1,112
Changes in operating assets and liabilities:		
Restricted cash	(131,994 )	220,586
Trade receivables	(39,960 )	(52,941 )
Inventory	(252,021 )	(198,028 )
Prepaid expenses and other current assets	(133,475 )	35,979
Accounts payable	256,298	(62,660 )
Accrued expenses and accrued interest	301,656	170,715
Deferred revenue	(5,964 )	(2,197 )
Net cash used in operating activities	(5,947,178 )	(2,935,421 )
<b>Cash Flows From Investing Activities:</b>		
Purchase of short-term investments	(13,382,581)	-
Purchase of equipment	(13,797 )	(19,613 )
Net cash used in investing activities	(13,396,378)	(19,613 )
<b>Cash Flows From Financing Activities:</b>		
Proceeds from Series C-3 preferred stock, net	-	743,884
Proceeds from Series C-3 preferred stock, related party	-	575,000
Proceeds from sale of common stock from an at-the-market program	23,982,275	-
Proceeds from exercise of warrants	14,658,160	-
Proceeds from exercise of stock options	452,460	213,650
Proceeds from short swing profit recovery	28,594	-
Payments for deferred financing costs	-	(2,366 )
Proceeds from sale of equity securities	-	6,723,248
Net cash provided by financing activities	39,121,489	8,253,416
Foreign exchange effect on cash	(6,637 )	(20,431 )
Net Increase In Cash	19,771,296	5,277,951
Cash – Beginning of Period	4,339,540	2,373,893
Cash – End of Period	\$24,110,836	\$7,651,844
Cash Paid for Interest	\$1,026	\$970

See Notes to Unaudited Condensed Consolidated Financial Statements.



## CORMEDIX INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS  
(Unaudited)

	For the Six Months Ended June 30, 2015	For the Six Months Ended June 30, 2014
Supplemental Disclosure of Non-Cash Financing Activities:		
Conversion of preferred stock to common stock	\$ 500	\$2,447,384
Conversion of accounts payable and accrued expenses to preferred stock	\$-	\$645,458
Reclassification of derivative liabilities to equity	\$-	\$6,235,398
Conversion of wages to common stock	\$50,000	\$5,000
Dividends, including beneficial conversion feature	\$33,121	\$54,602

See Notes to Unaudited Condensed Consolidated Financial Statements.

CORMEDIX INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 1 — Organization, Business and Basis of Presentation:

Organization and Business

CorMedix Inc. (“CorMedix” or the “Company”) was incorporated in the State of Delaware on July 28, 2006. The Company seeks to in-license, develop and commercialize prophylactic and therapeutic products for the prevention and treatment of infectious diseases in cardiac, renal and oncology patients. In 2013, the Company formed a wholly owned subsidiary, CorMedix Europe GmbH.

The Company’s primary activities since incorporation have been organizational activities, including recruiting personnel, establishing office facilities, acquiring licenses for its pharmaceutical product candidates, performing business and financial planning, performing research and development, seeking regulatory approval for its products and conducting initial commercialization activities for its product Neutrolin® in certain markets. The Company has in-licensed all of the product candidates in its pipeline.

The Company received CE Mark approval for Neutrolin in 2013 and began the commercial launch of Neutrolin in Germany for the prevention of catheter-related bloodstream infections and maintenance of catheter patency in hemodialysis patients using a tunneled, cuffed central venous catheter for vascular access. To date, Neutrolin is registered and may be sold in Austria, Germany, Italy, Malta, Saudi Arabia, Bahrain, Qatar, Kuwait and The Netherlands.

In September 2014, the TUV-SUD and The Medicines Evaluation Board of the Netherlands granted a label expansion for Neutrolin for expanded indications for the European Union (EU). In December 2014, the Company received approval from the Hessian District President in Germany to expand the label to include use in oncology patients receiving chemotherapy, intravenous (“IV”), hydration and IV medications via central venous catheters. The expansion also adds patients receiving medication and IV fluids via central venous catheters in intensive or critical care units (cardiac care unit, surgical care unit, neonatal critical care unit, and urgent care centers). An indication for use in total parenteral nutrition was also approved.

The Company plans to initiate a Phase 3 clinical trial in hemodialysis catheters in the U.S. in the fourth quarter of 2015 and a Phase 3 clinical trial in oncology/total parenteral nutrition in the second quarter of 2016. In January 2015, the U.S. Food and Drug Administration (“FDA”) granted Fast Track designation to Neutrolin® Catheter Lock Solution, pursuant to the Food and Drug Administration Safety and Innovation Act (FDASIA). Fast Track designation is granted to drug products designed to treat a serious condition, for which clinical data has been generated and shown to potentially address an unmet medical need. The Fast Track designation of Neutrolin provides the Company with the opportunity to meet with the FDA on a more frequent basis during the review process, and also ensures an expedited review of any marketing application.

The FDA designated Neutrolin as a Qualified Infectious Disease Product (QIDP) for oncology, hemodialysis, and critical care/intensive care patients, where catheter-related blood stream infections and clotting can be life-threatening in January 2015. The QIDP designation will make Neutrolin eligible to benefit from certain incentives such as FDA priority review, fast-track status and it also provides an additional five years of market exclusivity in addition to the five years granted for a New Chemical Entity under Hatch-Waxman patent exclusivity.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”) for interim financial information and with the instructions for Form 10-Q and Article 10 of Regulation S-X. Accordingly, these unaudited condensed consolidated financial statements do not include all information and footnotes required by GAAP for complete annual financial statements. In the opinion of management, the accompanying unaudited condensed consolidated financial statements reflect all adjustments, consisting of normal recurring adjustments, considered necessary for a fair presentation of such interim results. Interim operating results are not necessarily indicative of results that may be expected for the full year ending December 31, 2015 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 for the year ended December 31, 2014, which are included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2014 (the “2014 Form 10-K”) filed with the Securities and Exchange Commission (the “SEC”) on March 12, 2015. The accompanying condensed balance sheet as of December 31, 2014 has been derived from the audited financial statements included in the 2014 Form 10-K.

CORMEDIX INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 2 — Summary of Significant Accounting Policies:

Liquidity, Risks and Uncertainties

The Company's operations are subject to a number of factors that can affect its operating results and financial condition. Such factors include, but are not limited to: the results of clinical testing and trial activities of the Company's product candidates; the ability to obtain regulatory approval to market the Company's products; competition from products manufactured and sold or being developed by other companies, the price of, and demand for, Company products; the Company's ability to negotiate favorable licensing or other manufacturing and marketing agreements for its products; and the Company's ability to raise capital.

To date, the Company has not generated significant commercial revenues. Based on the current development plans for Neutrolin in both the United States ("U.S.") and foreign markets (including the planned Phase 3 clinical trials in the U.S.) and on the current revenue assumptions for Neutrolin in approved markets, management believes that the existing cash will be sufficient to fund its operations for at least the next 12 months following the balance sheet date.

The Company's continued operations, including the completion of its planned Phase 3 clinical trials for Neutrolin in hemodialysis and oncology/total parenteral nutrition patients in the U.S., will depend on its ability to raise additional capital through potential sources such as equity and/or debt financings, strategic relationships, out-licensing or distribution arrangements of its products and its ability to generate substantial revenue from sales of Neutrolin. However, the Company can provide no assurances that such financing or strategic relationships will be available on acceptable terms, or at all, or that the Company will achieve substantial levels of revenue from sales of Neutrolin. If the Company is unable to raise sufficient capital or find strategic partners, there would be a material adverse effect on its business. Further, the Company expects to incur increases in its cash used in operations as it continues to commercialize Neutrolin, increases its business development activities, incurs additional legal costs to defend its intellectual property and seeks FDA approval of Neutrolin in the U.S.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make certain 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.

## CORMEDIX INC. AND SUBSIDIARY

## NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

## Basis of Consolidation

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

## Cash and Cash Equivalents

The Company considers all highly liquid instruments with an original maturity of 90 days or less at the time of purchase to be cash equivalents. Cash and cash equivalents consist of deposits and other interest bearing accounts, the balances of which, at times, may exceed federally insured limits.

## Short-Term Investments

The Company determines the appropriate classification of marketable securities at the time of purchase and reevaluates such designation as of each balance sheet date. Investments in marketable debt and equity securities classified as available-for-sale are reported at fair value. Fair values of the Company's investments are determined using quoted market prices in active markets for identical assets or liabilities or quoted prices for similar assets or liabilities or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. Changes in fair value that are considered temporary are reported net of tax in other comprehensive income (loss). Realized gains and losses, amortization of premiums and discounts and interest and dividends earned are included in income (expense) on the condensed consolidated statements of operations and comprehensive income (loss). The cost of investments for purposes of computing realized and unrealized gains and losses is based on the specific identification method. For declines in the fair value of equity securities that are considered other-than-temporary, impairment losses are charged to other (income) expense, net. The Company considers available evidence in evaluating potential impairments of its investments, including the duration and extent to which fair value is less than cost and, for equity securities, the Company's ability and intent to hold the investments.

The Company's marketable securities are highly liquid and consist of U.S. government agency securities, high-grade corporate obligations and commercial paper with original maturities of more than 90 days. As of June 30, 2015, all of the Company's investments had contractual maturities which were less than one year. The following table summarizes the amortized cost, unrealized gains and losses and the fair value at June 30, 2015 of the Company's financial assets that are measured on a recurring basis:

	Amortized Cost	Gross Unrealized Losses	Gross Unrealized Gains	Fair Value
Money Market Funds included in Cash Equivalents	\$8,582,883	\$-	\$-	\$8,582,883
US Government Agency Securities	1,507,470	(360 )	-	1,507,110
Corporate Securities	10,876,000	(6,683 )	1,539	10,870,856
Commercial Paper	999,111	-	-	999,111
Subtotal	13,382,581	(7,043 )	1,539	13,377,077
	\$21,965,464	\$(7,043 )	\$1,539	\$21,959,960





## CORMEDIX INC. AND SUBSIDIARY

## NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

## Fair Value Measurements

The Company's financial instruments recorded in the consolidated balance sheets include cash and cash equivalents, accounts receivable, investment securities, accounts payable and accrued expenses. The carrying value of certain financial instruments, primarily cash and cash equivalents, accounts receivable, accounts payable, and accrued expenses approximate their estimated fair values based upon the short-term nature of their maturity dates.

The Company categorizes its financial instruments into a three-level fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The fair value hierarchy gives the highest priority to quoted prices in active markets for identical assets (Level 1) and the lowest priority to unobservable inputs (Level 3). If the inputs used to measure fair value fall within different levels of the hierarchy, the category level is based on the lowest priority level input that is significant to the fair value measurement of the instrument. Financial assets recorded at fair value on the Company's condensed consolidated balance sheets are categorized as follows:

Level 1 inputs—Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets.

Level 2 inputs— Significant other observable inputs (e.g., quoted prices for similar items in active markets, quoted prices for identical or similar items in markets that are not active, inputs other than quoted prices that are observable such as interest rate and yield curves, and market-corroborated inputs).

Level 3 inputs—Unobservable inputs for the asset or liability, which are supported by little or no market activity and are valued based on management's estimates of assumptions that market participants would use in pricing the asset or liability.

The following table provides the carrying value and fair value of the Company's financial assets measured at fair value on a recurring basis as of June 30, 2015:

	Carrying Value	Fair Value Measurement at June 30, 2015		
		Level 1	Level 2	Level 3
Money Market Funds	\$8,582,883	\$8,582,883	\$-	\$-
US Government Agency Securities	1,507,110	-	1,507,110	-
Corporate Securities	10,870,856	-	10,870,856	-
Commercial Paper	999,111	-	999,111	-
Subtotal	\$13,377,077	\$-	\$13,377,077	\$-
	\$21,959,960	\$8,582,883	\$13,377,077	\$-

## Foreign Currency Translation and Transactions

These condensed 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 year. Translation gains and losses are included in other comprehensive income (loss).

The Company has intercompany loans between the parent company based in New Jersey and its German subsidiary. Effective October 1, 2014, the Company assessed and determined that the intercompany loans outstanding are not expected to be repaid in the foreseeable future and the nature of the funding advanced is of a long-term investment nature. As such, beginning October 1, 2014, unrealized foreign exchange movements related to long-term intercompany loans are recognized in other comprehensive income (loss).

## CORMEDIX INC. AND SUBSIDIARY

## NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Foreign currency exchange transaction gain (loss) is the result of re-measuring transactions denominated in a currency other than the functional currency of the entity recording the transaction.

## Segment and Geographic Information

The Company operates in one business segment. The Company reported revenues of \$119,973 and \$151,237 for the three and six months ended June 30, 2015, respectively. Of the Company's revenues for the three and six months ended June 30, 2015, \$117,767 and \$146,825, respectively, were attributable to its European and Middle East operations, which are based in Germany. All of the Company's revenues of \$39,729 and \$51,932 for the three and six months ended June 30, 2014, respectively, were attributable to its European operations. Total assets at June 30, 2015 were \$38,796,026, of which \$37,816,669 were located in the United States, with the remainder in Germany. Net property and equipment at June 30, 2015 was \$44,652, of which \$13,065 was located in the United States, with the remainder located in Germany.

## 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, net

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:

	June 30, 2015	December 31, 2014
Raw materials	\$247,625	\$293,976
Work in process	460,945	166,807
Finished goods	6,479	2,246
Total	\$715,049	\$463,029

The Company maintained an inventory reserve of \$175,000 at June 30, 2015 and December 31, 2014.

## CORMEDIX INC. AND SUBSIDIARY

## NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

## Accrued Expenses

Accrued expenses consist of the following:

	June 30, 2015	December 31, 2014
Professional and consulting fees	\$216,125	\$225,726
Accrued payroll and payroll taxes	195,078	13,393
Market research	162,345	137,345
Monitoring program fees	80,013	82,861
Statutory taxes	65,773	34,548
Other	41,787	27,652
Total	\$761,121	\$521,525

## Revenue Recognition

The Company recognizes revenue in accordance with SEC Staff Accounting Bulletin (“SAB”) No. 101, Revenue Recognition in Financial Statements, as amended by SAB No. 104, Revenue Recognition and Financial Accounting Standard Board (“FASB”) Accounting Standards Codification (“ASC”) 605, Revenue Recognition. 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. The Company recognizes net sales upon shipment of product.

## 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 South Korea (the “Territory”). 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 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.

## Income (Loss) Per Common Share

Basic loss per common share excludes any potential dilution and is computed by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted net loss per common share reflects 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.

For the three and six months ended June 30, 2015 and 2014, basic income (loss) per common share is calculated by dividing net income (loss) available to common shareholders by the number of weighted average common shares issued and outstanding. Diluted earnings (loss) per common share is calculated by dividing net income (loss)

available to common shareholders by the weighted average number of common shares issued and outstanding for the period, plus amounts representing the dilutive effect from the exercise of stock options and warrants and the conversion of convertible preferred stock, as applicable. The Company calculates dilutive potential common shares using the treasury stock method, which assumes the Company will use the proceeds from the exercise of stock options and warrants to repurchase shares of common stock to hold in its treasury stock reserves. 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.

## CORMEDIX INC. AND SUBSIDIARY

## NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

	June 30,	
	2015	2014
Series B non-voting convertible preferred stock	-	454,546
Series C non-voting convertible preferred stock	2,865,000	3,500,000
Series D non-voting convertible preferred stock	1,479,240	1,148,000
Series E non-voting convertible preferred stock	1,959,759	1,104,280
Shares underlying outstanding warrants	4,422,188	11,571,233
Shares underlying outstanding stock options	3,594,545	4,048,000
Total	14,320,732	21,826,059

Each outstanding series of convertible preferred stock is considered to be a participating security under ASC 260, Earnings Per Share (“ASC 260”), which means the security may participate in undistributed earnings with common stock. The holders of each series of convertible preferred stock are entitled to share in dividends, on an as-converted basis, if the holders of common stock were to receive dividends. In accordance with ASC 260, a company is required to use the two-class method when computing basic earnings per share when it has a security that qualifies as a “participating security.” The two-class method uses an earnings allocation formula that determines earnings per share for each class of common stock and participating securities according to dividends declared (or accumulated) and participation rights in undistributed earnings. In determining the amount of net earnings to allocate to common stock holders, earnings are allocated to both common and participating securities based on their respective weighted-average shares outstanding for the period. In accordance with ASC 260, securities are considered to not be participating in losses if there is no obligation to fund such losses. As such, the two class method is not required to be disclosed for periods with losses.

The following table is the calculation of the basic and diluted net income (loss) per share of common stock:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Income (Loss) Per Common Share - Basic:				
Net income (loss)	\$ 4,135,100	\$ 3,509,290	\$ 9,632,769	\$ (13,204,001)
Less: Dividends on participating securities	-	(27,453 )	(33,121 )	(54,602 )
Less: Net income allocated to participating securities	-	(766,348 )	-	-
Net income (loss) available to common shareholders - basic	\$ 4,135,100	\$ 2,715,489	\$ 9,665,890	\$ (13,258,603)
Weighted average common shares outstanding – basic	31,623,100	21,993,384	27,793,627	20,036,671
Net income (loss) per common share – basic	\$ (0.13 )	\$ 0.12	\$ (0.35 )	\$ (0.64 )

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## NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Income (Loss) Per Common Share - Diluted:				
Net income (loss) available to common shareholders - basic	\$ 4,135,100	\$ 2,715,490	\$ 9,665,890	\$ (13,258,603)
Plus: Dividends declared on participating securities	-	27,452	-	-
Plus: Net income allocated to participating securities	-	766,348	-	-
Less: Change in fair value of derivative securities	-	(4,657,481)	-	-
Numerator for income per share - diluted	\$ 4,135,100	\$ (1,148,191)	\$ 9,665,890	\$ (13,258,603)
Weighted average common shares outstanding – basic	31,623,100	21,993,384	27,793,627	20,036,671
Weighted average effect of dilutive securities:				
Exercise of warrants	-	1,194,135	-	-
Conversion of preferred stock to common stock	-	2,252,280	-	-
Weighted average common shares outstanding – diluted	31,623,100	25,439,799	27,793,627	20,036,671
Net loss per common share – diluted	\$ (0.13 )	\$ (0.05 )	\$ (0.35 )	\$ (0.64 )

Warrants and options if exercised, and convertible preferred stock if converted, that would result in the issuance of 16,073,779 and 21,826,059 shares of common stock for the three and six months ended June 30, 2014, respectively, and 14,320,732 for the three and six months ended June 30, 2015 were excluded from the computation of diluted earnings (loss) per share because they were anti-dilutive.

## Stock-Based Compensation

The Company accounts for stock options granted to employees, officers and directors according to 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 using the Black-Scholes option pricing model, and is recognized as expense net of expected forfeitures, over the employee’s requisite service period on a straight-line basis.

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 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 historical forfeitures.

The Company accounts for stock options granted to non-employees on a fair value basis using the Black-Scholes option pricing model in accordance with ASC 718 and ASC No. 505-50, “Equity-Based Payments to Non-Employees”



("ASC 505"). The non-cash charge to operations for non-employee options with time based vesting provisions is based on the fair value of the options at the balance sheet date and amortized to expense over the related vesting period.

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NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Research and Development

Research and development costs are charged to expense as incurred. Research and development costs include fees associated for operational consultants, contract clinical research organizations, contract manufacturing organizations, contract laboratory research organizations and contract central testing laboratories, licensing activities, clinical site fees, and allocated executive, human resources and facilities expenses, among others. The Company accrues for costs incurred as the services are being provided.

Note 3 — Stockholders' Equity

Common Stock

On April 8, 2015, the Company entered into an At-the-Market Issuance Sales Agreement (the "Sales Agreement") with MLV & Co. LLC ("MLV") under which the Company may issue and sell up to \$40.0 million of shares of its common stock from time to time through MLV acting as agent, subject to limitations imposed by the Company, such as the number or dollar amount of shares registered under the registration statement to which the offering relates. When the Company wishes to issue and sell common stock under the Sales Agreement, it notifies MLV of the number of shares to be issued, the dates on which such sales are anticipated to be made, any minimum price below which sales may not be made and other sales parameters as the Company deems appropriate. MLV is entitled to a commission of up to 3% of the gross proceeds from the sale of common stock sold under the Sales Agreement. The shares of common stock to be sold under the Sales Agreement are registered under an effective registration statement filed with the SEC. During the six months ended June 30, 2015, the Company issued 3,603,733 shares of common stock and realized net proceeds of approximately \$23,982,275.

During the six months ended June 30, 2015, the Company issued the following shares of its common stock, resulting in gross proceeds of \$14,658,160 to the Company:

150,000 shares of common stock upon exercise of warrants with an exercise price of \$0.90 per share;

125,000 shares of common stock upon exercise of warrants with an exercise price of \$0.40 per share;

353,500 shares of common stock upon exercise of warrants with an exercise price of \$2.50 per share; and

3,953,283 shares of common stock upon exercise of warrants with an exercise price of \$3.4375 per share.

During the six months ended June 30, 2015, the Company issued 2,158,033 shares of its common stock upon a cashless exercise of 2,597,591 warrants.

During the six months ended June 30, 2015, the Company issued 454,955 shares of its common stock upon exercise of an aggregate of 454,955 stock options at a weighted average exercise price of \$0.99 per share, resulting in gross proceeds of \$452,460 to the Company.

During the six months ended June 30, 2015, the Company issued 454,546 shares of its common stock upon conversion of 454,546 shares of the Series B non-voting preferred stock.

During the six months ended June 30, 2015, the Company issued an aggregate of 425,000 shares of its common stock upon conversion of an aggregate of 42,500 shares of the Series C-3 non-voting preferred stock.

## CORMEDIX INC. AND SUBSIDIARY

## NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

During the six months ended June 30, 2015, the Company issued 61,598 shares of its common stock upon conversion of 2,817 shares of the Series E non-voting preferred stock.

During the six months ended June 30, 2015, wages in an aggregate amount of \$50,000 were converted into 10,728 shares of its common stock by an officer of the Company at prices per share of \$3.10 - \$8.55.

## Preferred Stock and Warrants

Under the terms of the Company's Amended and Restated Certificate of Incorporation, as amended, the Company's board of directors is authorized to issue up to 2,000,000 shares of preferred stock in one or more series without stockholder approval. The Company's board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock. Of the 2,000,000 shares of preferred stock authorized, the Company's board of directors has designated (all with par value of \$0.001 per share) the following:

	As of June 30, 2015			As of December 31, 2014		
	Preferred Shares Outstanding	Liquidation Preference (Per Share)	Total Liquidation Preference	Preferred Shares Outstanding	Liquidation Preference (Per Share)	Total Liquidation Preference
Series B	-	\$-	\$-	454,546	\$0.001	\$ 455
Series C-2	150,000	10.000	1,500,000	150,000	10.000	1,500,000
Series C-3	136,500	10.000	1,365,000	179,000	10.000	1,790,000
Series D	73,962	21.000	1,553,202	73,962	21.000	1,553,202
Series E	89,623	49.200	4,409,452	92,440	49.200	4,548,048
Total	450,085		\$ 8,827,654	949,948		\$ 9,391,705

## Stock Options

During the six months ended June 30, 2015, the Company granted to its officers, directors and consultant, ten-year non-qualified stock options under the 2013 Plan, covering an aggregate of 440,000 shares of the Company's common stock. Of these options, 150,000 vested on the date of grant and had an exercise price of \$5.00 per share, 250,000 will vest one year after the grant date and had an exercise price of \$5.62 per share, 20,000 options with an exercise price of \$3.62 per share and the remaining 20,000 options with an exercise price of \$6.07 per share, will vest upon achievement of various performance milestones.

During the six months ended June 30, 2015 and 2014 total compensation expense was \$1,987,702 and \$1,775,753, respectively, and \$960,778 and \$360,509 for the three months ended June 30, 2015 and 2014, respectively.

The fair value of the grants at grant dates are determined using the Black-Scholes option pricing model with the following assumptions for the six months ended June 30, 2015:

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## NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Expected term (years)	4.5 – 10
Volatility	94%
Dividend yield	0.0%
Risk-free interest rate	1.47% - 2.18%
Weighted-average fair value of options granted during the period	\$ 3.90

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. Prior to 2015, the expected volatility used in the valuation of the Company's stock options was based on the historical volatility of publicly traded peer group companies due to the limited trading history of the Company's common stock. Beginning in the first quarter of 2015, the expected stock price volatility for the Company's stock options is calculated based on the historical volatility since the initial public offering of the Company's common stock in March 2010. 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.

At June 30, 2015, a summary of the Company's stock option activity and related information is as follows:

	Shares	Weighted Average Exercise Price
Outstanding at beginning of period	3,664,500	\$ 1.25
Exercised	(454,955 )	\$ 0.99
Forfeited	(55,000 )	\$ 1.83
Expired	-	\$-
Granted	440,000	\$ 5.34
Outstanding at end of period	3,594,545	\$ 1.77
Options exercisable	3,102,295	\$ 1.43
Expected to vest	414,475	\$ 3.88
Weighted average remaining contractual life of stock options outstanding (years)		8.2
Weighted average remaining contractual life of stock options exercisable (years)		8.0
Weighted average vesting period over which total compensation expense related to non-vested options not yet recognized (years)		0.7
Aggregate intrinsic value of stock options exercised		\$ 3,139,678
Aggregate intrinsic value of stock options outstanding		\$ 7,720,544
Compensation expense related to non-vested options not yet recognized		\$ 1,270,587

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 the end of the reporting period for those options that have an exercise price below the quoted closing price.



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## NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

## Warrants

On March 2, 2015, the Company's board of directors approved an extension to April 30, 2015 of the expiration date of the Company's publicly traded warrants which resulted in deemed dividend of \$33,121.

In March 2015, the Company issued two warrants exercisable for an aggregate of up to 283,400 common shares with an exercise price of \$7.00 per share and a term of five years as a result of entering into a backstop agreement with Manchester Securities Corp. ("Manchester") (See Note 4). Additionally, the expiration date of March 24, 2015 of warrants to purchase 390,720 shares of common stock issued to Manchester in connection with the Company's initial public offering ("IPO") was extended by one year to March 24, 2016. The Company recorded non-cash general and administrative expense of \$1,583,252 for these warrants using the Black-Scholes option pricing model with the following assumptions:

Expected term (years)	5
Volatility	75.81% - 104.08%
Dividend yield	0.0%
Risk-free interest rate	0.01% - 1.61%

During the six months ended June 30, 2015, the Company issued 774 warrants upon the exercise of a unit warrant related to the IPO. These warrants were subsequently exercised resulting in the issuance of 774 shares of common stock and gross proceeds of \$2,661 to the Company.

During the six months ended June 30, 2015, the Company extended the expiration date for an aggregate of 38,400 warrants with an exercise price of \$3.4375. The Company accounted for this transaction as a modification of warrants and recorded additional paid in capital and non-cash general and administrative expense in the amount of \$112,982. The warrants were valued using the Black-Scholes option pricing model with the following assumptions:

Expected term (days)	5
Volatility	88.17%
Dividend yield	0.0%
Risk-free interest rate	.003%

The following table is the summary of warrant activity for the six months ended June 30, 2015:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life
Outstanding at beginning of period	11,520,762	\$1.99	2.57
Granted	284,174	\$6.99	4.93
Expired	(203,374 )	\$3.44	-
Exercised	(7,179,374 )	\$2.27	-
Outstanding at end of period	4,422,188	\$1.80	2.50





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NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Short Swing Profit Recovery

In June 2015, a member of the board of directors of the Company paid a total of \$28,594 to the Company representing the disgorgement of short swing profits under Section 16(b) under the Exchange Act. The amount was recorded as additional paid in capital.

Note 4 — Related-Party Transactions:

On March 3, 2015, the Company entered into a backstop agreement with an existing institutional investor, Manchester, a wholly owned subsidiary of Elliott Associates, L.P., and a beneficial holder of more than 5% of the Company's outstanding common stock. Pursuant to the backstop agreement, Manchester agreed to lend the Company, at its request, up to \$4,500,000 less the dollar amount of gross proceeds received by the Company upon the exercise of warrants to purchase common stock issued in connection with its IPO on or before April 30, 2015, provided that the loan could not exceed \$3,000,000. The Company had received approximately \$5.7 million through March 31, 2015 from the exercise of warrants issued in connection with its IPO therefore, the Company did not access the loan and the loan expired on April 30, 2015.

On April 7, 2015, the Company entered into a one year agreement with a consultant to advise management with their investment banking relationships and assist in the negotiations with potential external parties, if applicable. The consultant is a member of the board of directors of Sterling HSA which was founded by the Chairman of the Board of Directors of the Company. The arrangement calls for a \$30,000 retainer, a monthly fee of \$6,000, and a multiple of the price per share upon a merger or acquisition or a percentage of any strategic partnership. Either party can terminate the agreement with a 30 day advance notice. Upon termination, the Company is liable for any services rendered through the termination date.

Note 5 — Commitments and Contingencies:

Contingency Matters

In February 2007, Geistlich Söhne AG für Chemische Industrie, Switzerland ("Geistlich") brought an action against the European Sodemann Patent covering the Company's Neutrolin product candidate, which is owned by ND Partners, LLC ("NDP") and licensed to the Company pursuant to the License and Assignment Agreement between the Company and NDP. The action that was brought at the Board of the European Patent Office ("EPO") opposition division (the "Opposition Board") 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 of the prior art. The Opposition Board rejected the opposition by Geistlich. On August 27, 2008, Geistlich appealed the court's ruling, alleging the same arguments as presented during the opposition proceedings. The Company filed a response to the appeal of Geistlich on March 25, 2009 requesting a dismissal of the appeal and maintenance of the patent as granted. On November 28, 2012, the Board of Appeals of the EPO (the "Appeals Board") held oral proceedings and verbally upheld the counterpart of the Sodemann Patent covering Neutrolin, but remanded the proceeding to the lower court to consider restricting certain claims of the counterpart of the Sodemann Patent. The Company received the Appeals Board's 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 EPO reopened the proceedings before the first instance and gave their preliminary non-binding opinion that the patent as amended during the appeal proceedings fulfills 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 Opposition Board 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. On November 5, 2014, the Opposition Division at the EPO issued the interlocutory decision to maintain the patent on the basis of the claims as amended during the appeal proceedings. This decision became final because no further appeal was lodged by Geistlich by January 15, 2015.

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On September 9, 2014, the Company 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 the Company’s European Patent EP 1 814 562 B1, which was granted by the EPO on January 8, 2014 (the “Prosl European Patent”). The Prosl European Patent covers a low dose heparin catheter lock solution for maintaining patency and preventing infection in a hemodialysis catheter. In this action, the Company claims that the Defendants infringe on the Prosl European Patent by manufacturing and distributing catheter locking solutions to the extent they are covered by the claims of the Prosl European Patent. The Company believes that its patent is sound, and is seeking injunctive relief and raising claims for information, rendering of accounts, calling back, destruction and damages. Separately, TauroPharm has filed an opposition with the EPO against the Prosl European Patent alleging that it lacks novelty and inventive step. The Company cannot predict what other defenses the Defendants may raise, or the ultimate outcome of either of these related matters.

In the same complaint against the same Defendants, the Company also alleged an infringement (requesting the same remedies) of NDP’s utility model DE 20 2005 022 124 U1 (the “Utility Model”), which the Company believes is fundamentally identical to the Prosl European Patent in its main aspects and claims. The Mannheim court separated the two proceedings and the Prosl European Patent and the Utility Model claims are now being tried separately. TauroPharm has filed a cancellation action against the Utility Model before the German Patent and Trademark Office based on the similar arguments as those in the opposition against the Prosl European Patent.

On March 27, 2015, the Mannheim District Court held a hearing to evaluate whether the Utility Model has been infringed by TauroPharm in connection with the manufacture, sale and distribution of its TauroLock-HEP100TM and TauroLock-HEP500TM products. A hearing before the same court was held on January 30, 2015 on the separate, but related, question of infringement of the Prosl European Patent by TauroPharm.

The District Court of Mannheim issued its decisions on May 8, 2015 staying both proceedings. In its decisions, the Court found that the commercialization by TauroPharm in Germany of its TauroLock catheter lock solutions Hep100 and Hep500 infringes both the Prosl European Patent and the Utility Model and further that there is no prior use right that would allow TauroPharm to continue to make, use or sell its product in Germany. However, the Court declined to issue an injunction in favor of the Company that would preclude the continued commercialization by TauroPharm based upon its finding that there is a sufficient likelihood that the European Patent Office (“EPO”), in the case of the Prosl European Patent, or the German Patent and Trademark Office (the “German PTO”), in the case of the Utility Model, may find that such patent or utility model is invalid. Specifically, the Court noted the possible publication of certain instructions for product use that may be deemed to constitute prior art. As such, the District Court determined that it will defer any consideration of the request by the Company for injunctive and other relief until such time as the EPO or the German PTO has ruled on the underlying validity of the Prosl European Patent and the Utility Model.

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NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Both the opposition proceedings against the Prosl European Patent before the EPO and the cancellation action against the Utility Model before the German PTO are ongoing. The EPO has scheduled a hearing for the end of 2015. The Company does not expect a decision from the EPO before the end of 2015, and that decision would be subject to appeal. However, in its preliminary consideration of the matter, the EPO (and the German Patent and Trademark office) regarded the patent as not inventive or novel due to publication of prior art. While the Company continues to believe that the referenced publication and instructions for use do not, in fact, constitute prior art and that the Prosl European Patent and the Utility Model validly claim inventions that will be found to be such by the EPO and the German PTO, there can be no assurance that the Company will prevail in this matter. The Company does not expect a decision from the German PTO in the Utility Model matter before late 2015, with any such decision also being subject to appeal.

On January 16, 2015, the Company filed a complaint against TauroPharm GmbH and its managing directors in the District Court of Cologne, Germany. In the complaint, the Company alleges violation of the German Unfair Competition Act by TauroPharm for the unauthorized use of its proprietary information obtained in confidence by TauroPharm. The Company alleges that TauroPharm is improperly and unfairly using its proprietary information relating to the composition and manufacture of Neutrolin, in the manufacture and sale of TauroPharm's products TauroLock™, TauroLock-HEP100 and TauroLock-HEP500. The Company seeks a cease and desist order against TauroPharm from continuing to manufacture and sell any product containing taurolidine (the active pharmaceutical ingredient ("API") of Neutrolin) and citric acid in addition to possible other components, damages for any sales in the past and the removal of all such products from the market. A hearing in this matter was scheduled for July 2, 2015, but was postponed by the Court. A new hearing date has not yet been issued.

In connection with the aforementioned proceedings against TauroPharm, the Company was required by the District Court Mannheim to provide a security deposit of approximately \$132,000----- to cover legal fees in the event TauroPharm is entitled to reimbursement of these costs. The Company recorded the deposit as restricted cash for the six months ended June 30, 2015. The Company will shortly have to provide a deposit in the amount of €36,000 in connection with the unfair competition proceedings in Cologne.

Commitments

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 supply taurolidine (the API for CRMD003) to the Company on an exclusive worldwide basis in the field of the prevention and treatment of human infection and/or dialysis so long as the Company purchased a minimum of \$350,000 of product from Navinta by December 30, 2010, which the Company achieved, and following the Company's first commercial sale of a product incorporating taurolidine, purchases a minimum of \$2,250,000 of product on an annual basis for five years. The Company did not purchase the required amount in 2014 and as a result, lost its exclusive manufacturing rights. The Company is also required to make certain cash payments to Navinta upon the achievement of certain sales-based milestones which is based on a tiered approach and does not commence until the Company achieves a designated net sales threshold. The maximum aggregate amount of such payments, assuming achievement of all milestones, is \$1,975,000 over five years.



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On March 24, 2015, the Company and Navinta LLC entered into an amendment to the Taurolidine Supply Agreement to extend the term of the Agreement to March 31, 2016 and to lower the price per kilogram of API that the Company purchases from Navinta LLC under the Navinta Agreement. The Company also agreed to purchase a minimum amount of product from Navinta LLC during 2015, which replaces the prior minimum purchase requirement. The Navinta Agreement may be terminated by either party upon 30 days written notice.

In 2008, the Company entered into a License and Assignment Agreement (the “NDP License Agreement”) with NDP. Pursuant to the NDP License Agreement, NDP granted the Company 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”). The Company acquired such licenses and patents through its assignment and assumption of NDP’s rights under certain separate license agreements by and between NDP and Dr. Hans-Dietrich Polaschegg, Dr. Klaus Sodemann and Dr. Johannes Reinmueller. 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 a 5% equity interest in the Company, consisting of 39,980 shares of the Company’s common stock.

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 is 145,543 shares. During the year ended December 31, 2014, a certain milestone was achieved resulting in the release of 36,386 shares held in escrow. The number of shares held in escrow as of June 30, 2015 is 109,157 shares of common stock. The maximum aggregate amount of cash payments upon achievement of milestones is \$3,000,000 with \$2,500,000 remaining at June 30, 2015. Events that trigger milestone payments include but are not limited to the reaching of various stages of regulatory approval and upon achieving certain worldwide net sales amounts.

On April 11, 2013, the Company entered into an amendment to the NDP License Agreement. Under Article 6 of the NDP License Agreement as the Company was obligated to make a milestone payment of \$500,000 to NDP upon the first issuance of a CE Marking for a licensed product, which payment was payable to NDP within 30 days after such issuance. 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, anytime within 12 months after the achievement of such issuance. As consideration for the amendment, the Company issued NDP a warrant to purchase 125,000 shares of the Company’s common stock at an exercise price of \$1.50 per share. The warrant is exercisable immediately upon issuance and has a term of five years. In January 2014, the Company settled this milestone payment which resulted in the issuance of 50,000 shares of the Company’s Series C-3 non-voting convertible preferred and 250,000 shares issuable upon exercise of warrants at an exercise price of \$1.25 per share which was decreased to \$0.90 per share. Through June 30, 2015, no other milestone payments have been earned by or paid to NDP.

The NDP License Agreement may be terminated by the Company on a country-by-country basis upon 60 days prior written notice. If the NDP License Agreement is terminated by either party, the Company’s rights to the NDP Technology will revert back to NDP.

On April 9, 2015, the Company announced a program aimed at reducing the cost of goods of Neutrolin through a more efficient, custom synthesis of the active ingredient taurolidine. As part of that program, on April 8, 2015, the Company entered into a Preliminary Services Agreement with [RC]2 Pharma Connect LLC (“RC2”), pursuant to which

RC2 will coordinate certain manufacturing services related to taurolidine, which is a key ingredient in Neutrolin. Specifically, RC2 will undertake a critical parameters evaluation for the Company's manufacturing needs and coordinate the cGMP processes set forth in the agreement that the Company believe are necessary for the submission of its planned new drug application for Neutrolin to the FDA, as well as any foreign regulatory applications. The total cost for RC2's services under the preliminary services agreement is approximately \$1.7 million which is expected to be incurred under the terms of this agreement through the first quarter of 2016. To date, the Company has paid RC2 approximately \$380,000 for their services related to this agreement. If Neutrolin is approved for use in the U.S., to the extent that cGMP validation batches of taurolidine called for under the agreement are completed and in compliance with cGMP, those batches may be available for inclusion in Neutrolin as commercial product available for sale. The Company and RC2 are also in the process of negotiating a manufacturing services agreement. RC2 also agreed to an expected price per kilogram for taurolidine for any future commercial supply agreement the Company may negotiate with RC2.

## CORMEDIX INC. AND SUBSIDIARY

## NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

The Company is also working with RC2 under a service agreement for the manufacture of clinical supplies to support its Phase 3 clinical trials. The Company may terminate this agreement upon 30 days written notice and is only obligated for project costs and reasonable project shut down costs provided through that date.

The Company entered into sublease for 4,700 square feet of office space in Bedminster, New Jersey, which sublease runs from April 1, 2015 until March 31, 2018. Rent is \$5,000 per month plus occupancy costs such as utilities, maintenance and taxes. In accordance with the lease agreement, the Company has deposited \$5,000 with the landlord, the equivalent of one month rent.

The Company's subsidiary entered into a lease agreement for its offices in Fulda, Germany with ITZ GmbH. The lease has a term of 36 months which commenced on September 1, 2013 for a base monthly payment of €498. The total 36 month lease obligation is approximately €17,900 (\$20,000).

Under the Company's current lease agreements, the total remaining lease obligation as of June 30, 2015 is set forth below:

2015	\$33,733
2016	66,236
2017	60,784
2018	15,000
Total	\$175,753

Note 6 — Subsequent Events:

On July 7, 2015, a putative class action lawsuit was commenced against the Company and certain of its current and former officers in the United States District Court for the District of New Jersey, captioned Li v. Cormedix Inc., et al., Case 3:15-cv-05264. The complaint asserts claims that the Company and the individual defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder and Section 20(a) of the Exchange Act. Plaintiff alleges generally that the defendants made materially false or misleading statements and omissions concerning, among other things, the Company's Neutrolin product, the alleged use of stock promoters and alleged sales of stock by Company insiders. The complaint seeks unspecified damages, interest, attorneys' fees, and other costs. The Company believes that it has substantial legal and factual defenses to the claims in the class action and intends to vigorously defend the case.



CORMEDIX INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

On July 17, 2015, the Company's Board of Directors announced that it will seek a successor to Randy Milby as Chief Executive Officer. The Company has begun an executive search for a senior executive with more substantial regulatory, clinical and reimbursement experience. Mr. Milby is expected to continue to serve as Chief Executive Officer during the interim period and to remain as a member of the Board of Directors.

In anticipation of the termination of Mr. Milby's employment, the Company entered into a Release of Claims and Severance Modification with Mr. Milby. In exchange for the release of various claims by Mr. Milby against the Company, including claims related to his employment with Company and the termination of same and claims for additional compensation or benefits other than the compensation and benefits set forth in his employment agreement, the Company agreed to amend Mr. Milby's employment agreement, dated as of March 31, 2014, to specify that Mr. Milby may not compete against the Company by engaging in any business involving the development or commercialization of (i) a preventive anti-infective product that would be a direct competitor of Neutrolin or (ii) a product containing taurodine. The non-compete term did not change and remains at 12 months following termination of his employment. The employment agreement was also amended to allow Mr. Milby a period in which to exercise all vested options and warrants until the later of 60 months following the termination date of his employment or 60 months following the date on which his service on the Company's Board of Directors ends, provided in no event shall he be able to exercise after the respective expiration date of any stock option or warrant.

Pursuant to the terms of his employment agreement, Mr. Milby will be entitled to receive his base salary and benefits for a period of 12 months following the effective date of the termination of his employment, or, in the case of benefits, until such time as he receives equivalent coverage and benefits under plans and programs of a subsequent employer. In addition, all shares of restricted stock and all unvested options to purchase shares of Company capital stock then held by Mr. Milby will be accelerated and deemed to have vested as of the effective date of the termination of his employment. To the extent any of the aforementioned benefits cannot be provided to former employees, the Company will pay Mr. Milby a lump-sum payment in the amount necessary to allow Mr. Milby to purchase the equivalent benefits.

## 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 Annual Report on Form 10-K for the year ended December 31, 2014, filed with the Securities and Exchange Commission (the "SEC"), on March 12, 2015.

### 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 (the "Exchange Act"). Forward-looking statements are often identified by the use of words such as, but not limited to, "anticipate," "believe," "can," "continue," "could," "estimate," "expect," "intend," "may," "will," "plan," "project," "seek," "s," "would," and similar expressions or variations intended to identify forward-looking statements. Examples of forward looking statements contained in this report include statements regarding the following: our product development and commercialization plans for Neutrolin, including with respect to clinical trials and plans to obtain regulatory approval in the U.S. and commercialization efforts in Europe and other foreign markets; our expectation that research and development and selling, general and administrative expenses will increase in the future; our expectation that we may continue to experience operating losses for the foreseeable future; the cost, timing and effect on our business of pending litigation; valuation of stock options and warrants; the expected impact of recent accounting pronouncements and guidance on our financial statements; and the period of time through which our financial resources will be adequate to support our operations. 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 discussed in this report, 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, 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. and Subsidiary (referred to herein as "we," "us," "our" and the "Company"), is a commercial pharmaceutical and medical device company. We seek to 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 have the worldwide rights to develop and commercialize our product candidates, CRMD003 (Neutrolin®) and CRMD004, which 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 Neutrolin, a catheter lock solution, for the prevention of catheter-related infections and thrombosis in the central venous catheter markets such as dialysis, critical care, and oncology. Catheter related blood stream infections cause extensive morbidity and mortality, prolonged hospital stays and cost the U.S. healthcare system over \$11 billion per year. Neutrolin is a novel formulation of taurolidine, citrate and heparin 1000 u/ml that provides a combination preventative solution to decrease the development of biofilm in order to reduce infection and

thrombosis and thereby keep catheters operating optimally in clinical settings in hemodialysis, critical care/intensive care and oncology. Our initial target market for Neutrolin was hemodialysis using a tunneled central vein catheter, and we launched Neutrolin as a medical device in our first geographical market, Germany, in December 2013.

According to the United States Renal Disease System, there were approximately 636,905 patients on dialysis in 2012. It has been reported that patients requiring catheter represent over 127 million catheter days annually. The market in the critical care/intensive care units is approximately 35 million catheter days per year in the United States alone. There were over 13 million patients living with cancer in the United States in 2010 with an estimated 4 million having a long-term central venous catheter. However, when stages of disease, chemotherapy regimens and catheter types are factored, we believe the oncology market is approximately 43 million catheter days. Infection and thrombosis represent key complications among critical care/intensive care and cancer patients with central venous catheters. These complications can lead to treatment delays and increased costs to the healthcare system when they occur due to hospitalizations, need for intravenous (“IV”) antibiotic treatment, long-term anticoagulation therapy, removal/replacement of the central venous catheter, related treatment costs and increased mortality when they occur.

In July 2013, we received CE Mark approval for Neutrolin. As a result, in December 2013, we began the commercial launch of Neutrolin in Germany for the prevention of catheter-related bloodstream infections (“CRBI”), and maintenance of catheter patency in hemodialysis patients using a tunneled, cuffed central venous catheter for vascular access. To date, Neutrolin is registered and may be sold in Austria, Germany, Italy, Malta, Saudi Arabia, Bahrain, Qatar, Kuwait and The Netherlands for such treatment.

We have entered into agreements with human4farma, a German contract sales company, to market and sell Neutrolin for hemodialysis, critical care/intensive care and oncology patients in Germany and with Wonik Corporation, a South Korean company, to market, sell and distribute Neutrolin for hemodialysis, critical care/intensive care and oncology patients in that country upon receipt of regulatory approval. We also have independent sales representatives in The Netherlands, Austria and the Middle East.

In December 2014, we received approval from the Hessian District President in Germany to expand the label to include use in oncology patients receiving chemotherapy, intravenous, or IV, hydration and IV medications via central venous catheters. The expansion also adds patients receiving medication and IV fluids via central venous catheters in intensive or critical care units (cardiac care unit, surgical care unit, neonatal critical care unit, and urgent care centers). An indication for use in total parenteral nutrition was also approved. In September 2014, the TUV-SUD and The Medicines Evaluation Board of the Netherlands granted a label expansion for Neutrolin for these same expanded indications for the European Union (“EU”).

In late 2013, we met with the U.S. Food and Drug Administration (the “FDA”) to determine the pathway for U.S. approval of Neutrolin. Based on our discussions with the FDA, we expect to conduct at least one Phase 3 clinical trial in hemodialysis catheters and one Phase 3 clinical trial in oncology/total parenteral nutrition. We have worked with the FDA to design the protocol for a planned Phase 3 clinical trial in hemodialysis patients with a central venous catheter; this protocol was accepted in August 2014 and we filed an investigational new drug application (“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 3 clinical trial in hemodialysis patients can be initiated in the U.S. On June 17, 2015, we received guidance from the FDA on the acceptable design of the second pivotal Phase 3 trial in oncology/total parenteral nutrition patients and are working with the FDA to finalize the details. We plan to initiate the Phase 3 clinical trial in hemodialysis in the fourth quarter of 2015 and the Phase 3 trial in oncology in the second quarter of 2016 using our own resources, although we also plan to continue to seek one or more strategic partners or other sources of capital to complete the development of Neutrolin in the U.S.

In January 2015, the FDA granted Fast Track designation to Neutrolin® Catheter Lock Solution, pursuant to the Food and Drug Administration Safety and Innovation Act (FDASIA). Fast Track designation is granted to drug products designed to treat a serious condition, for which clinical data has been generated and shown to potentially address an unmet medical need. The Fast Track designation of Neutrolin provides us with the opportunity to meet with the FDA on a more frequent basis during the review process, and also ensures an expedited review of any marketing application.

The FDA designated Neutrolin as a Qualified Infectious Disease Product (QIDP) for oncology, hemodialysis, and critical care/intensive care patients, where catheter-related blood stream infections and clotting can be life-threatening in January 2015. The QIDP designation will make Neutrolin eligible to benefit from certain incentives such as FDA priority review, fast-track status and it also provides an additional five years of market exclusivity in addition to the five years granted for a New Chemical Entity under Hatch-Waxman patent exclusivity.

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, soft tissue 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.

We have the worldwide rights to develop and commercialize our product candidates, CRMD003 (Neutrolin) and CRMD004, which 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.

In March 2015, we commenced a process to evaluate our strategic alternatives in order to accelerate the global development of Neutrolin and maximize shareholder value. We engaged investment bank Evercore Group L.L.C. to provide financial advice and assist us with our evaluation process. As a result of the process with Evercore, we announced in July 2015 that we expect to continue to pursue product development and commercialization opportunities as we move forward with the planned Phase 3 clinical trials, rather than pursuing a possible sale of our company as this time. There can be no assurance that the exploration of strategic alternatives will result in any agreements or transactions, or that, if completed, any agreements or transactions will be successful or on attractive terms.

Since our inception, we have had not generated significant 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, initial commercialization activities for Neutrolin, 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 markets, increase our business development activities, incur additional legal costs to defend our intellectual property and seek FDA approval of Neutrolin in the U.S. As of June 30, 2015, we had an accumulated deficit of approximately \$86.0 million. 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 and other foreign markets 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.

### Deferred Revenue

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 South Korea (the “Territory”). 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 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.

### Research and Development Expense

Research and development (“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.

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

	Six Months Ended June 30,			
	2015		2014	
CRMD003 (Neutrolin)	98	%	98	%
CRMD004	2	%	2	%

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

Development timelines, probability of success and development costs vary widely. Our current focus is on clinical development efforts in the U.S. and optimization of sales in markets where Neutrolin is approved and gaining utilization. We are seeking to develop Neutrolin in the U.S. Based on our discussions with the FDA, we plan to conduct at least one Phase 3 clinical trial in hemodialysis catheters and, subject to finalization of the protocol, one Phase 3 clinical trial in oncology/total parenteral nutrition. We plan to initiate the Phase 3 clinical trial in hemodialysis catheters in the fourth quarter of 2015 and the Phase 3 trial in oncology/total parenteral nutrition in the second quarter of 2016 using our own resources, although we also plan to continue to seek one or more strategic partners or other sources of capital to complete the development of Neutrolin in the U.S. We currently estimate that the planned Phase 3 trial for hemodialysis will cost approximately \$19 million to \$22 million and will take 18 months to complete after initiation. We are still finalizing the details of the protocol for the planned second Phase 3 trial for oncology/total parenteral nutrition and are unable to provide a cost estimate at this time.

#### Selling, General and Administrative Expense

Selling, general and administrative ("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 and other markets, and as a result of the reporting obligations applicable to public companies.

#### Foreign Currency Exchange Transaction Gain (Loss)

Foreign currency exchange transaction gain (loss) is the result of re-measuring transactions denominated in a currency other than our functional currency and is reported in the consolidated statement of operations as a separate line item within other income (expense). In 2014, foreign currency exchange transaction gain (loss) consists of foreign exchange transaction gains and losses on intercompany loans that are in place between us, the parent company based in New Jersey and its German subsidiary. Effective October 1, 2014, we assessed and determined that the intercompany loans outstanding are not expected to be repaid in the foreseeable future and the nature of the funding advanced is of a long-term investment nature. As such, beginning October 1, 2014, unrealized foreign exchange movements related to long-term intercompany loans are recorded in other comprehensive income (loss).





#### Loss on Issuance of Preferred Stock and Warrants

We issued preferred stock and related warrants during the six months ended June 30, 2014. The loss on the issuance of preferred stock and related warrants represents the difference on the issuance date between the combined derivative related 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 Derivative Liabilities

As previously disclosed, we entered into consent and exchange agreements with investors holding our outstanding Series C-2, Series C-3, Series D, and Series E non-voting convertible preferred stock. We modified certain terms within the preferred stock which resulted in the reclassification of the remaining derivative liability to equity in September 2014.

The change in the fair value of derivative liabilities 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 were recorded at fair value on a recurring basis under accounting principles generally accepted in the United States (“GAAP”). 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.

#### Results of Operations

Three months ended June 30, 2015 compared to three months ended June 30, 2014

**Revenue.** Revenue was approximately \$120,000 for the three months ended June 30, 2015 compared to approximately \$40,000 in the prior year, an increase of approximately \$80,000. The majority of the revenue is from sales of Neutrolin in Germany and Middle East markets. In addition, we realized approximately \$2,000 associated with the amortization of deferred revenue from a non-refundable payment received from a distribution agreement.

**Cost of Sales.** Cost of sales was approximately \$102,000 for the three months ended June 30, 2015 compared to \$54,000 in the same period last year, an increase of approximately \$48,000. Cost of sales for the three months ended June 30, 2015 are primarily comprised of direct cost of materials of approximately \$65,000 and on-going stability studies of approximately \$35,000. Cost of sales for the three months ended June 30, 2014 was comprised of services performed in the management of our manufacturing of approximately \$27,000, on-going stability studies of approximately \$13,000, direct cost of materials of approximately \$9,000, costs associated with transitioning Neutrolin to new labels and packaging of approximately \$2,000 and other costs of approximately \$3,000.

**Research and Development Expense.** R&D expense was approximately \$1,798,000 for the three months ended June 30, 2015, an increase of approximately \$1,626,000, from approximately \$172,000 for the same period last year. The increase was primarily attributable to higher costs related to manufacturing process development activities of approximately \$524,000 to support the U.S. clinical trials, non-cash stock based compensation of approximately \$483,000, pharmacoeconomics, pricing and market research studies of approximately \$356,000, consulting fees of approximately \$195,000, and personnel cost of approximately \$43,000.

**Selling, General and Administrative Expense.** SG&A expense was approximately \$2,355,000 for the three months ended June 30, 2015, an increase of approximately \$652,000 from approximately \$1,703,000 for the same period last year. The increase was primarily attributable to increases in legal fees due mainly to ongoing intellectual property litigation of approximately \$248,000; costs related to business development activities of approximately \$183,000; non-cash stock-based compensation expense of approximately \$117,000; a non-cash charge of approximately

\$113,000 for modification of warrants and personnel costs of approximately \$96,000. These increases were offset by a decrease in costs related to commercialization of Neutrolin in the EU of approximately \$61,000 and a reduction in consulting fees of approximately \$45,000.

**Change in Fair Value of Derivative Liabilities.** The change in the fair value of derivative liabilities for the three months ended June 30, 2014 of approximately \$5,419,000 consists of decreases in the fair value of preferred stock conversion options and warrants between March 31, 2014 and June 30, 2014 of approximately \$1,924,000 and approximately \$3,495,000, 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 March 31, 2014 and the relevant conversion and redemption dates and (ii) the change in fair value of the preferred stock conversion options not converted between March 31, 2014 and June 30, 2014. Due to the modification of certain terms within the preferred stock which resulted in the reclassification of the remaining derivative liability to equity in September 2014, there was no charge to earnings for the three months ended June 30, 2015.

**Interest Income.** Interest income was approximately \$9,000 for the three months ended June 30, 2015 as compared to approximately \$1,000 for the same period last year, an increase of approximately \$8,000. The increase was attributable to higher interest-bearing cash balance during the second quarter of 2015 compared to the same quarter in 2014.

**Interest Expense.** Interest expense was approximately \$4,000 for the three months ended June 30, 2015 as compared to approximately \$500 for the same period last year, an increase of approximately \$3,500.

**Other Comprehensive Income (Loss).** Unrealized foreign exchange movements related to long-term intercompany loans and the translation of the foreign affiliate financial statements to U.S. dollars and unrealized movements related to short-term investment are recorded in other comprehensive income totaling approximately \$9,000 loss for the three months ended June 30, 2015.

Six months ended June 30, 2015 compared to six months ended June 30, 2014

**Revenue.** Revenue was approximately \$151,000 for the six months ended June 30, 2015 as compared to approximately \$52,000 for the same period last year, an increase of approximately \$99,000. The majority of the revenue is from sales of Neutrolin in Germany and Middle East markets. In addition, we realized approximately \$4,000 associated with the amortization of deferred revenue from a non-refundable payment received from a distribution agreement.

**Cost of Sales.** Cost of sales was approximately \$119,000 for the six months ended June 30, 2015 compared to \$136,000 in the same period last year, a decrease of approximately \$17,000. Cost of sales for the six months ended June 30, 2015 are primarily comprised of direct cost of materials of approximately \$67,000 and on-going stability studies of approximately \$50,000. Cost of sales for the six months ended June 30, 2014 are primarily comprised of costs associated with transitioning Neutrolin to new labels and packaging of approximately \$47,000, services performed in the management of our manufacturing of approximately \$44,000, on-going stability studies of approximately \$29,000, direct cost of materials of approximately \$12,000, and other costs of approximately \$4,000.

**Research and Development Expense.** R&D expense was approximately \$3,032,000 for the six months ended June 30, 2015, an increase of approximately \$2,507,000, from approximately \$525,000 for the same period last year. The increase was primarily attributable to non-cash stock based compensation of approximately \$760,000, pharmacoeconomics, pricing and market research studies of approximately \$703,000 to support the U.S. clinical trials, higher costs related to manufacturing process development activities of approximately \$607,000, consulting fees of approximately \$307,000, and personnel costs of approximately \$99,000.

**Selling, General and Administrative Expense.** SG&A expense was approximately \$6,632,000 for the six months ended June 30, 2015, an increase of approximately \$2,416,000 from approximately \$4,216,000 for the same period last year. The increase was primarily attributable to a non-cash charge for warrants issued in connection with the backstop agreement of approximately \$1,583,000. Additionally, there were increases in legal fees due mainly to ongoing intellectual property litigation of approximately \$497,000; costs related to business development activities of approximately \$362,000; personnel cost of approximately \$306,000 and a non-cash charge of approximately \$113,000 for modification of warrants. These increases were offset by a decrease in non-cash stock-based compensation expense of approximately \$548,000, costs related to commercialization of Neutrolin in the EU of approximately \$77,000 and a reduction in consulting fees of approximately \$49,000.

**Loss on Issuance of Preferred Stock, Convertible Notes and Warrants.** The loss on the issuance of preferred stock and warrants in the six months ended June 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. Due to the elimination of the downround protection of these derivative liabilities through an agreement modification in September 2014 which resulted in the reclassification of derivative liabilities to equity, there was no charge to earnings in the six months ended June 30, 2015.

**Change in Fair Value of Derivative Liabilities.** The change in the value of derivative liabilities for the six months ended June 30, 2014 of approximately \$8,263,000 consists of increases in the fair value of preferred stock conversion options and warrants between December 31, 2013 and June 30, 2014 of approximately \$6,758,000 and approximately \$1,505,000, 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 June 30, 2014. The change in fair value of the warrants is the difference between the fair value at December 31, 2013 and June 30, 2014. Due to the modification of certain terms within the preferred stock which resulted in the reclassification of the remaining derivative liability to equity in September 2014, there was no charge to earnings during the six months ended June 30, 2015.

**Interest Income.** Interest income was approximately \$9,000 for the six months ended June 30, 2015 as compared to approximately \$2,000 for the same period last year, an increase of approximately \$7,000. The increase was attributable to higher interest-bearing cash balance during the second quarter of 2015 compared to the same period in 2014.

**Interest Expense.** Interest expense was approximately \$5,000 for the six months ended June 30, 2015 as compared to approximately \$1,000 for the same period last year, an increase of approximately \$4,000.

**Other Comprehensive Income (Loss).** Unrealized foreign exchange movements related to long-term intercompany loans and the translation of the foreign affiliate financial statements to U.S. dollars and unrealized movements related to short-term investment are recorded in other comprehensive income totaling approximately \$6,000 loss for the six months ended June 30, 2015.

## 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.

During the six months ended June 30, 2015, we received net proceeds of approximately \$39,000,000 from the following:

- sale of our common stock in an at-the-market program resulting in the issuance of 3,603,733 shares of common stock at a weighted average price of \$6.90 per share;

- exercise of 4,581,783 warrants at a weighted average exercise price of \$3.20 per share, which resulted in the issuance of 4,581,783 shares of common stock; and

- exercise of 454,955 stock options at a weighted average exercise price of \$0.99 per share, which resulted in the issuance of 454,955 shares of common stock.

### Net Cash Used in Operating Activities

Net cash used in operating activities was approximately \$5,947,000 for the six months ended June 30, 2015 as compared to approximately \$2,935,000 for the same period last year. The net loss of approximately \$9,633,000 for the six months ended June 30, 2015 was higher than cash used in operating activities by approximately \$3,686,000. The difference is attributable primarily to a non-cash charge for warrants issued in connection with the backstop agreement of approximately \$1,583,000, non-cash stock-based compensation of approximately \$1,988,000, value of warrants related to the extension of the expiration date of approximately \$113,000. The net loss of approximately \$13,204,000 for the six months ended June 30, 2014 was higher than cash used in operating activities by approximately \$10,269,000. The difference is attributable primarily to revaluation of preferred stock conversion options and warrants of approximately \$8,263,000, non-cash stock-based compensation of approximately \$1,776,000 and loss on issuance of preferred stock of approximately \$90,000.

### Net Cash Used in Investing Activities

Cash used in investing activities for the six months ended June 30, 2015 was approximately \$13,396,000, attributable to the purchase of short-term investments as compared to approximately \$20,000 for the same period last year, due to the purchase of software for our German subsidiary.

### Net Cash Provided by Financing Activities

Net cash provided by financing activities was approximately \$39,121,000 for the six months ended June 30, 2015 as compared to approximately \$8,253,000 for the same period last year, an increase of approximately \$30,868,000. During the six months ended June 30, 2015, we received net proceeds of approximately \$23,982,000 from the sale of our common stock in an at-the-market program, approximately \$14,658,000 from the exercise of warrants and approximately \$452,000 from the exercise of stock options and approximately \$29,000 from short swing profit recovery, as compared to the net proceeds from the sale of common stock of approximately \$6,723,000, Series C-3 preferred stock of approximately \$1,319,000, and exercise of stock options of approximately \$214,000 for the same period last year.



## Funding Requirements

Our total cash on hand and short-term investments as of June 30, 2015 was approximately \$37,488,000 excluding restricted cash, compared to approximately \$4,340,000 at December 31, 2014. Because our business has not currently generated positive operating cash flow, we will need to raise additional capital before we exhaust our current cash resources in order to continue to fund our research and development activities and our business development activities, as well as to fund operations generally. Our continued operations and completion of the Phase 3 U.S. trials will depend on whether we are able to raise additional funds through various potential sources, such as equity, debt financings, strategic relationships, out-licensing or distribution arrangements of our products and our ability to generate substantial revenue from sales of Neutrolin. However, we can provide no assurances that financing or strategic relationships will be available on acceptable terms, or at all, or that we will achieve substantial levels of revenue from sales of Neutrolin.

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 currently have approximately \$15 million available under our at-the market program, however, we may seek to sell additional equity or debt securities, obtain a bank credit facility, or enter into a corporate collaboration or licensing arrangement, 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. Raising additional funds through collaboration or licensing arrangements with third parties may require us to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or to grant licenses on terms that may not be favorable to us or our stockholders. Our actual cash requirements may vary materially from those now planned, however, because of a number of factors including any change in the focus and direction of our research and development programs, any acquisition or 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 do not anticipate that we will generate significant product sales revenue for 2015. In the absence of such revenue, we would experience continuing operating cash flow deficits. We expect to incur increases in our cash used in operations as we continue to commercialize Neutrolin in Europe and other foreign markets, increase our business development activities, incur additional legal costs to defend our intellectual property and seek FDA approval of Neutrolin in the U.S.

Based on our cash resources at June 30, 2015, our expectations on the current 2015 revenue assumptions for Neutrolin in the approved markets and the current development plans for Neutrolin in both the U.S. and foreign markets including the planned initiation of the Phase 3 clinical trial in hemodialysis catheters in the U.S. in the fourth quarter of 2015 and the planned initiation of the Phase 3 clinical trial in oncology/total parenteral nutrition in the U.S. in the second quarter of 2016, we believe that our existing cash will be sufficient to fund our operations for at least the next 12 months following the balance sheet date. We will need additional financing thereafter. If we are unable to raise additional funds when needed, we may not be able to complete our planned Phase 3 clinical trials or market our products and we could be required to delay, scale back or eliminate some or all of our research and development programs. Each of these alternatives would likely have a material adverse effect on our business and raise substantial doubt about our ability to continue as a going concern.

## Critical Accounting Policies

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

While our significant accounting policies are more fully described in our Annual Report on Form 10-K for the year ended December 31, 2014 filed with the SEC on March 12, 2015, 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 Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("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 model in accordance with ASC 718 and ASC No. 505-50, Equity-Based Payments to Non-Employees ("ASC 505"). 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 use 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 ASC 505. 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.

Valuations incorporate several variables, including expected term, expected volatility, expected dividend yield and a risk-free interest rate. We estimate the expected term of the options granted based on anticipated exercises in future periods. Prior to 2015, the expected volatility used in the valuation of our stock options was based on the historical volatility of publicly traded peer group companies due to the limited trading history of our common stock. Beginning in the first quarter of 2015, the expected stock price volatility for our stock options is calculated based on the historical volatility since the initial public offering of our common stock in March 2010. The expected dividend yield reflects our current and expected future policy for dividends on our common stock. 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.



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. For an upfront payment related to an exclusive distribution agreement, we record it as deferred revenue and recognize revenue on a straight-line basis over the contractual term of the agreement.

#### Inventory Valuation

We engage third parties to manufacture and package inventory held for sale and warehouse such goods until packaged for final distribution and sale. Inventories are stated at the lower of cost or market price with cost determined on a first-in, first-out basis. Inventories are reviewed periodically to identify slow-moving or obsolete inventory based on sales activity, both projected and historical, as well as product shelf-life. In evaluating the recoverability of our inventories, we consider the probability that revenue will be obtained from the future sale of the related inventory and, if required, will write down inventory quantities in excess of expected requirements. Expired inventory is disposed of and the related costs are recognized as cost of product sales in our consolidated statements of operations.

We analyze our inventory levels to identify inventory that may expire prior to sale, inventory that has a cost basis in excess of its estimated realizable value, or inventory in excess of expected sales requirements. Although the manufacturing of our products is subject to strict quality controls, certain batches or units of product may no longer meet quality specifications or may expire, which would require adjustments to our inventory values.

In the future, reduced demand, quality issues or excess supply beyond those anticipated by management may result in an adjustment to inventory levels, which would be recorded as an increase to cost of product sales. The determination of whether or not inventory costs will be realizable requires estimates by our management. A critical input in this determination is future expected inventory requirements based on our internal sales forecasts which we then compare to the expiry dates of inventory on hand. To the extent that inventory is expected to expire prior to being sold, we will write down the value of inventory. If actual results differ from those estimates, additional inventory write-offs may be required.

#### Short-Term Investments

We determine the appropriate classification of marketable securities at the time of purchase and reevaluates such designation as of each balance sheet date. Investments in marketable debt and equity securities classified as available-for-sale are reported at fair value. Fair values of our investments are determined using quoted market prices in active markets for identical assets or liabilities or quoted prices for similar assets or liabilities or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. Our marketable securities are highly liquid and consist of U.S. government agency securities, high-grade

corporate obligations and commercial paper with maturities of more than 90 days but less than 12 months. Changes in fair value that are considered temporary are reported net of tax in other comprehensive income (loss). Realized gains and losses, amortization of premiums and discounts and interest and dividends earned are included in income (expense) on the condensed consolidated statements of operations and comprehensive income (loss). The cost of investments for purposes of computing realized and unrealized gains and losses is based on the specific identification method. Investments with maturities beyond one year, if any, are classified as short-term based on management's intent to fund current operations with these securities or to make them available for current operations. For declines, if any, in the fair value of equity securities that are considered other-than-temporary, impairment losses are charged to other (income) expense, net. We consider available evidence in evaluating potential impairments of its investments, including the duration and extent to which fair value is less than cost and, for equity securities, our ability and intent to hold the investments.

## Fair Value Measurements

We categorize our financial instruments into a three-level fair value hierarchy that prioritize the inputs to valuation techniques used to measure fair value. The fair value hierarchy gives the highest priority to quoted prices in active markets for identical assets (Level 1) and the lowest priority to unobservable inputs (Level 3). If the inputs used to measure fair value fall within different levels of the hierarchy, the category level is based on the lowest priority level input that is significant to the fair value measurement of the instrument. Financial assets recorded at fair value on our condensed consolidated balance sheets are categorized as follows:

Level 1 inputs—Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets.

Level 2 inputs— Significant other observable inputs (e.g., quoted prices for similar items in active markets, quoted prices for identical or similar items in markets that are not active, inputs other than quoted prices that are observable such as interest rate and yield curves, and market-corroborated inputs).

Level 3 inputs—Unobservable inputs for the asset or liability, which are supported by little or no market activity and are valued based on management's estimates of assumptions that market participants would use in pricing the asset or liability.

## 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.

In April 2015, the FASB issued ASU 2015-03 – Simplifying the Presentation of Debt Issuance Costs , which requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. This ASU requires retrospective adoption and will be effective for us beginning in the first quarter of 2016. Early adoption is permitted. We do not expect this adoption to have a material impact on our financial statements.

In July 2015, the FASB issued ASU 2015-11, “Simplifying the Measurement of Inventory,” (“ASU 2015-11”). ASU 2015-11 requires inventory be measured at the lower of cost and net realizable value and options that currently exist for market value be eliminated. ASU 2015-11 defines net realizable value as estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The guidance is effective for reporting periods beginning after December 15, 2016 and interim periods within those fiscal years with early adoption permitted. ASU 2015-11 should be applied prospectively. We are evaluating the impact the adoption of this guidance will have on the determination or reporting of our financial results.

#### Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

#### Item 4. Controls and Procedures.

##### Evaluation of Disclosure Controls and Procedures

Under the supervision of our principal executive officer and principal financial officer, we evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of June 30, 2015. Although we have taken actions toward remediating our material weakness in internal control over financial reporting, we believe that the material weakness was not fully remediated as of June 30, 2015. Based on that evaluation, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were not effective as of June 30, 2015 to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely discussion regarding required disclosures.

##### Changes in Internal Control Over Financial Reporting

Our management previously determined that as of December 31, 2014, we had a material weakness in our internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act) 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. Although we have taken actions toward remediating our material weakness in internal control over financial reporting (as disclosed in Form 10-K for the year ended December 31, 2014), we believe that the material weakness was not fully remediated as of June 30, 2015.

There were no additional changes in our internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act during the quarter ended June 30, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.



PART II  
OTHER INFORMATION

Item 1. Legal Proceedings.

On July 7, 2015, a putative class action lawsuit was commenced against us, John C. Houghton, Brian Lenz, Richard M. Cohen, Randy Milby, Steven Lefkowitz and Harry O'Grady in the United States District Court for the District of New Jersey, captioned *Li v. Cormedix Inc., et al.*, Case 3:15-cv-05264. The complaint in this action asserts claims, purportedly on behalf of a class of persons who purchased or acquired our stock between March 12, 2011 and June 29, 2015, that we and the individual defendants, who are current or former officers of our company, violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder and Section 20(a) of the Exchange Act. Plaintiff alleges generally that the defendants made materially false or misleading statements and omissions concerning among other things, our Neutrolin product, the alleged use of stock promoters and alleged sales of stock by our insiders. The complaint seeks unspecified damages, interest, attorneys' fees, and other costs. We and the individual defendants intend to vigorously defend the case.

Item 1A. Risk Factors.

An investment in our stock involves a high degree of risk. You should carefully consider the risks set forth in the Risk Factors section of our Annual Report on Form 10-K for the year ended December 31, 2014. In addition, you should also consider the risk factor set forth below, which amends and supplements the risks set forth in the Risk Factors section of our Annual Report.

Risks Related to Our Business and Industry

We are subject to a putative securities class action, which may require significant management time and attention and significant legal expenses and may result in an unfavorable outcome, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

We and certain of our officers have been named as defendants in a putative securities class action lawsuit that generally alleges that we and certain of our current and former officers violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder and Section 20(a) of the Exchange Act by making materially false or misleading statements and omissions concerning among other things, our Neutrolin product, the alleged use of stock promoters and alleged sales of stock by our insiders. While we believe that we have substantial legal and factual defenses to the claims in the class action and intend to vigorously defend the case, this lawsuit could divert management's attention from our ordinary business operations, the outcome of the pending litigation is difficult to predict and quantify, and the defense against the underlying claims could be costly. The ultimate resolution of this matter could result in payments of monetary damages or other costs, materially and adversely affect our business, financial condition, results of operations and cash flows, or adversely affect our reputation, and consequently, could negatively impact the trading price of our common stock.

We have various insurance policies related to the risks associated with our business, including directors' and officers' liability insurance policies. However, there is no assurance that our insurance coverage will be sufficient or that our insurance carriers will cover all claims in that litigation. If we are not successful in our defense of the claims asserted in the putative class action and those claims are not covered by insurance or exceed our insurance coverage, we may have to pay damage awards, indemnify our officers from damage awards that may be entered against them and pay the costs and expenses incurred in defense of, or in any settlement of, such claims.

In addition, there is the potential for additional shareholder litigation, and we could be similarly materially and adversely affected by such matters.

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

During the three months ended June 30, 2015, Randy Milby, our CEO, elected pursuant to his employment agreement with us to receive \$31,250 of his compensation in the form of 5,590 unregistered shares of our common stock. The deemed per share prices were between \$3.88 and \$8.55, corresponding to the closing prices of our common stock as reported on NYSE MKT on the dates on which Mr. Milby acquired the shares. 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 5. Other Information

On July 17, 2015, our Board of Directors announced that it will seek a successor to Randy Milby as Chief Executive Officer. We have begun an executive search for a senior executive with more substantial regulatory, clinical and reimbursement experience. Mr. Milby is expected to continue to serve as Chief Executive Officer during the interim period and to remain as a member of the Board of Directors.

In anticipation of the termination of Mr. Milby's employment, on August 3, 2015, we entered into a Release of Claims and Severance Modification with Mr. Milby. In exchange for the release of various claims by Mr. Milby against us, including claims related to his employment with us and the termination of same and claims for additional compensation or benefits other than the compensation and benefits set forth in his employment agreement, we agreed to amend Mr. Milby's employment agreement, dated as of March 31, 2014, to specify that Mr. Milby may not compete against us by engaging in any business involving the development or commercialization of (i) a preventive anti-infective product that would be a direct competitor of Neutrolin or (ii) a product containing tauroloidine. The non-compete term did not change and remains at 12 months following termination of his employment. The employment agreement was also amended to allow Mr. Milby a period in which to exercise all vested options and warrants until the later of 60 months following the termination date of his employment or 60 months following the date on which his service on our Board of Directors ends, provided in no event shall he be able to exercise after the respective expiration date of any stock option or warrant.

Pursuant to the terms of his employment agreement, Mr. Milby will be entitled to receive his base salary and benefits for a period of 12 months following the effective date of the termination of his employment, or, in the case of benefits, until such time as he receives equivalent coverage and benefits under plans and programs of a subsequent employer. In addition, all shares of restricted stock and all unvested options to purchase shares of our capital stock then held by Mr. Milby will be accelerated and deemed to have vested as of the effective date of the termination of his employment. To the extent any of the aforementioned benefits cannot be provided to former employees, we will pay Mr. Milby a lump-sum payment in the amount necessary to allow Mr. Milby to purchase the equivalent benefits.





## Item 6. Exhibits.

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

## Exhibit Description

## Number

4.1	Warrant to Purchase Common Stock issued March 25, 2015 to Kingsbrook Opportunities Master Fund LP (incorporated by reference to Exhibit 4.25 to CorMedix Inc.'s Registration Statement on Form S-3 filed on April 9, 2015).
<u>10.1</u> *	Preliminary Services Agreement dated April 8, 2015, between CorMedix Inc. and [RC]2 Pharma Connect LLC.
<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 June 30, 2015, formatted in Extensible Business Reporting Language (XBRL): (i) Condensed Consolidated Balance Sheets at June 30, 2015 and December 31, 2014, (ii) Condensed Consolidated Statements of Operations and Comprehensive Income (Loss) for the three and six months ended June 30, 2015 and 2014, (iii) Condensed Consolidated Statements of Changes in Stockholders' Equity for the six months ended June 30, 2015, (iv) Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2015 and 2014, and (v) Notes to the Unaudited Condensed Consolidated Financial Statements.

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\*Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the SEC.

\*\*Furnished herewith and not deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act.

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

SIGNATURES

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

CORMEDIX INC.

Date: August 6, 2015

By: /s/ Randy Milby  
Name: Randy Milby  
Title: Chief Executive Officer  
(Principal Executive Officer)

Date: August 6, 2015

By: /s/ Harry O'Grady  
Name: Harry O'Grady  
Title: Chief Financial Officer  
(Principal Financial and Accounting  
Officer)

## EXHIBIT INDEX

## E x h i b i t Description

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