CorMedix Inc.
Form 10-Q
November 12, 2015

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

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

For the quarterly period ended September 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	20-5894890
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
1430 US Highway 206, Suite 200, Bedminster, NJ	07921
(Address of Principal Executive Offices)	(Zip Code)

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

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

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

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

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ý

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

The number of shares outstanding of the issuer's common stock, as of November 10, 2015 was 35,376,502.

CORMEDIX INC.

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PART I

FINANCIAL INFORMATION

Item 1. Consolidated Financial Statements.

CORMEDIX INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	September 30, 2015	December 31, 2014
ASSETS		
Current assets		
Cash and cash equivalents	$14,246,979	$4,339,540
Restricted cash	171,553	-
Short-term investments	23,604,615	-
Trade receivables	124,745	80,183
Inventories, net	699,148	463,029
Prepaid expense, clinical	86,191	-
Prepaid expenses and other current assets	327,276	155,210
Total current assets	39,260,507	5,037,962
Property and equipment, net	41,075	41,458
Security deposit	5,000	18,342
TOTAL ASSETS	$39,306,582	$5,097,762
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$1,424,668	$893,385
Accrued expenses	1,450,157	521,525
Deferred revenue	6,769	10,477
Total current liabilities	2,881,594	1,425,387
Deferred revenue, long term	33,391	37,903
TOTAL LIABILITIES	2,914,985	1,463,290
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY		
Preferred stock - $0.001 par value: 2,000,000 shares authorized; 450,085 and 949,948 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	450	950
Common stock - $0.001 par value: 80,000,000 shares authorized; 35,376,502 and 22,461,668 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	35,377	22,461
Deferred stock issuances	(110)	(110)
Accumulated other comprehensive income	99,786	98,972
Additional paid-in capital	126,781,405	79,716,265
Accumulated deficit	(90,525,311)	(76,204,066)
TOTAL STOCKHOLDERS' EQUITY	36,391,597	3,634,472
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$39,306,582	$5,097,762

See Notes to Unaudited Condensed Consolidated Financial Statements.

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

	For the Three Months Ended September 30, 2015	For the Three Months Ended September 30, 2014	For the Nine Months Ended September 30, 2015	For the Nine Months Ended September 30, 2014
Revenue:				
Net sales	$35,947	$52,441	$187,184	$104,373
Cost of sales	(35,396)	(36,675)	(154,514)	(172,180)
Gross profit (loss)	551	15,766	32,670	(67,807)
Operating Expenses:				
Research and development	(1,764,468)	(292,688)	(4,796,571)	(817,635)
Selling, general and administrative	(2,948,643)	(1,586,614)	(9,580,174)	(5,802,364)
Total Operating Expenses	(4,713,111)	(1,879,302)	(14,376,745)	(6,619,999)
Loss From Operations	(4,712,560)	(1,863,536)	(14,344,075)	(6,687,806)
Other Income (Expense):				
Interest income	25,019	645	30,817	2,153
Foreign exchange transaction gain (loss)	674	(122,645)	(5,352)	(150,803)
Loss on issuance of preferred stock, convertible notes and warrants	-	-	-	(89,590)
Change in fair value of derivative liabilities	-	(586,440)	-	(8,848,953)
Loss on modification of equity instruments and extinguishment of derivative liabilities	-	(2,462,588)	-	(2,462,588)
Interest expense	(1,609)	(553)	(2,635)	(1,531)
Total Income (Expense)	24,084	(3,171,581)	22,830	(11,551,312)
Net (Loss)	(4,688,476)	(5,035,117)	(14,321,245)	(18,239,118)
Other Comprehensive Income (Loss):				
Unrealized loss from investments	5,852	-	348	-
Foreign currency translation gain	1,230	118,319	466	126,302
Total Other Comprehensive Income	7,082	118,319	814	126,302
Comprehensive (Loss)	(4,681,394)	(4,916,798)	(14,320,431)	(18,112,816)
Net (loss)	(4,688,476)	(5,035,117)	(14,321,245)	(18,239,118)
Dividends, including beneficial conversion feature	-	(27,125)	(33,121)	(81,727)
Net (Loss) Attributable To Common Shareholders	$(4,688,476)	$(5,062,242)	$(14,354,366)	$(18,320,845)
Net (Loss) Per Common Share – Basic and Diluted	$(0.14)	$(0.23)	$(0.48)	$(0.87)
Weighted Average Common Shares Outstanding – Basic and Diluted	34,585,543	22,080,673	30,082,478	21,161,532

See Notes to Unaudited Condensed Consolidated Financial Statements.

CORMEDIX INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY
(Unaudited)
For the Nine Months Ended September 30, 2015

	Common Stock Shares	Common Stock Amount	Non-Voting Preferred Stock – Series B, Series C-2, Series C-3, Series D and Series E Shares	Non-Voting Preferred Stock – Series B, Series C-2, Series C-3, Series D and Series E Amount	Deferred Stock Issuances	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	4,582					14,653,579		14,658,161
Stock issued in connection with warrants cashless exercised	2,158,033	2,158					(2,158)		-
Stock issued in connection with stock options exercised	499,955	500					492,460		492,960

Stock issued in connection with sale of common stock	4,723,191	4,723					27,238,029		27,242,752
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							2,908,855		2,908,855
Other comprehensive income						814			814
Net loss								(14,321,245)	(14,321,245)
Balance at September 30, 2015	35,376,502	$35,377	450,085	$450	$(110)	$99,786	$126,781,405	$(90,525,311)	$36,391,597

See Notes to Unaudited Condensed Consolidated Financial Statements.

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

	For the Nine Months Ended September 30, 2015	For the Nine Months Ended September 30, 2014
Cash Flows From Operating Activities:		
Net loss	$(14,321,245)	$(18,239,118)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	2,908,855	1,942,192
Value of warrants issued in connection with backstop financing	1,583,252	-
Modification of warrant agreement	112,982	-
Loss on foreign currency transactions	-	150,803
Loss on issuance of warrants and preferred stock	-	89,590
Loss on modification of equity instruments and extinguishment of derivative liabilities		2,462,588
Revaluation of derivative liabilities	-	8,848,953
Depreciation	11,087	11,467
Changes in operating assets and liabilities:		
Restricted cash	(171,553)	220,586
Trade receivables	(50,178)	(47,353)
Inventory	(236,120)	(597,396)
Prepaid expenses, clinical	(86,191)	-
Prepaid expenses and other current assets	(161,240)	95,611
Accounts payable	538,533	(170,898)
Accrued expenses	988,198	441,469
Deferred revenue and rent	(8,221)	44,830
Net cash used in operating activities	(8,891,841)	(4,746,676)
Cash Flows From Investing Activities:		
Purchase of short-term investments	(23,604,267)	-
Purchase of equipment	(13,796)	(25,898)
Net cash used in investing activities	(23,618,063)	(25,898)
Cash Flows From Financing Activities:		
Proceeds from Series C-3 preferred stock, net	-	743,884
Proceeds from Series C-3 preferred stock, related party	-	575,000
Proceeds from sale of common stock from an at-the-market program	27,242,752	-
Proceeds from exercise of warrants	14,658,161	-
Proceeds from exercise of stock options	492,960	309,450
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	42,422,467	8,349,216
Foreign exchange effect on cash	(5,124)	(30,515)
Net Increase In Cash	9,907,439	3,546,127
Cash – Beginning of Period	4,339,540	2,373,893
Cash – End of Period	$14,246,979	$5,920,020

Cash Paid for Interest	$2,635	$1,531

See Notes to Unaudited Condensed Consolidated Financial Statements.

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

	For the Nine Months Ended September 30, 2015	For the Nine Months Ended September 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	$-	$17,955,143
Conversion of wages to common stock	$50,000	$42,500
Dividends, including beneficial conversion feature	$33,121	$81,727

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 Neutrolin and CRMD004 (see Note 6 related to CRMD004) and filed provisional patents for the other 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, United Arab Emirates 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 mid-2016. In January 2015, the U.S. Food and Drug Administration ("FDA") granted Fast Track designation to Neutrolin® Catheter Lock Solution for the prevention of catheter-related blood stream infections. Fast Track designation is granted to drug products designed to treat a serious condition and 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 drug development process, and also ensures eligibility for priority review and rolling review of the marketing application.

The FDA designated Neutrolin as a Qualified Infectious Disease Product (QIDP) in January 2015 for catheter-related blood stream infections in hemodialysis patients, which can be life-threatening. The QIDP designation will make Neutrolin eligible to benefit from certain incentives, such as priority review, and it also allows for an additional five years of marketing exclusivity when approval is granted by FDA.

CORMEDIX INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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.

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's commercial operations have not generated enough revenues to make the Company profitable. Based on the current development plans for Neutrolin in both the United States ("U.S.") and foreign markets (including the planned hemodialysis Phase 3 clinical trial 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 this balance sheet date.

Nevertheless, the Company's continued operations, including the completion of its planned Phase 3 clinical trial for Neutrolin in hemodialysis 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, and/or out-licensing or distribution arrangements of its products. The Company also plans to conduct an oncology/total parenteral nutrition patient Phase 3 clinical trial in the U.S. for which additional funds over and above the funds needed for the hemodialysis Phase 3 clinical trial will be required to complete that study. However, the Company can provide no assurances that such financing or strategic relationships will be available on acceptable terms, or at all. 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 use from operations as it continues to commercialize Neutrolin internationally, increase its business development activities, incur legal costs to defend its intellectual property and seek FDA approval of Neutrolin in the U.S.

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CORMEDIX INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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.

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. There were no deemed permanent impairments at September 30, 2015.

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 September 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 September 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	$3,334,894	$-	$-	$3,334,894

US Government Agency Securities	6,550,635	(298)	773	6,551,110
Corporate Securities	15,054,267	(2,076)	1,949	15,054,140
Commercial Paper	1,999,365	-	-	1,999,365
Subtotal	23,604,267	(2,374)	2,722	23,604,615
	$26,939,161	$(2,374)	$2,722	$26,939,509

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 September 30, 2015:

		Fair Value Measurement at September 30, 2015		
	Carrying Value	Level 1	Level 2	Level 3
Money Market Funds	$3,334,894	$3,334,894	$-	$-
US Government Agency Securities	6,551,110	-	6,551,110	-
Corporate Securities	15,054,140	-	15,054,140	-
Commercial Paper	1,999,365	-	1,999,365	-
Subtotal	$23,604,615	$-	$23,604,615	$-
	$26,939,509	$3,334,894	$23,604,615	$-

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).

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CORMEDIX INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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).

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 $35,947 and $187,184 for the three and nine months ended September 30, 2015, respectively. Of the Company's revenues for the three and nine months ended September 30, 2015, $33,741 and $180,566, respectively, were attributable to its European and Middle East operations, which are based in Germany. Of the Company's revenues for the three and nine month ended September 30, 2014, $50,970 and $102,902 respectively, were attributable to its European operations. Total assets at September 30, 2015 were $39,306,582, of which $38,257,032 were located in the United States, with the remainder in Germany. Net property and equipment at September 30, 2015 was $41,075, of which $11,754 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:

	September 30, 2015	December 31, 2014
Raw materials	$245,358	$293,976
Work in process	542,812	341,807
Finished goods	85,978	2,246
Inventory reserve	(175,000)	(175,000)
Total	$699,148	$463,029

CORMEDIX INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Accrued Expenses

Accrued expenses consist of the following:

	September 30, 2015	December 31, 2014
Professional and consulting fees	$318,721	$225,726
Accrued payroll and payroll taxes	477,726	13,393
Clinical trial and manufacturing development	366,459	-
Market research	108,320	137,345
Monitoring program fees	56,432	82,861
Statutory taxes	69,736	34,548
Other	52,763	27,652
Total	$1,450,157	$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.

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 nine months ended September 30, 2015 and 2014, basic loss per common share is calculated by dividing net loss available to common shareholders by the number of weighted average common shares issued and outstanding. Diluted loss per common share is calculated by dividing net 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

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	September 30,	
	2015	2014
Series B non-voting convertible preferred stock	-	454,546
Series C non-voting convertible preferred stock	2,865,000	3,340,000
Series D non-voting convertible preferred stock	1,479,240	1,479,240
Series E non-voting convertible preferred stock	1,959,759	2,021,358
Shares underlying outstanding warrants	4,422,188	11,571,233
Shares underlying outstanding stock options	3,689,545	3,653,500
Total	14,415,732	22,519,877

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 loss per share of common stock:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Loss Per Common Share – Basic and Diluted:				
Net loss	$(4,688,476)	$(5,035,117)	$(14,321,245)	$(18,239,118)
Less: Dividends on participating securities	-	(27,125)	(33,121)	(81,727)
Net loss available to common shareholders – basic and diluted	$(4,688,476)	$(5,062,242)	$(14,354,366)	$(18,320,845)
Weighted average common shares outstanding – basic and diluted	34,585,543	22,080,673	30,082,478	21,161,532
Net loss per common share – basic and diluted	$(0.14)	$(0.23)	$(0.48)	$(0.87)

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"). 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.

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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. The non-cash charge to operations for non-employee options with performance based vesting provisions is recorded when the achievement of the performance condition is probable.

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 nine months ended September 30, 2015, the Company issued 4,723,191 shares of common stock under the Sales Agreement and realized net proceeds of approximately $27,242,752.

During the nine months ended September 30, 2015, the Company issued the following shares of its common stock, resulting in gross proceeds of $14,658,161 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.

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

During the nine months ended September 30, 2015, the Company issued 499,955 shares of its common stock upon exercise of 499,955 stock options at a weighted average exercise price of $0.99 per share, resulting in gross proceeds of $492,960 to the Company.

During the nine months ended September 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 nine months ended September 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.

During the nine months ended September 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 nine months ended September 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 September 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

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Stock Options

During the nine months ended September 30, 2015, the Company granted ten-year non-qualified stock options under the 2013 Plan covering an aggregate of 640,000 shares of the Company's common stock to its officers, directors and consultants.

In August 2015, the Company entered into a Release of Claims and Severance Modification Agreement with Randy Milby (See Note 5), the Company's CEO, due to Mr. Milby's anticipated termination of employment. As a result, the Company recorded a total of $507,341 compensation expense for the incremental value of an aggregate of 762,500 options during the nine months ended September 30, 2015 using the Black-Scholes option pricing model with the following assumptions:

Expected term (years)	0.25 – 5	
Volatility	94% - 97	%
Dividend yield	0.0	%
Risk-free interest rate	0.05% - 1.61	%

During the three and nine months ended September 30, 2015 total compensation expense was $921,153 and $2,908,855(including $507,341 expense recorded for the modification of Mr. Milby's stock options), respectively and $166,439 and $1,942,192 for the three and nine months ended September 30, 2014, respectively.

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

Expected term (years)	5 – 10	
Volatility	93% - 94	%
Dividend yield	0.0	%
Risk-free interest rate	1.47% - 2.26	%
Weighted-average fair value of options granted during the period	$3.46	

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.

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At September 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	(499,955)	$0.99
Forfeited	(115,000)	$2.08
Expired	-	$-
Granted	640,000	$4.60
Outstanding at end of period	3,689,545	$1.84
Options exercisable	3,151,712	$1.46

Weighted average remaining contractual life of stock options outstanding (years)	7.8
Weighted average remaining contractual life of stock options exercisable (years)	7.6
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	$3,260,728
Aggregate intrinsic value of stock options outstanding	$2,325,974
Compensation expense related to non-vested options not yet recognized	$956,462

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.

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)	1 - 5
Volatility	75.81% - 104.08%
Dividend yield	0.0%
Risk-free interest rate	0.01% - 1.61%

During the nine months ended September 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 nine months ended September 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:

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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 nine months ended September 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

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. Additionally, the Company granted Manchester the right for as long as it or its affiliates hold any of the Company's common stock or securities convertible into its common stock the right to appoint up to two members to the Company's board of directors and/or to have up to two observers attend board meetings in a non-voting capacity. As of September 30, 2015, one board member had been appointed to the Company's board of directors under this provision.

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. This agreement was terminated at the end of August 2015.

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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. This action was brought at the Board of the European Patent Office ("EPO") opposition division (the "Opposition Board") based upon alleged 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 as no further appeal was lodged by Geistlich.

On September 9, 2014, the Company filed in the District Court of Mannheim, Germany 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 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.

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On March 27, 2015, the 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 Court 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 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.

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 expects a decision from the EPO by November 25, 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 or early 2016, 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 TauroLockTM, 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 to November 19, 2015.

In connection with the aforementioned patent and utility model infringement 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 nine months ended September 30, 2015. The Company furthermore had to provide a deposit in the amount of €36,000 ($39,559) in connection with the unfair competition

proceedings in Cologne.

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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.

Commitments

Manufacturing

Navinta LLC, a U.S.-based API developer, provides API manufacturing (manufactured in India at an FDA-compliant facility) and a Drug Master File for CRMD003, pursuant to a supply agreement dated December 7, 2009 (the "Navinta Agreement"). The Navinta Agreement provides that Navinta will supply taurolidine (the API for CRMD003) to the Company on an exclusive worldwide basis in the field of the prevention and treatment of human infection and/or dialysis so long as the Company purchased a minimum of $350,000 of product from Navinta by December 30, 2010, which the Company achieved, and following the Company's first commercial sale of a product incorporating taurolidine, 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.

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.

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. Through September 30, 2015, RC2 completed and the Company recognized expense of approximately $562,000 for its services related to this agreement. The Company and RC2 are also in the process of negotiating a manufacturing services agreement.

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The Company is also working with RC2 under several service agreements for the manufacture of clinical supplies to support its Phase 3 clinical trials for an aggregate amount of $1.9 million. As of September 30, 2015, approximately $464,000 of services was completed by RC2 and $45,000 was prepaid. The Company recognized research and development expense of approximately $436,000 and $464,000 for the three and nine months ended September 30, 2015, respectively. The Company may terminate these agreements upon 30 days written notice and is only obligated for project costs and reasonable project shut down costs provided through the date of termination.

Clinical and Regulatory

On July 6, 2015, the Company entered into a Letter of Agreement ("LOA") with PPD Development, LP ("PPD") under which PPD and/or one or more of its global affiliates would begin to provide services related to the Company's planned Phase 3 multicenter, double-blind, randomized active control study to demonstrate the safety and effectiveness of Neutrolin in preventing catheter-related bloodstream infections in subjects receiving hemodialysis therapy as treatment for end stage renal disease (the "Project"). Following the execution of the LOA, the Company paid PPD $164,766 as an advance payment for services provided under the LOA and for the reimbursement of indirect pass-through expenses related to the provision of those services. As of September 30, 2015, PPD had completed approximately $124,000 under the LOA. The Company recognized this amount as research and development expense for the three and nine months ended September 30, 2015. Either party may terminate the agreement upon 30 days written notice to the other party.

On July 28, 2015, the Company entered into an amendment to the original LOA ("Amendment #1") to revise and expand the scope of services provided by PPD. These services are primarily related to activities in connection with the identification, activation and management of 70 U.S. sites for the clinical trials for the Project described above. The services to be provided under Amendment #1 amounted to $2.75 million, including the amount in the original LOA. Through September 30, 2015, the services provided by PPD under Amendment #1 amounted to approximately $366,000. The Company recognized this amount as research and development expense during the three and nine months ended September 30, 2015.

In-Licensing

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 September 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 September 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.

CORMEDIX INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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 January 30, 2008, the Company also entered into an Exclusive License and Consulting Agreement with Dr. Polaschegg (the "Polaschegg License Agreement"). The Polaschegg License Agreement replaced the original license agreement between NDP and Dr. Polaschegg that the Company was assigned and the Company assumed under the NDP License Agreement. Pursuant to the Polaschegg License Agreement, Dr. Polaschegg granted the Company an exclusive, worldwide license for a certain antimicrobial solution and certain taurolidine treatments and the corresponding United States patent applications (the "Polaschegg Technology"), and agreed to provide the Company with certain consulting services. As consideration for the rights to the Polaschegg Technology, the Company paid Dr. Polaschegg an initial payment of $5,000 and agreed to pay Dr. Polaschegg certain royalty payments ranging from 1% to 3% of the net sales of the Polaschegg Technology. The Polaschegg License Agreement also sets forth certain minimum royalty payments (on an annual basis) to be made to Dr. Polaschegg in connection with the Polaschegg Technology, which payments range from $10,000 to $45,000. As compensation for Dr. Polaschegg's consulting services to be provided under the Polaschegg License Agreement, Dr. Polaschegg was paid €200 per hour for services consisting of scientific work and €250 per hour for services consisting of legal work. The Company may terminate the Polaschegg License Agreement with respect to any piece of the Polaschegg Technology upon 60 days notice. If the Polaschegg License Agreement is terminated with respect to any piece of the Polaschegg Technology by either party, all rights with respect to such portion of the Polaschegg Technology will revert to Dr. Polaschegg. During the three and nine months ended September 30, 2015, the Company expensed $7,500 and $22,500, respectively, in connection with the Polaschegg License Agreement.

Other

On August 3, 2015, the Company entered into a Release of Claims and Severance Modification with Randy Milby, its Chief Executive Officer, due to the anticipated termination of Mr. Milby's employment. 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 taurolodine. 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. During the three and nine months ended September 30, 2015, the Company recorded non-cash expense of $507,341 as a result of this modification.

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 if such receipt is prior to the expiration of the 12-month period. 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. The Company accrued $325,000 of severance pay during the three and nine months ended September 30, 2015.

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).

CORMEDIX INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

2015	$16,864
2016	66,236
2017	60,784
2018	15,000
Total	$158,884

Note 6 — Subsequent Events:

On October 28, 2015 the Company signed an agreement for central laboratory services to support the Company's Phase 3 clinical trial in hemodialysis patients. The agreement is for $152,800 and is scheduled to run from November 2015 to March 2017. The Company provided JMI Laboratories with an advance payment of $30,500 in November 2015. The laboratory will perform the following key activities over the life of this agreement: specimens from 160 patients (average 2 isolates per patient) will be analyzed for identification and confirmation of the isolates, antimicrobial susceptibility testing and storage for up to three years after the study completion.

On November 5, 2015, the Company gave notice of its termination of the Polaschegg Exclusive License and Consulting Agreement, dated January 30, 2008, covering the CRMD004 gel formulation. Pursuant to the terms of the Polaschegg License Agreement, the termination will be effective in 60 days. The Company determined that the CRMD004 gel technology patent targeting catheter locks was narrow in scope and limited in market potential. Based on technical analysis of the other patents under the Polaschegg License Agreement, the Company determined that extensive investment would be required to strengthen the patents. Upon termination of the Polaschegg License Agreement, all rights to the Polaschegg CRMD004 gel technology patent will revert to the patent originators. CRMD004 was in preclinical development.

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," "sh "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 its wholly owned subsidiary (referred to collectively 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 the worldwide rights to develop and commercialize our product CRMD003 (Neutrolin®), which we believe addresses 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 20 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 90 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, United Arab Emirates 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 oncolytic patients in Germany and with Wonik Corporation, a South Korean company, to market, sell and distribute Neutrolin for hemodialysis, critical care/intensive care and oncolytic patients in that country upon receipt of regulatory approval. We also have independent sales representatives in The Netherlands 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, 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 for the prevention of catheter-related blood stream infections. Fast Track designation is granted to drug products designed to treat a serious condition and to 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 drug development process, and also ensures eligibility for priority review and rolling review of the marketing application.

The FDA designated Neutrolin as a Qualified Infectious Disease Product (QIDP) in January 2015 for catheter-related blood stream infections in hemodialysis patients, which can be life-threatening. The QIDP designation will make Neutrolin eligible to benefit from certain incentives, such as priority review, and it also allows for an additional five years of marketing exclusivity when approval is granted by FDA.

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. On November 5, 2015, we gave notice of our termination of the Polaschegg Exclusive License and Consulting Agreement, dated January 30, 2008, covering the CRMD004 gel formulation. Pursuant to the terms of the Polaschegg License Agreement, the termination will be effective in 60 days. We determined that the CRMD004 gel technology patent targeting catheter locks was narrow in scope and limited in market potential. Based on technical analysis of the other patents under the Polaschegg License Agreement, we determined that extensive investment would be required to strengthen the patents. Upon termination of the Polaschegg License Agreement, all rights to the Polaschegg CRMD004 gel technology patent will revert to the patent originators. CRMD004 was in preclinical development.

We are evaluating opportunities for the possible expansion of indications for taurolidine. Provisional patents have been submitted in four areas, antimicrobial sutures, nanofiber webs, wound management, and osteoarthritis and visco-supplementation. There exists a need to control and protect against surgical site infections upon closure with sutures. We believe taurolidine could offer benefits not currently available in marketed antimicrobial sutures. We also believe that the nanofiber webs used for absorbable meshes could benefit from taurolidine's minimal inflammatory response and infection control. Taurolidine incorporated into webs or hydrogels could also be used for wound management especially wounds in less sterile environments and burn patients. Lastly, incorporating taurolidine into formulations for osteoarthritis and visco-supplementation may benefit from the taurolidine's anti-inflammatory and anti-infection properties.

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. After 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 not generated enough revenue from product sales to be profitable. 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 September 30, 2015, we had an accumulated deficit of approximately $90.5 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

Our commercial operations have not generated enough revenues to be profitable. 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.

	Nine Months Ended September 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. 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 our company, which is based in New Jersey and our German subsidiary. Effective October 1, 2014, we 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 nine months ended September 30, 2014. The loss on the issuance of preferred stock and related warrants represents the difference on the issuance date between the combined 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 in the September 30, 2014 Form 10-Q and December 31, 2014 Form 10-K, 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.

Loss on Modification of Equity Instruments and Extinguishment of Derivative Liabilities

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

Results of Operations

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

Summary Table.

The following is a tabular presentation of our condensed consolidated operating results for the three months ended September 30, 2015 and 2014 (in thousands):

	For the Three Months Ended September 30,		% of Change Increase (Decrease)
	2015	2014	
Revenue	$36	$52	(31)%
Cost of sales	(35)	(37)	(3)%
Gross profit	1	15	(97)%
Operating Expenses:			
Research and development	(1,764)	(293)	>100%
Selling, general and administrative	(2,949)	(1,586)	86%
Total operating expenses	(4,713)	(1,879)	>100%
Loss from operations	(4,712)	(1,864)	>100%

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	For the Three Months Ended September 30,		% of Change Increase (Decrease)
	2015	2014	
Interest income	25	1	>100 %
Foreign exchange transaction loss	1	(123)	>100 %
Change in fair value of derivative liabilities	-	(586)	100 %
Loss on modification of equity instruments and extinguishment of derivative liabilities	-	(2,462)	100 %
Interest expense	(2)	(1)	>100 %
Net loss	(4,688)	(5,035)	(7)%
Other comprehensive income	7	118	(94)%
Comprehensive loss	$(4,681)	$(4,917)	(5)%

Revenue. Revenue was approximately $36,000 for the three months ended September 30, 2015 compared to approximately $52,000 in the prior year, a decrease of approximately $16,000. 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 $35,000 for the three months ended September 30, 2015 compared to $37,000 in the same period last year, a decrease of approximately $2,000. The decrease was primarily due to decreases in ongoing stability studies and other manufacturing expenses of approximately $18,000 offset by an increase in direct cost of materials of approximately $16,000 due to the use of new commercial batches as compared to the use of old research and development batches in 2014. Research and development batches were previously expensed because it had been manufactured prior to the approval of the CE Mark.

Research and Development Expense. R&D expense was approximately $1,764,000 for the three months ended September 30, 2015, an increase of approximately $1,471,000, from approximately $293,000 for the same period last year. The increase was primarily attributable to higher costs to support the U.S. clinical trials consisting of manufacturing process development activities of approximately $560,000, preliminary clinical trial preparation of approximately $490,000 and pharmacoeconomics, pricing and market research studies of approximately $53,000. Additionally, there were increases in consulting fees pertaining to manufacturing process activities of approximately $273,000 and non-cash stock based compensation of approximately $72,000.

Selling, General and Administrative Expense. SG&A expense was approximately $2,949,000 for the three months ended September 30, 2015, an increase of approximately $1,362,000 from approximately $1,587,000 for the same period last year. The increase was primarily attributable to increases in non-cash stock-based compensation expense of approximately $683,000, mostly due to the modification of the stock options of the Company's CEO; personnel cost of approximately $371,000, due to employee benefits and the Release of Claims and Severance Modification with the Company's CEO; accounting and consulting fees of approximately $158,000; legal fees due mainly to ongoing intellectual property litigation of approximately $75,000; costs related to business development activities of approximately $45,000;. These increases were offset by a decrease in costs related to commercialization of Neutrolin in the EU of approximately $37,000.

Change in Fair Value of Derivative Liabilities. The change in the fair value of derivative liabilities for the three months ended September 30, 2014 of approximately $586,000 consists of decreases in the fair value of preferred stock conversion options and warrants between June 30, 2014 and September 15, 2014 (date of equity instrument

modification and discontinuance of derivative instruments) of approximately $380,000 and approximately $206,000, respectively. 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 September 30, 2015.

Loss on Modification of Equity Instruments and Extinguishment of Derivative Liabilities. The loss on extinguishment of derivative liabilities for the three months ended September 30, 2014 of approximately $2,462,000 represents the change in the fair value of the preferred stock hybrid instruments of approximately $2,118,000 and liability classified warrants of approximately $344,000 resulting from the modifications made to those instruments on September 15, 2014 for the purpose of changing the balance sheet classification from liability to equity.

Interest Income. Interest income was approximately $25,000 for the three months ended September 30, 2015 as compared to approximately $1,000 for the same period last year, an increase of approximately $24,000. The increase was attributable to higher interest-bearing cash balances during the third quarter of 2015 compared to the same quarter in 2014.

Interest Expense. Interest expense was approximately $2,000 for the three months ended September 30, 2015 as compared to approximately $1,000 for the same period last year, an increase of approximately $1,000.

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 $7,000 income for the three months ended September 30, 2015.

Nine months ended September 30, 2015 compared to nine months ended September 30, 2014

Summary Table.

The following is a tabular presentation of our condensed consolidated operating results for the nine months ended September 30, 2015 and 2014 (in thousands):

	For the Nine Months Ended September 30,		% of Change Increase (Decrease)
	2015	2014	
Revenue	$187	$104	79 %
Cost of sales	(154)	(172)	(10)%
Gross profit (loss)	33	(68)	>100%
Operating Expenses:			
Research and development	(4,797)	(818)	>100%
Selling, general and administrative	(9,580)	(5,802)	65 %
Total operating expenses	(14,377)	(6,620)	>100%
Loss from operations	(14,344)	(6,688)	>100%
Interest income	31	2	>100%
Foreign exchange transaction loss	(5)	(151)	(96)%
Loss on issuance of preferred stock, convertible notes and warrants	-	(89)	100 %
Change in fair value of derivative liabilities	-	(8,849)	100 %

	For the Nine Months Ended September 30,		% of Change Increase (Decrease)
	2015	2014	
Loss on modification of equity instruments and extinguishment of derivative liabilities	-	(2,462)	100%
Interest expense	(3)	(2)	72%
Net loss	(14,321)	(18,239)	(21)%
Other comprehensive income	1	126	(99)%
Comprehensive loss	$(14,320)	$(18,113)	(21)%

Revenue. Revenue was approximately $187,000 for the nine months ended September 30, 2015 as compared to approximately $104,000 for the same period last year, an increase of approximately $83,000. The majority of the revenue is from sales of Neutrolin in Germany and Middle East markets. In addition, we realized approximately $7,000 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 $154,000 for the nine months ended September 30, 2015 compared to $172,000 in the same period last year, a decrease of approximately $18,000. The decrease was primarily due to decreases in ongoing stability studies and services performed in the management of manufacturing of approximately $59,000 and other manufacturing expenses mainly due to costs in transitioning Neutrolin to new labels and packaging of approximately $32,000, offset by an increase in direct cost of materials of approximately $73,000 due to the use of new commercial batches as compared to the use of old research and development batches in 2014. Research and development batches were previously expensed because it had been manufactured prior to the approval of the CE Mark.

Research and Development Expense. R&D expense was approximately $4,797,000 for the nine months ended September 30, 2015, an increase of approximately $3,979,000, from approximately $818,000 for the same period last year. The increase was primarily attributable to higher costs to support the U.S. clinical trials consisting of manufacturing process development activities of approximately $1,167,000, preliminary clinical trial preparation of approximately $490,000 and pharmacoeconomics, pricing and market research studies of approximately $756,000. Additionally, there were increases in non-cash stock based compensation of approximately $832,000; consulting fees pertaining to manufacturing process activities of approximately $582,000; and personnel costs of approximately $104,000.

Selling, General and Administrative Expense. SG&A expense was approximately $9,580,000 for the nine months ended September 30, 2015, an increase of approximately $3,778,000 from approximately $5,802,000 for the same period last year. The increase was 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 personnel cost of approximately $677,000, due to employee benefits and the Release of Claims and Severance Modification with the Company’s CEO; legal fees due mainly to ongoing intellectual property litigation of approximately $571,000; costs related to business development activities of approximately $407,000; accounting and consulting fees of approximately $286,000; and a non-cash charge of approximately $135,000 for stock-based compensation expense due to the modification of the stock options of the Company’s CEO and approximately $113,000 for modification of warrants. These increases, among others of lesser significance were offset by a decrease in costs related to commercialization of Neutrolin in the EU of approximately $217,000.

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Loss on Issuance of Preferred Stock, Convertible Notes and Warrants. The loss on the issuance of preferred stock and warrants in the nine months ended September 30, 2014 represents the difference on the issuance date between the combined fair value of the conversion option and the warrants of approximately $2,054,000, and the combined proceeds received and liabilities settled, net of all issuance-related fees and expenses of approximately $1,965,000. 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 nine months ended September 30, 2015.

Change in Fair Value of Derivative Liabilities. The change in the value of derivative liabilities for the nine months ended September 30, 2014 of approximately $8,849,000 consists of increases in the fair value of preferred stock conversion options and warrants between December 31, 2013 and September 15, 2014 of approximately $7,138,000 and approximately $1,711,000, respectively. 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 nine months ended September 30, 2015.

Loss on Modification of Equity Instruments and Extinguishment of Derivative Liabilities. The loss on extinguishment of derivative liabilities for the nine months ended September 30, 2014 of approximately $2,462,000 represents the change in the fair value of the preferred stock hybrid instruments of approximately $2,119,000 and liability classified warrants of approximately $344,000 resulting from the modifications made to those instruments on September 15, 2014 for the purpose of changing the balance sheet classification from liability to equity.

Interest Income. Interest income was approximately $31,000 for the nine months ended September 30, 2015 as compared to approximately $2,000 for the same period last year, an increase of approximately $29,000. The increase was attributable to a higher interest-bearing cash balances during the third quarter of 2015 compared to the same period in 2014.

Interest Expense. Interest expense was approximately $3,000 for the nine months ended September 30, 2015 as compared to approximately $1,000 for the same period last year, an increase of approximately $2,000.

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 $800 income for the nine months ended September 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 nine months ended September 30, 2015, we received net proceeds of approximately $42,394,000 from the following:

- sale of our common stock in an at-the-market program resulting in the issuance of 4,723,191 shares of common stock at a weighted average price of $6.00 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 499,955 stock options at a weighted average exercise price of $0.99 per share, which resulted in the issuance of 499,955 shares of common stock.

Net Cash Used in Operating Activities

Net cash used in operating activities was approximately $8,892,000 for the nine months ended September 30, 2015 as compared to approximately $4,747,000 for the same period last year. The net loss of approximately $14,321,000 for the nine months ended September 30, 2015 was higher than cash used in operating activities by approximately $5,429,000. 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 $2,909,000 and value of warrants related to the extension of the expiration date of approximately $113,000. The net loss of approximately $18,239,000 for the nine months ended September 30, 2014 was higher than cash used in operating activities by approximately $13,492,000. The difference is attributable primarily to revaluation of derivative liabilities of approximately $8,849,000, non-cash loss on extinguishment of derivative liabilities of approximately $2,463,000, non-cash stock-based compensation of approximately $1,942,000 and losses on foreign currency transactions and issuance of preferred stock of approximately $151,000 and $90,000, respectively.

Net Cash Used in Investing Activities

Cash used in investing activities for the nine months ended September 30, 2015 was approximately $23,618,000, attributable to the purchase of short-term investments as compared to approximately $25,900 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 $42,422,000 for the nine months ended September 30, 2015 as compared to approximately $8,349,000 for the same period last year, an increase of approximately $34,073,000. During the nine months ended September 30, 2015, we received net proceeds of approximately $27,243,000 from the sale of our common stock in an at-the-market program, approximately $14,658,000 from the exercise of warrants and approximately $493,000 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 $309,000 for the same period last year.

Funding Requirements and Liquidity Risks

Our total cash on hand and short-term investments as of September 30, 2015 was approximately $37,852,000 excluding restricted cash of approximately $172,000, 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 our planned Phase 3 clinical trial for Neutrolin in hemodialysis patients in the U.S. 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. We also plan to conduct an oncology/total parenteral nutrition patient Phase 3 clinical trial in the U.S. for which additional funds over and above the funds needed for the hemodialysis Phase 3 clinical trial will be required to complete that study. 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 $12 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, we do not anticipate that we will generate significant product sales revenue in the forseeable future. 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 September 30, 2015, our expectations for Neutrolin assumptions in the currently approved markets and the planned initiation of the Phase 3 clinical trial in hemodialysis catheters in the U.S. in the fourth quarter of 2015, 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. With additional funding planned to be raised over and above the hemodialysis clinical trial, we plan to initiate an oncology/total parenteral nutrition clinical trial in the U.S. in mid-2016. 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.

Contractual Obligations

We 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, we had deposited $5,000 with the landlord, the equivalent of one month rent.

Our 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 our current lease agreements, the total remaining lease obligation as of September 30, 2015 is set forth below:

2015	$16,864
2016	66,236
2017	60,784
2018	15,000
Total	$158,884

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 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 reevaluate 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 our 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 Chief Executive Officer (who is 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 September 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 September 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 September 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 principal executive officer and principal 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) and have enhanced our internal controls, we believe that the material weakness has not yet been fully remediated as of September 30, 2015. Progress and remediation is expected to continue in the fourth quarter of 2015.

Other than the continued remediation discussed above, 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 September 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 6. Exhibits.

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

Exhibit Number	Description
10.1	Release of Claims and Severance Modification, dated August 3, 2015, between CorMedix Inc. and Randy Milby.
31.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer and 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.

* 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: November 12, 2015	By:	/s/ Randy Milby Randy Milby Chief Executive Officer (Principal Executive Officer and Principal Financial and Accounting Officer)

EXHIBIT INDEX

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