

CorMedix Inc.
Form 10-Q
May 07, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2015

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

For the transition period from _____ to _____

Commission file number 001-34673

CORMEDIX INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

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

Organization)

1430 US Highway 206, Suite 200,
Bedminster, NJ
(Address of Principal Executive Offices)

07921
(Zip Code)

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

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

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

The number of shares outstanding of the issuer’s common stock, as of May 6, 2015 was 31,052,608.

CORMEDIX INC. AND SUBSIDIARY

INDEX

PART I FINANCIAL INFORMATION

| | |
|--|----|
| Item 1. Unaudited Condensed Consolidated Financial Statements | |
| Condensed Consolidated Balance Sheets as of March 31, 2015 and December 31, 2014 | 3 |
| Condensed Consolidated Statements of Operations and Comprehensive Income (Loss) for the Three Months Ended March 31, 2015 and 2014 | 4 |
| Condensed Consolidated Statement of Changes in Stockholders' Equity for the Three Months Ended March 31, 2015 | 5 |
| Condensed Consolidated Statements of Cash Flows for the Three Months Ended March 31, 2015 and 2014 | 6 |
| Notes to Unaudited Condensed Consolidated Financial Statements | 7 |
| Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations | 20 |
| Item 4. Controls and Procedures | 30 |
| PART II OTHER INFORMATION | |
| Item 2. Unregistered Sales of Equity Securities and Use of Proceeds | 32 |
| Item 6. Exhibits | 32 |
| SIGNATURES | 33 |

PART I
FINANCIAL INFORMATION

Item 1. Consolidated Financial Statements.

CORMEDIX INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

| | March 31, 2015 | December 31, 2014 |
|---|--------------------|-------------------------|
| ASSETS | | |
| Current assets | | |
| Cash and cash equivalents | \$8,799,328 | \$4,339,540 |
| Restricted cash | 131,994 | - |
| Trade receivables | 69,359 | 80,183 |
| Inventories, net | 461,405 | 463,029 |
| Other prepaid expenses and current assets | 224,313 | 155,210 |
| Total current assets | 9,686,399 | 5,037,962 |
| Property and equipment, net | 47,011 | 41,458 |
| Security deposit | 18,342 | 18,342 |
| TOTAL ASSETS | \$9,751,752 | \$5,097,762 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities | | |
| Accounts payable | \$1,428,717 | \$893,385 |
| Accrued expenses | 682,155 | 521,525 |
| Deferred revenue | 9,026 | 10,477 |
| Total current liabilities | 2,119,898 | 1,425,387 |
| Deferred revenue, long term | 35,647 | 37,903 |
| TOTAL LIABILITIES | 2,155,545 | 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 March 31, 2015 and December 31, 2014, respectively | 450 | 950 |
| Common stock - \$0.001 par value: 80,000,000 shares authorized; 27,864,841 and 22,461,668 shares issued and outstanding at March 31, 2015 and December 31, 2014, respectively | 27,865 | 22,461 |
| Deferred stock issuances | (110) | (110) |
| Accumulated other comprehensive income | 101,782 | 98,972 |
| Additional paid-in capital | 89,167,955 | 79,716,265 |
| Accumulated deficit | (81,701,735) | (76,204,066) |
| TOTAL STOCKHOLDERS' EQUITY | 7,596,207 | 3,634,472 |
| TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY | \$9,751,752 | \$5,097,762 |

See Notes to Unaudited Condensed Consolidated Financial Statements.

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

(Unaudited)

| | March 31, | |
|---|----------------|----------------|
| | 2015 | 2014 |
| Revenue | | |
| Net sales | \$31,264 | \$12,203 |
| Cost of sales | (17,319) | (81,026) |
| Gross profit (loss) | 13,945 | (68,823) |
| Operating Expenses | | |
| Research and development | (1,234,515) | (353,018) |
| Selling, general and administrative | (4,276,354) | (2,512,709) |
| Total operating expenses | (5,510,869) | (2,865,727) |
| Loss From Operations | (5,496,924) | (2,934,550) |
| Other Income (Expense) | | |
| Interest income | 543 | 521 |
| Foreign exchange transaction loss | (429) | (7,638) |
| Loss on issuance of preferred stock, convertible notes and warrants | - | (89,590) |
| Change in fair value of derivative liabilities | - | (13,681,569) |
| Interest expense | (859) | (465) |
| Net Loss | (5,497,669) | (16,713,291) |
| Other Comprehensive Income (Loss) | | |
| Foreign currency translation gain (loss) | 2,810 | (1,361) |
| Comprehensive Loss | \$(5,494,859) | \$(16,714,652) |
| Net Loss | \$(5,497,669) | \$(16,713,291) |
| Dividends, including beneficial conversion feature | (33,121) | (27,150) |
| Net Loss Attributable To Common Shareholders | \$(5,530,790) | \$(16,740,441) |
| Net Loss Per Common Share – Basic and Diluted | \$(0.23) | \$(0.87) |
| Weighted Average Common Shares Outstanding – Basic and Diluted | 23,921,605 | 19,264,884 |

See Notes to Unaudited Condensed Consolidated Financial Statements.

CORMEDIX INC. AND SUBSIDIARY

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

| | Common Stock | | Non-Voting Preferred Stock –Series B, Series C-2, Series C-3, Series D and Series E | | Deferred Stock Issuances | Accumulated Other Comprehensiv Income | Additional Paid-in Capital | Accumulated Deficit | Total Stockholders' Equity |
|--|--------------|----------|--|--------|--------------------------------|--|----------------------------------|------------------------|----------------------------------|
| | Shares | Amount | Shares | Amount | | | | | |
| 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 | 2,248,858 | 2,249 | | | | | 6,699,919 | | 6,702,168 |
| Stock issued in connection with warrants cashless exercised | 2,158,033 | 2,158 | | | | | (2,158) | | - |
| Stock issued in connection with stock options exercised | 50,000 | 50 | | | | | 125,450 | | 125,500 |

| | | | | | | | | | |
|---|------------|----------|---------|-------|---------|-----------|--------------|----------------|--------------|
| Stock issued in connection with conversion of wages | 5,138 | 5 | | | | | 18,745 | | 18,750 |
| Warrants issued in connection with backstop agreement | | | | | | | 1,583,252 | | 1,583,252 |
| Stock-based compensation | | | | | | | 1,026,924 | | 1,026,924 |
| Other comprehensive income | | | | | | | 2,810 | | 2,810 |
| Net loss | | | | | | | | (5,497,669) | (5,497,669) |
| Balance at March 31, 2015 | 27,864,841 | \$27,865 | 450,085 | \$450 | \$(110) | \$101,782 | \$89,167,955 | \$(81,701,735) | \$7,596,207 |

See Notes to Unaudited Condensed Consolidated Financial Statements.

CORMEDIX INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

| | For the Three Months Ended March 31, | |
|---|---|----------------|
| | 2015 | 2014 |
| CASH FLOWS FROM OPERATING ACTIVITIES: | | |
| Net loss | \$(5,497,669) | \$(16,713,291) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Stock-based compensation | 1,026,924 | 1,415,244 |
| Warrants issued in connection with backstop agreement | 1,583,252 | - |
| Loss on foreign currency transactions | 429 | 7,638 |
| Loss on issuance of preferred stock, convertible notes and warrants | - | 89,590 |
| Revaluation of derivative liability | - | 13,681,569 |
| Depreciation | 3,158 | 2,446 |
| Changes in operating assets and liabilities: | | |
| Restricted cash | (131,994) | (76) |
| Trade receivables | 2,304 | (11,813) |
| Inventory | 1,624 | 16,288 |
| Prepaid expenses and other current assets | (76,146) | 10,456 |
| Accounts payable | 546,379 | 117,511 |
| Accrued expenses and accrued interest | 197,150 | (44,156) |
| Deferred revenue | (3,708) | (695) |
| Net cash used in operating activities | (2,348,297) | (1,429,289) |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | |
| Purchase of equipment | (12,944) | - |
| Net cash used in investing activities | (12,944) | - |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | |
| Proceeds from Series C-3 preferred stock, net | - | 743,884 |
| Proceeds from Series C-3 preferred stock, related party | - | 575,000 |
| Proceeds from exercise of warrants | 6,702,168 | - |
| Proceeds from exercise of stock options | 125,500 | 213,650 |
| Payments for deferred financing costs | - | (2,366) |
| Proceeds from sale of equity securities | - | 6,723,248 |
| Net cash provided by financing activities | 6,827,668 | 8,253,416 |
| Foreign exchange effect on cash | (6,639) | (8,622) |
| NET INCREASE IN CASH | 4,459,788 | 6,815,505 |
| CASH – BEGINNING OF PERIOD | 4,339,540 | 2,373,893 |
| CASH – END OF PERIOD | \$8,799,328 | \$9,189,398 |
| Cash paid for interest | \$859 | \$465 |
| 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 liability to equity | \$- | \$6,235,398 |
| Conversion of wages and fees to common stock | \$18,750 | \$- |
| Dividend, including beneficial conversion feature | \$33,121 | \$27,150 |

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 has in-licensed all of the product candidates in its pipeline.

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, initial commercialization activities for its product Neutrolin® in certain markets, and raising funds through the issuance of debt and equity securities.

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, or CRBI, and maintenance of catheter patency in hemodialysis patients using a tunneled, cuffed central venous catheter for vascular access.

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, 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, or IV, nutrition was also approved. In September 2014, the TUV-SUD and The Medicinal Evaluation Board of the Netherlands (MEB) granted a label expansion for Neutrolin for these same expanded indications for the European Union (EU).

To date, Neutrolin is registered and may be sold in Austria, Germany, Italy, Malta, Saudi Arabia, Kuwait and The Netherlands for such treatment.

Basis of Presentation

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

CORMEDIX INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 2 — Summary of Significant Accounting Policies:

Liquidity, Risks and Uncertainties

The Company's operations are subject to a number of factors that can affect its operating results and financial condition. Such factors include, but are not limited to: the results of clinical testing and trial activities of the Company's product candidates, the ability to obtain regulatory approval to market its 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.

The financial statements have been prepared in conformity with generally accepted accounting principles which contemplate continuation of the Company as a going concern. As of March 31, 2015, the Company had an accumulated deficit of \$81.7 million, had incurred operating losses of \$5.5 million for the three months ended March 31, 2015 and \$8.9 million for the year ended December 31, 2014.

To date, the Company has not generated significant commercial revenues. Based on the current 2015 revenue assumptions for Neutrolin in the approved markets, the current development plans for Neutrolin in both the United States ("U.S.") and other markets (excluding the expected Phase III clinical trial in the U.S.) and the proceeds received from the exercise of warrants, stock options (see Notes 3 and 6) and capital raised under the MLV Sales Agreement through April 30, 2015 (See Note 6), management believes that the existing cash will be sufficient to fund its operations for at least the next twelve months following the balance sheet date. However, should the Company commence the Phase III clinical trial for Neutrolin in hemodialysis patients in the U.S. in the fourth quarter of 2015, at present there is only sufficient funding to support operations and expected clinical trial expenditures into the first quarter of 2016.

The Company's continued operations, including the commencement and completion of its planned Phase III clinical trial for Neutrolin in hemodialysis patients in the U.S. will depend on its ability to generate substantial revenue from the sale of Neutrolin and on its ability raise additional capital through potential sources such as equity and/or debt financings, strategic relationships, or out-licensing of its products, until it achieves profitability, if ever. However, the Company can provide no assurances on future sales of Neutrolin or that such financing or strategic relationships will be available on acceptable terms, or at all. If the Company is unable to raise sufficient capital, find strategic partners or generate substantial revenue from the sale of Neutrolin, there would be a material adverse effect on its business. Further, the Company expects to incur increases in its cash used in operations as it continues to commercialize Neutrolin in Europe and other foreign markets, increases its business development activities, incurs additional legal costs to defend its intellectual property and seeks U.S. Food and Drug Administration ("FDA") approval of Neutrolin in the U.S.

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 estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

Basis of Consolidation

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

Cash and Cash Equivalents

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents. The Company maintains its cash and cash equivalents in bank deposits and other interest bearing accounts, the balances of which exceed federally insured limits.

Foreign Currency Translation and Transactions

The consolidated financial statements are presented in U.S. Dollars ("USD"), the reporting currency of the Company. For the financial statements of the Company's foreign subsidiary, whose functional currency is the EURO, foreign currency asset and liability amounts, are translated into USD at end-of-period exchange rates. Foreign currency income and expenses are translated at average exchange rates in effect during the year. Translation gains and losses are included in other comprehensive income (loss).

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

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.

Geographic Information

The Company reported revenues of \$31,264 and \$12,203 for the three months ended March 31, 2014 and 2014, respectively. Of the Company's first quarter 2015 revenue, \$29,058 was attributable to its European and Mideast operations which are based in Germany. All of the Company's 2014 revenue was attributable to its European operations. Total assets at March 31, 2015 were \$9,751,752, of which \$9,003,018 were located in the United States, with the remainder in Germany. Net property and equipment at March 31, 2015 was \$47,011, of which \$13,523 was located in the United States, with the remainder located in Germany.

CORMEDIX INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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:

| | March 31, 2015 | December 31, 2014 |
|-----------------|-------------------|-------------------------|
| Raw materials | \$293,756 | \$293,976 |
| Work in process | 166,807 | 166,807 |
| Finished goods | 842 | 2,246 |
| Total | \$461,405 | \$463,029 |

The Company has an inventory reserve of \$175,000 at March 31, 2015 and December 31, 2014.

Accrued Expenses

Accrued expenses consist of the following:

| | March 31, 2015 | December 31, 2014 |
|-----------------------------------|-------------------|-------------------------|
| Professional and consulting fees | \$325,942 | \$225,726 |
| Accrued payroll and payroll taxes | \$130,751 | \$13,393 |
| Market research | 70,816 | 137,345 |
| Monitoring program fees | 119,350 | 82,861 |
| Other | 35,296 | 62,200 |
| Total | \$682,155 | \$521,525 |

Revenue Recognition

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

CORMEDIX INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Deferred Revenue

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

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. However, since their effect is anti-dilutive, the Company has excluded potentially dilutive shares. The following potentially dilutive shares have been excluded from the calculation of diluted net loss per share as their effect would be anti-dilutive.

| | Three Months Ended | |
|---|--------------------|-------------------|
| | March 31, 2015 | March 31, 2014 |
| Series B non-voting convertible preferred stock | - | 454,546 |
| Series C non-voting convertible preferred stock | 2,865,000 | 3,500,000 |
| Series D non-voting convertible preferred stock | 1,479,240 | 1,148,000 |
| Series E non-voting convertible preferred stock | 1,959,759 | 1,104,280 |
| Shares underlying outstanding warrants | 6,890,327 | 11,571,233 |
| Shares underlying outstanding stock options | 4,014,500 | 3,804,000 |
| Total | 17,208,826 | 21,582,059 |

Stock-Based Compensation

The Company accounts for stock options granted to employees, officers and directors 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 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.

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 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 upon the change in the fair value of the options and amortized to expense over the related vesting period.

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.

CORMEDIX INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Research and Development

Research and development costs are charged to expense as incurred. Research and development includes fees associated with operational consultants, contract clinical research organizations, contract manufacturing organizations, clinical site fees, contract laboratory research organizations, contract central testing laboratories, licensing activities, and allocated executive, human resources and facilities expenses. The Company accrues for costs incurred as the services are being provided by monitoring the status of the trial and the invoices received from its external service providers. Costs related to the acquisition of technology rights and patents for which development work is still in process are charged to operations as incurred and considered a component of research and development expense.

Note 3 — Stockholders' Equity

Common Stock

During the quarter ended March 31, 2015, the Company issued the following shares of its common stock upon exercise of warrants resulting in gross proceeds of \$6,702,168 to the Company:

125,000 shares of common stock with an exercise price of \$0.90 per share;
125,000 shares of common stock with an exercise price of \$0.40 per share;
353,500 shares of common stock with an exercise price of \$2.50 per share; and
1,645,358 shares of common stock with an exercise price of \$3.4375 per share.

During the quarter ended March 31, 2015, the Company issued 50,000 shares of its common stock upon exercise of an aggregate of 50,000 stock options resulting in gross proceeds of \$125,500 to the Company.

During the quarter ended March 31, 2015, the Company issued 2,158,033 shares of its common stock upon a cashless exercise of 2,597,591 warrants.

During the quarter ended March 31, 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.

In March 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.

In March 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.

CORMEDIX INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Preferred Stock and Warrants

Under the terms of our Amended and Restated Certificate of Incorporation, as amended, our board of directors is authorized to issue up to 2,000,000 shares of preferred stock in one or more series without stockholder approval. Our 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, our board of directors has designated (all with par value of \$0.001 per share) the following:

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

Stock Options

During the three months ended March 31, 2015, the Company granted to its officers, directors and consultant, ten-year non-qualified stock options under the 2013 Plan, covering an aggregate of 420,000 shares of the Company's common stock. Of these options, 150,000 vested on the date of grant and had an exercise price of \$5.00 per share, 250,000 will vest one year after the grant date and had an exercise price of \$5.62 per share and the remaining 20,000 options had an exercise price of \$3.62 per share will vest upon achievement of various performance milestones.

During the three months ended March 31, 2015 and 2014, total compensation expense for stock options issued to employees, directors, officers and consultants was \$1,026,924 and \$1,415,244, respectively.

The fair value of the grants are determined using the Black-Scholes option pricing model with the following assumptions:

| | Three Months Ended | |
|-------------------------|--------------------|----------------|
| | March 31, 2015 | March 31, 2014 |
| Expected Term | 5 – 10 years | 5 – 9.75 years |
| Volatility | 94 % | 96% - 113 % |
| Dividend yield | 0.0 % | 0.0 % |
| Risk-free interest rate | 1.47% - 2.11 % | 1.51% - 2.88 % |

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. The estimation of the number of stock awards that will ultimately vest requires judgment, and to the extent actual results or updated estimates differ from the Company's current estimates, compensation expense may need to be revised. The Company considers many factors when estimating expected forfeitures for stock awards granted to employees, officers and directors, including types of awards, employee class, and an analysis of the Company's historical forfeitures.

CORMEDIX INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

| | Three Months Ended March 31, | | | |
|--|------------------------------|--|------------|--|
| | 2015 | | 2014 | |
| | Shares | Weighted Average Exercise Price | Shares | Weighted Average Exercise Price |
| Outstanding at beginning of period | 3,664,500 | \$ 1.25 | 3,453,630 | \$ 1.06 |
| Exercised | (50,000) | \$ 2.51 | (275,000) | \$ 0.78 |
| Forfeited | (20,000) | - | - | - |
| Expired | - | - | (274,630) | \$ 3.16 |
| Granted | 420,000 | \$ 5.30 | 900,000 | \$ 2.05 |
| Outstanding at end of period | 4,014,500 | \$ 1.65 | 3,804,000 | \$ 1.16 |
| Options exercisable | 3,384,000 | \$ 1.34 | 2,765,000 | \$ 1.19 |
| Expected to vest | 530,881 | \$ 3.31 | 706,520 | \$ 1.08 |
| Weighted-average fair value of options granted during the period | | \$ 3.84 | | \$ 1.49 |

The weighted average remaining contractual life of stock options outstanding at March 31, 2015 is 8.2 years. The weighted average remaining contractual life of stock options exercisable at March 31, 2015 is 8.0 years.

The aggregate intrinsic value is calculated as the difference between the exercise prices of the underlying options and the quoted closing price of the common stock of the Company at the end of the reporting period for those options that have an exercise price below the quoted closing price. The aggregate intrinsic value of all stock options exercised during the three months ended March 31, 2015 was \$134,600. The aggregate intrinsic value of outstanding stock options at March 31, 2015 was \$30,542,180.

As of March 31, 2015, the total compensation expense related to non-vested options not yet recognized totaled \$1,674,298. The weighted-average vesting period over which the total compensation expense related to non-vested options not yet recognized at March 31, 2015 was approximately 0.7 years.

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.

CORMEDIX INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

In March 2015, the Company issued two warrants exercisable into 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 the Backstop Agreement with Manchester Securities Corp. (See Note 4). Additionally, the expiration date of March 24, 2015 of warrants to purchase 390,720 shares of common stock issued to Manchester Securities Corp. in connection with the Company's 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 | 5 years |
| Volatility | 75.81% - 104.08% |
| Dividend yield | 0.0% |
| Risk-free interest rate | 0.01% - 1.61% |

During the quarter ended March 31, 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.

The following table is the summary of warrant activity for the three months ended March 31, 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 | (68,160) | \$3.44 | - |
| Exercised | (4,846,449) | \$1.72 | - |
| Outstanding at end of period | 6,890,327 | \$2.38 | 2.50 |

Note 4 — Related Party Transactions:

On March 3, 2015, the Company entered into a backstop agreement with an existing institutional investor, Manchester Securities Corp., an affiliate of Elliott Associates, L.P., pursuant to which 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 may not exceed \$3,000,000. The Company was able to access this financing until April 30, 2015. However, because the Company had received approximately \$5.7 million through March 31, 2015 from the exercise of warrants issued in connection with its IPO, the Company cannot and did not access the loan and the loan expired.

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 Cora Tellez, 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 advanced notice, upon termination the Company is liable for any services rendered through the termination date.

CORMEDIX INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 5 — Commitments and Contingencies:

Contingency Matters

In February 2007, Geistlich Söhne AG für Chemische Industrie, Switzerland, or Geistlich, brought an action against the European Sodemann Patent covering the Company's Neutrolin® product candidate which is owned by ND Partners, LLC and licensed to the Company pursuant to the License and Assignment Agreement between the Company and ND Partners LLC. The action that was brought against the counterpart of the Sodemann Patent in Germany at the Board of the European Patent Office opposition division was for lack of inventiveness in the use of citric acid and a pH value in the range of 4.5 to 6.5 with having the aim to provide an alternative lock solution through having improved anticoagulant characteristics compared to the lock solutions of the prior art. The Board of the European Patent Office opposition division rejected the opposition by Geistlich. On August 27, 2008, Geistlich appealed the court's ruling, alleging the same arguments as presented during the opposition proceedings. The Company filed a response to the appeal of Geistlich on March 25, 2009 where the Company requested a dismissal of the appeal and to maintain the patent as granted. As of March 27, 2014, no further petitions have been filed by ND Partners or Geistlich. On October 10, 2012, the Company became aware that the Board of Appeals of the European Patent Office issued, on September 4, 2012, a summons for oral proceedings. On November 28, 2012, the Board of Appeals of the European Patent Office held oral proceedings and verbally upheld the counterpart of the Sodemann Patent covering Neutrolin®, but remanded the proceeding to the lower court to consider restricting certain of the counterpart of the Sodemann Patent claims. The Company received the Appeals Board final written decision on March 28, 2013 which was consistent with the oral proceedings. In a letter dated September 30, 2013, the Company was notified that the opposition division of the European Patent Office reopened the proceedings before the first instance again, and has given their preliminary non-binding opinion that the patent as amended during the appeal proceedings fulfils the requirements of Clarity, Novelty, and Inventive Step, and invited the parties to provide their comments and/or requests by February 10, 2014. The Company filed its response on February 3, 2014 to request that the patent be maintained as amended during the appeal proceedings. Geistlich did not provide any filing by February 10, 2014; however, the Board of the European Patent Office opposition division has 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 becomes final if no further appeal is lodged by Geistlich by January 15, 2015. As of the date of this report, the Company had not received a communication from the European Patent Office that Geistlich has filed such an appeal.

On September 9, 2014, the Company filed in the Mannheim, Germany District Court a patent infringement action against TauroPharm GmbH and Tauro-Implant GmbH as well as their respective CEOs (the "Defendants") claiming infringement of the Company's European Patent EP 1 814 562 B1, which was granted by the European Patent Office on January 8, 2014 (the "Prosl European Patent"). The Prosl European Patent covers a low heparin catheter lock solution for maintaining patency and preventing infection in a hemodialysis catheter. In this action, the Company claim 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 European Patent Office 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.

CORMEDIX INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

In the same complaint against the same Defendants, the Company also alleged an infringement (requesting the same remedies) of ND Partners' utility model DE 20 2005 022 124 U1 (the "Utility Model") which is basically identical to the Prosl European Patent in its main aspects and claims. The Mannheim court separated the two proceedings so that the Prosl European Patent and the Utility Model proceeding are now tried separately and independently from each other due to the slightly differing requirements for both IP rights. TauroPharm has filed a cancellation action against the Utility Model before the German Patent and Trademark Office based on the same arguments as the opposition against the Prosl European Patent. The Company cannot predict what other defenses the Defendants may raise, or the ultimate outcome of this matter.

On March 27, 2015, the Mannheim District Court held a hearing to evaluate whether the Utility Model has been infringed by TauroPharm in connection with the manufacture, sale and distribution of its TauroLock-HEP100 and HEP500 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 based upon the same circumstances. While the Court had indicated that it might render a decision in the patent infringement matter, it has now informed the Company that decisions in each of these related matters likely will be issued on May 8, 2015, although the Company cannot assure that any decision will be rendered on that date. The Court's decisions will be subject to appeal.

Parallel to the Court proceedings, both the opposition proceedings against the Prosl European Patent before the European Patent Office, or EPO, and the cancellation action against the Utility Model before the German Patent and Trademark Office, or German PTO, are ongoing. The Company does not expect a decision from the EPO before the middle of 2016 (in the case of the Prosl European Patent) or late 2015 from the German PTO (in the case of the Utility Model), with each such decision 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 its product Neutrolin®, which is approved for sale in Germany, in its manufacture and sale of TauroPharm's products TauroLock™, TauroLock-HEP100™ and TauroLock-HEP500™. The Company seeks a cease and desist order against TauroPharm from continuing to manufacture and sell any product containing taurolidine as well as 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 has been scheduled in the District Court of Cologne for July 2, 2015.

In connection with the aforementioned proceedings against Tauropharm, the Company was required by the District Court Mannheim to provide a security deposit of approximately \$132,000----- to cover legal fees in the event Tauropharm is entitled to reimbursement of these costs. The Company recorded the deposit as restricted cash for the quarter ended March 31, 2015.

CORMEDIX INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Commitments

Navinta LLC, a U.S.-based Active Pharmaceutical Ingredient (“API”) developer, provides API manufacturing (manufactured in India at an FDA-compliant facility) and a Drug Master File for CRMD003, pursuant to a supply agreement dated December 7, 2009 (the “Navinta Agreement”). The Navinta Agreement provides that Navinta supply taurolidine (the API for CRMD003) to the Company on an exclusive worldwide basis in the field of the prevention and treatment of human infection and/or dialysis so long as the Company purchased a minimum of \$350,000 of product from Navinta by December 30, 2010, which the Company achieved, and following the Company’s first commercial sale of a product incorporating taurolidine, purchases a minimum of \$2,250,000 of product on an annual basis for five years. The Company did not purchase the required amount in 2014 and as a result, lost its exclusive manufacturing rights. The Company is also required to make certain cash payments to Navinta upon the achievement of certain sales-based milestones. 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.

In 2008, the Company entered into a License and Assignment Agreement (the “NDP License Agreement”) with ND Partners LLC, a Delaware limited liability company (“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 35,886 shares held in escrow. The number of shares held in escrow as of March 31, 2014 is 109,657 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 March 31, 2015. Events that trigger milestone payments include but are not limited to the reaching of various stages of regulatory approval processes and certain worldwide net sales amounts.

CORMEDIX INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

On April 11, 2013, the Company entered into an amendment to the NDP License Agreement. Under Article 6 of the NDP License Agreement, the Company was obligated to make a milestone payment of \$500,000 to ND Partners upon the first issuance of a CE Marking for a licensed product, which payment was payable to ND Partners within 30 days after such issuance. Pursuant to the terms of the amendment, the Company and ND Partners agreed to delay such milestone payment to a time, to be chosen by the Company, anytime within 12 months after the achievement of such issuance. As consideration for the amendment, the Company issued ND Partners a warrant to purchase 125,000 shares of the Company's common stock at an exercise price of \$1.50 per share. The warrant is exercisable immediately upon issuance and has a term of five years. In January 2014, the Company settled this milestone payment which resulted in the issuance of 50,000 shares of the Company's Series C-3 non-voting convertible preferred and 250,000 shares issuable upon exercise of warrants at an exercise price of \$1.25 per share which was decreased to \$0.90 per share. Through March 31, 2015, no other milestone payments have been earned by or paid to Navinta.

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.

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. Additionally, its subsidiary leases its copier pursuant to a lease agreement dated October 10, 2013 with Frima Buromaschinen Schafer GmbH & Co. KG. The lease has a term of 48 months which commenced on November 1, 2013 for a monthly payment of €59. The total 48 month lease obligation is approximately €2,800.

Under the Company's current lease agreements, the total remaining lease obligation as of March 31, 2015 is set forth below:

| | |
|-------|-----------|
| 2015 | \$51,662 |
| 2016 | 66,236 |
| 2017 | 60,784 |
| 2018 | 15,000 |
| Total | \$193,682 |

Note 6 — Subsequent Events:

From April 1, 2015 to April 30, 2015, the following were exercised resulting in aggregate gross proceeds of approximately \$8.0 million.

stock options to purchase 230,000 shares of common stock with a weighted average exercise price of \$0.86 per share;

warrants to purchase 25,000 shares of common stock with an exercise price of \$0.90 per share by a director of the Company and;

warrants to purchase 2,268,117 shares of common stock with an exercise price of \$3.4375 per share.

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 will notify 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 will be 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. Through April 30, 2015, the Company issued 472,412 shares of common stock and realized net proceeds of approximately \$3.9 million.

On April 9, 2015, the Company announced a new 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 during the remainder of 2015. To date, the Company has not paid RC2 for their services related to this agreement. The Company and RC2 are to negotiate a manufacturing services agreement within 60 days of the preliminary services agreement. RC2 also agreed to an expected price per kilogram for taurolidine for any future commercial supply agreement the Company may negotiate with RC2.

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 2014 Annual Report on Form 10-K, filed with the Securities and Exchange Commission, or 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 or the Exchange Act. Forward-looking statements are often identified by the use of words such as, but not limited to, "anticipate," "believe," "can," "continue," "could," "estimate," "expect," "intend," "may," "will," "plan," "project," "seek," "solicit," "would," and similar expressions or variations intended to identify forward-looking statements. These statements are based on the beliefs and assumptions of our management based on information currently available to management. Such forward-looking statements are subject to risks, uncertainties and other important factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed in the section titled "Risk Factors" included in our most recent annual report on Form 10-K, as well as any amendments thereto, as filed with the SEC and which are incorporated herein by reference. Furthermore, such forward-looking statements speak only as of the date of this report. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

Overview

CorMedix Inc. and Subsidiary (referred to herein as "we," "us," "our" and the "Company"), is a commercial pharmaceutical and medical device company. We seek to in-license, develop and commercialize prophylactic and therapeutic products for the prevention and treatment of infectious diseases in cardiac, renal and oncology patients. As of the date of this report, we have in-licensed all of the product candidates in our pipeline.

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

Our primary product is Neutrolin, a catheter lock solution, for the prevention of catheter-related infections and thrombosis in the central venous catheter markets such as dialysis, critical care, and oncology. Catheter related blood stream infections (CRBSI) 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, which reduces infection and thrombosis thereby keeping catheters operating optimally in the clinical settings in hemodialysis, critical care/intensive care and oncology. Hemodialysis using a tunneled central vein catheter was our initial target market with Germany being the first market in which we launched Neutrolin as a medical device in December 2013. According to the United States Renal Disease System, there were 636,905 patients on dialysis. It has been reported that patients requiring catheter represent over 127 million catheter days. The market in the critical care/intensive care units is approximately 35 million catheter days per year in the United States alone. There were over 13 million patients living with cancer in the United States in 2010 with an estimated 4 million having a long-term central venous

catheter. However, when stages of disease, chemotherapy regimens and catheter types are factored, we believe the oncology market is approximately 43 million catheter days. Infection and thrombosis represent key complications among critical care/intensive care and cancer patients with central venous catheters. These complications can lead to treatment delays and increased costs to the healthcare system when they occur due to hospitalizations, need for IV antibiotic treatment, long-term anticoagulation therapy, removal/replacement of the central venous catheter, related treatment costs and increased mortality when they occur. We estimate that catheter related bloodstream infections and thrombosis cost the U.S. healthcare system approximately \$11 billion dollars each year.

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, or 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, Kuwait and The Netherlands for such treatment.

We have entered into agreements with human4farma, a German contract sales company, and with Arabian Trade House, a Saudi Arabian company, Medvision, a Kuwait company, to market and sell Neutrolin for hemodialysis, critical care/intensive care and oncolytic patients in Germany, Saudi Arabia and Kuwait, respectively, 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 Austria.

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, or IV, nutrition was also approved. In September 2014, the TUV-SUD and The Medicinal Evaluation Board of the Netherlands (MEB) granted a label expansion for Neutrolin for these same expanded indications for the E.U.

In late 2013, we met with 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 trial in hemodialysis patients with a central venous catheter; this protocol was accepted in August 2014 and we filed an investigational new drug application, or 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. We are seeking one or more strategic partners or other sources of capital to complete the development of Neutrolin in the U.S.

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

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

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

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

In March 2015, we commenced a process to evaluate our strategic alternatives in order to accelerate the global development of Neutrolin and maximize shareholder value. No timetable has been set for completion of this evaluation process, and there can be no assurance that any transaction will result. We engaged investment bank Evercore Group L.L.C. to provide financial advice and assist us with our evaluation process. Strategic alternatives we may pursue could include, but are not limited to, joint ventures or partnering or other collaboration agreements, licensing arrangements, or another transaction intended to maximize shareholder value, such as a merger, a sale of our company or some or all of our assets, or another strategic transaction. There can be no assurance that the exploration of strategic alternatives will result in any agreements or transactions, or that, if completed, any agreements or transactions will be successful or on attractive terms.

Since our inception, we have had not generated significant revenue from product sales. Our operations to date have been primarily limited to organizing and staffing, licensing product candidates, developing clinical trials for our product candidates, establishing manufacturing for our product candidates, performing business and financial planning, performing research and development, seeking regulatory approval for our products, initial commercialization activities for Neutrolin, and maintaining and improving our patent portfolio. We have funded our operations primarily with debt and equity financings. We have generated significant losses to date, and we expect to incur increases in our cash used in operations as we continue to commercialize Neutrolin in Europe and other markets, increase our business development activities, incur additional legal costs to defend our intellectual property and seek FDA approval of Neutrolin in the U.S. As of March 31, 2015, we had an accumulated deficit of approximately \$81.7 million. We are unable to predict the extent of any future losses or when we will become profitable, if at all.

Financial Operations Overview

Revenue

We have not generated substantial revenue since our inception. If the commercialization for Neutrolin in Europe and other foreign markets is successful and our product development efforts in the United States result in clinical success, regulatory approval and successful commercialization, we could generate revenue from sales or licenses of any such products.

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

Our product Neutrolin received CE Mark in Europe in July 2013 and product shipments to dialysis centers began in December 2013. Orders are processed through a distributor. The distributor remits payment to us upon collection from the customer. We recognize net sales upon shipment of product to the dialysis centers.

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 Korea. Upon execution of the Agreement, Wonik paid us a non-refundable \$50,000 payment and will pay an additional \$50,000 upon receipt of the product registration necessary to sell Neutrolin in the Republic of Korea (the “Territory”). The term of the agreement commenced on August 8, 2014 and will continue for three years after the first commercial sale of Neutrolin in the Territory. 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, or R&D, expense consists of: (i) internal costs associated with our development activities; (ii) payments we make to third party contract research organizations, contract manufacturers, investigative sites, and consultants; (iii) technology and intellectual property license costs; (iv) manufacturing development costs; (v) personnel related expenses, including salaries, stock-based compensation expense, benefits, travel and related costs for the personnel involved in drug development; (vi) activities relating to regulatory filings and the advancement of our product candidates through preclinical studies and clinical trials; and (vii) facilities and other allocated expenses, which include direct and allocated expenses for rent, facility maintenance, as well as laboratory and other supplies. All R&D is expensed as incurred.

Conducting a significant amount of development is central to our business model. Product candidates in later-stage clinical development generally have higher development costs than those in earlier stages of development, primarily due to the significantly increased size and duration of the clinical trials. We plan to increase our R&D expenses for the foreseeable future in order to complete development of Neutrolin in the U.S.

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

| | Three Months Ended March 31, | | | |
|---------|---------------------------------|---|------|---|
| | 2015 | % | 2014 | % |
| CRMD003 | 99 | % | 98 | % |
| CRMD004 | 1 | % | 2 | % |

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

Development timelines, probability of success and development costs vary widely. During the third quarter of 2011, we received a notice from the FDA that our product candidate, Neutrolin, had been assigned to the Center for Drug Evaluation and Research, or CDER. As a result of this, and given our limited resources, we decided to change our business strategy and focus the majority of our resources on the research and development of Neutrolin rather than CRMD004 and to seek regulatory and commercialization approval for Neutrolin in Europe through a CE Mark application rather than pursue FDA approval at that time.

On July 5, 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, or CRBI, and maintenance of catheter patency in hemodialysis patients using a tunneled, cuffed central venous catheter for vascular access. 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, or IV, nutrition was also approved. In September 2014, the TUV-SUD and The Medicinal Evaluation Board of the Netherlands (MEB) granted a label expansion for Neutrolin for these same expanded indications for the EU.

To date, Neutrolin is registered and may be sold in Austria, Germany, Italy, Malta, Saudi Arabia, Kuwait and The Netherlands for such treatment.

Our current focus on commercializing Neutrolin in Europe and other markets may impact our other development efforts and timelines. We are seeking to develop Neutrolin in the U.S. 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 are seeking one or more strategic partners or other sources of capital to complete the development of Neutrolin in the U.S.

Selling, General and Administrative Expense

Selling, general and administrative, or SG&A, expense includes costs related to commercial personnel, medical education professionals, marketing and advertising, salaries and other related costs, including stock-based compensation expense, for persons serving in our executive, sales, finance and accounting functions. Other SG&A expense includes facility-related costs not included in R&D expense, promotional expenses, costs associated with industry and trade shows, and professional fees for legal services and accounting services. We expect that our SG&A expenses will increase due to marketing of our Neutrolin product in Europe and other markets, and as a result of the reporting obligations applicable to public companies.

Foreign Currency Exchange Transaction Gain (Loss)

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

Loss on Issuance of Preferred Stock and Warrants

We issued preferred stock and related warrants during the quarter ended March 31, 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

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 are recorded at fair value on a recurring basis under generally accepted accounting principles. This includes any changes in fair value resulting from the re-measurement of the derivative liabilities in connection with the redemption or conversion of the preferred stock and the exercise of warrants.

Interest Income

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

Interest Expense

Interest expense consists of interest incurred on financing of expenses.

Results of Operations

Three months ended March 31, 2015 compared to three months ended March 31, 2014

Revenue. Revenue was approximately \$31,000 for the three months ended March 31, 2015 compared to approximately \$12,000 in the prior year. The majority of the revenue is from sales of Neutrolin. The majority of the sales occurred in Germany and Middle East markets. In addition, we realized \$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 \$17,000 for the three months ended March 31, 2015 compared to \$81,000 in the same period last year. Cost of sales for the three months ended March 31, 2015 are primarily comprised of on-going stability studies of approximately \$11,000, and direct cost of materials of approximately \$4,000. Cost of sales for the three months ended March 31, 2014 was approximately \$81,000, primarily comprised of costs associated with transitioning Neutrolin to new labels and packaging of approximately \$45,000, management of our contract manufacturer of approximately \$17,000, on-going stability testing of approximately \$16,000 and other

costs of approximately \$3,000. For the three months ended March 31, 2015 and 2014, a substantial part of the costs of raw materials and the cost to manufacture the product sold were previously charged to research and development expense because it had been purchased and manufactured prior to the receipt of the CE Mark.

Research and Development Expense. R&D expense was approximately \$1,235,000 for the three months ended March 31, 2015, an increase of approximately \$882,000, from approximately \$353,000 for the three months ended March 31, 2013. The increase was primarily attributable to higher costs related to regulatory development of Neutrolin in the U.S. of approximately \$557,000 and an increase in non-cash stock based compensation of approximately \$276,000.

Selling, General and Administrative Expense. SG&A expense was approximately \$4,276,000 for the three months ended March 31, 2015, an increase of approximately \$1,763,000 from approximately \$2,513,000 for the three months ended March 31, 2014. The increase was primarily attributable to a non-cash charge for warrants issued in connection with the backstop agreement of approximately \$1,583,000. Additionally, there were increases in legal fees due mainly to ongoing intellectual property litigation of approximately \$362,000; personnel cost of approximately \$216,000; costs related to business development activities of approximately \$179,000; costs related to commercialization of Neutrolin in the EU of approximately \$39,000; and accounting fees of approximately \$42,000. These increases were offset by a decrease in non-cash stock-based compensation expense of approximately \$665,000.

Loss on Issuance of Preferred Stock Convertible Notes and Warrants. The loss on the issuance of preferred stock and warrants in the three months ended March 31, 2014 represents the difference on the issuance date between the combined fair value of the conversion option and the warrants of approximately \$2,054,000, and the combined proceeds received and liabilities settled, net of all issuance-related fees and expenses of approximately \$1,964,000. On September 15, 2014, the downround protection of these derivative liabilities was eliminated through an agreement modification resulting in the reclassification of derivative liabilities to equity.

Change in Fair Value of Derivative Liabilities. The change in fair value of derivative liabilities of approximately \$13,682,000 in the three months ended March 31, 2014 consists of increases in the fair value of preferred stock and warrants between December 31, 2013 and March 31, 2014 of approximately \$8,682,000 and approximately \$5,000,000, respectively. The change in the fair value of the preferred stock includes the combined changes in (i) the fair value of the converted and redeemed amounts between December 31, 2013 and the relevant conversion and redemption dates and (ii) the change in fair value of the preferred stock between December 31, 2013 and March 31, 2014. The change in fair value of the warrants is the difference between the fair value at December 31, 2013 and March 31, 2014. On September 15, 2014, the downround protection of these derivative liabilities was eliminated through an agreement modification resulting in the reclassification of derivative liabilities to equity.

Interest Income. Interest income was approximately \$500 for the three months ended March 31, 2015 and 2014.

Interest Expense. Interest expense was approximately \$900 for the three months ended March 31, 2015 as compared to approximately \$500 for the same period last year, an increase of approximately \$400.

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 are recorded in other comprehensive income totaling approximately \$3,000 gain for the three months ended March 31, 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. We received CE Mark approval for our Neutrolin product in July 2013 and launched our product in the EU in December 2013.

During the quarter ended March 31, 2015, we received gross proceeds of approximately \$6,828,000 from the following exercises of warrants and stock options:

125,000 shares of common stock with an exercise price of \$0.90 per share;
125,000 shares of common stock with an exercise price of \$0.40 per share;
353,500 shares of common stock with an exercise price of \$2.50 per share;
1,645,358 shares of common stock with an exercise price of \$3.4375 per share; and
50,000 shares of common stock with exercise prices ranging from \$2.10 to \$3.125.

Net Cash Used in Operating Activities

Net cash used in operating activities was approximately \$2,349,000 for the three months ended March 31, 2015 as compared to approximately \$1,429,000 for the same period last year. The net loss of approximately \$5,498,000 for the three months ended March 31, 2015 was higher than cash used in operating activities by approximately \$3,149,000. The difference is attributable primarily to non-cash charge for warrants issued in connection with the backstop agreement of approximately \$1,583,000, non-cash stock-based compensation of approximately \$1,027,000 and increases in accounts payable and accrued expenses of approximately \$546,000 and \$197,000, respectively, partially offset by an increases in restricted cash and prepaid expenses of approximately \$132,000 and \$76,000, respectively. The net loss of approximately \$16,713,000 for the three months ended March 31, 2014 was higher than cash used in operating activities by approximately \$15,284,000. The difference is attributable primarily to revaluation of preferred stock and warrants of approximately \$13,682,000, non-cash stock-based compensation of approximately \$1,415,000, an increase in accounts payable of approximately \$118,000 and a loss on issuance of preferred stock of approximately \$90,000.

Net Cash Used in Investing Activities

Cash used in investing activities for the three months ended March 31, 2015 was approximately \$13,000. There was no cash used in investing activities for the three months ended March 31, 2014.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was approximately \$6,828,000 for the three months ended March 31, 2015 as compared to approximately \$8,253,000 for the same period last year, a decrease of approximately \$1,425,000. During the three months ended March 31, 2015, we received net proceeds of approximately \$6,702,000 and \$126,000 from the exercise of warrants and stock options, respectively, as compared to the net proceeds from the sale of common stock of approximately \$6,723,000 and Series C-3 preferred stock of approximately \$1,319,000, and exercise of stock options of approximately \$214,000 for the same period last year.

Funding Requirements

Our total cash on hand as of March 31, 2015 was approximately \$8,799,000, 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 will depend on whether we are able to generate substantial revenue from the sale of Neutrolin and on our ability to raise additional funds through various potential sources, such as equity, debt financings, strategic relationships, out-licensing or distribution arrangements of our products, until we achieve profitability, if ever. However, we can provide no assurances that we will achieve substantial levels of revenue from sales of Neutrolin or that financing or strategic relationships will be available on acceptable terms, or at all.

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 may seek to sell additional equity or debt securities, obtain a bank credit facility, or enter into a corporate collaboration or licensing arrangement, but can provide no assurances that such financing will be available on acceptable terms, or at all. Moreover, the incurrence of indebtedness in connection with a debt financing would result in increased fixed obligations and could also result in covenants that would restrict our operations. Raising additional funds through collaboration or licensing arrangements with third parties may require us to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or to grant licenses on terms that may not be favorable to us or our stockholders. Our actual cash requirements may vary materially from those now planned, however, because of a number of factors including any change in the focus and direction of our research and development programs, any acquisition or pursuit of development of new product candidates, competitive and technical advances, costs of commercializing any of our product candidates, and costs of filing, prosecuting, defending and enforcing any patent claims and any other intellectual property rights.

While we expect to grow product sales substantially, we do not anticipate that we will generate significant product sales revenue for 2015. In the absence of such revenue, we would experience continuing operating cash flow losses. 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 March 31, 2015, our expectations on the current 2015 revenue assumptions for Neutrolin in the approved markets, the current development plans for Neutrolin in both the U.S. and other markets (excluding the expected Phase III clinical trial in the U.S.) and the proceeds received from the exercise of warrants, stock options and capital raised under the MLV Sales Agreement through April 30, 2015 (See Note 6), we believe that our existing cash will be sufficient to fund our operations for at least the next twelve months following the balance sheet date. However, should the Company commence the Phase III clinical trial for Neutrolin in hemodialysis patients in the U.S. in the fourth quarter of 2015, at present there is only sufficient funding to support operations and expected clinical trial expenditures into the first quarter of 2016. Additionally, we will need additional financing thereafter until we can achieve profitability, if ever. If we are unable to raise additional funds when needed, we may not be able to market our products as planned or continue the development and regulatory approval of our products, or we could be required to delay, scale back or eliminate some or all of our research and development programs. Each of these alternatives would likely have a material adverse effect on our business and raise substantial doubt about our ability to continue as a going concern.

Critical Accounting Policies

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

While our significant accounting policies are more fully described in our annual report on Form 10-K 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 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 FASB ASC No. 505-50 ("ASC 505"), "Equity-Based Payments to Non-Employees." 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.

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.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Item 4. Controls and Procedures.

Under the supervision of our Chief Executive Officer and Chief 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 March 31, 2015. Although we have taken actions remediating our material weakness in internal control over financial reporting, we believe that the material weakness was not fully remediated as of March 31, 2015. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were not effective as of March 31, 2015 to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely discussion regarding required disclosures.

Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures are designed only to provide reasonable assurance that information to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. As of the end of the period covered by this report, our management, including our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures.

Based on their evaluation of our disclosure controls and procedures, and as a result of the material weakness described above, our management, including our principal executive officer and principal financial officer, have concluded that our disclosure controls and procedures were not effective as of March 31, 2015 to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is (a) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (b) accumulated and communicated to management, including our principal executive officer and principal financial officer, as appropriate to allow for timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

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 Securities Exchange Act of 1934, as amended, or the Exchange Act) related to our limited finance staff and the resulting ineffective management review over financial reporting, coupled with increasingly complex accounting treatments associated with our financing activities and European expansion. We have concluded that this material weakness in our internal control over financial reporting was due to the fact that we did not yet have the appropriate resources with the appropriate level of experience and technical expertise to oversee our closing and financial reporting processes.

There were no changes in our internal control over financial reporting during the quarter ended March 31, 2015, or in other factors that could significantly affect these controls, that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II
OTHER INFORMATION

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

In connection with the backstop financing announced on March 4, 2015, we issued on March 25, 2015 to Kingsbrook Opportunities Master Fund LP, or Kingsbrook, a warrant, exercisable for five years, to purchase 83,400 shares of our common stock at a per share exercise price of \$7.00.

Kingsbrook will be prohibited from exercising any of the warrant if, as a result of such exercise, it, together with its affiliates, would own more than 9.99% of the total number of shares of our common stock then issued and outstanding. Kingsbrook may waive the ownership limitation, provided that any such waiver will be effective 61 days after notice is delivered to us.

The warrant was issued in a transaction exempt from registration under the Securities Act of 1933, as amended, in reliance on Section 4(2) thereof.

Item 6. Exhibits.

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

| Exhibit Number | Description |
|----------------|---|
| 10.1+ | Amendment No. 2, dated as of March 10, 2015, to Taurolodine Supply Agreement.* |
| 31.1 | Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.* |
| 31.2 | Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.* |
| 32.1 | Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.* |
| 32.2 | Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.* |
| 101 | The following materials from CorMedix Inc. Form 10-Q for the quarter ended March 31, 2015, formatted in Extensible Business Reporting Language (XBRL): (i) Condensed Consolidated Balance Sheets at March 31, 2015 and December 31, 2014, (ii) Condensed Consolidated Statements of Operations for the three months ended March 31, 2015 and 2014, (iii) Condensed Consolidated Statements of Changes in Stockholders' Equity for the three months ended March 31, 2015, (iv) Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2015 and 2014, and (v) Notes to the Unaudited Condensed Consolidated Financial Statements.** |

*

Filed herewith.

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

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

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: May 7, 2015 By: /s/ Randy Milby
Name: Randy Milby
Title: Chief Executive Officer
(Principal Executive Officer)

Date: May 7, 2015 By: /s/ Harry O'Grady
Name: Harry O'Grady
Title: Chief Financial Officer
(Principal Financial and Accounting
Officer)

EXHIBIT INDEX

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| 32.1 | Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.* |
| 32.2 | Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.* |
| 101 | The following materials from CorMedix Inc. Form 10-Q for the quarter ended March 31, 2015, formatted in Extensible Business Reporting Language (XBRL): (i) Condensed Consolidated Balance Sheets at March 31, 2015 and December 31, 2014, (ii) Condensed Consolidated Statements of Operations for the three months ended March 31, 2015 and 2014, (iii) Condensed Consolidated Statements of Changes in Stockholders' Equity for the three months ended March 31, 2015, (iv) Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2015 and 2014, and (v) Notes to the Unaudited Condensed Consolidated Financial Statements.** |

* Filed herewith.

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

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