

CorMedix Inc.
Form 10-Q
May 15, 2018

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, 2018

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

For the transition period from _____ to _____

Commission file number 001-34673

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

Delaware 20-5894890
(State or Other Jurisdiction of (I.R.S. Employer
Incorporation or Organization) Identification No.)

400 Connell Drive, Suite 5000, Berkeley Heights, NJ 07922
(Address of Principal Executive Offices) (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 (Do not check if a smaller reporting company) | Smaller reporting company |
| | Emerging growth company |

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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 11, 2018 was 81,903,027.

CORMEDIX INC. AND SUBSIDIARY

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PART I
FINANCIAL INFORMATION

Item 1.
Consolidated Financial Statements.

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

| | March 31, 2018 | December 31, 2017 |
|--|--------------------|----------------------|
| ASSETS | | |
| Current assets | | |
| Cash and cash equivalents | \$8,162,034 | \$10,379,729 |
| Restricted cash | 171,553 | 171,553 |
| Short-term investments | - | 1,604,198 |
| Trade receivables | 8,651 | 64,148 |
| Inventories, net | 578,912 | 594,194 |
| Prepaid research and development expenses | 80,613 | 86,652 |
| Other prepaid expenses and current assets | 401,903 | 367,177 |
| Total current assets | 9,403,666 | 13,267,651 |
| Property and equipment, net | 205,303 | 186,282 |
| TOTAL ASSETS | \$9,608,969 | \$13,453,933 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities | | |
| Accounts payable | \$3,659,744 | \$1,808,311 |
| Accrued expenses | 5,090,886 | 4,363,867 |
| Deferred revenue | 17,647 | 88,404 |
| Total current liabilities | 8,768,277 | 6,260,582 |
| TOTAL LIABILITIES | 8,768,277 | 6,260,582 |
| COMMITMENTS AND CONTINGENCIES | | |
| STOCKHOLDERS' EQUITY | | |
| Preferred stock - \$0.001 par value: 2,000,000 shares authorized; 419,585 shares issued and outstanding at March 31, 2018 and December 31, 2017 | 420 | 420 |
| Common stock - \$0.001 par value: 160,000,000 shares authorized; 81,786,902 and 71,413,790 shares issued and outstanding at March 31, 2018 and December 31, 2017, respectively | 81,787 | 71,414 |
| Accumulated other comprehensive income | 97,008 | 98,433 |
| Additional paid-in capital | 163,003,806 | 159,197,950 |

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| | | |
|--|---------------|---------------|
| Accumulated deficit | (162,342,329) | (152,174,866) |
| TOTAL STOCKHOLDERS' EQUITY | 840,692 | 7,193,351 |
| TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY | \$9,608,969 | \$13,453,933 |

See Notes to Unaudited Condensed Consolidated Financial Statements.

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

| | For the Three Months Ended March 31, | |
|--|---|---------------|
| | 2018 | 2017 |
| Revenue | | |
| Net sales | \$23,210 | \$39,559 |
| Cost of sales | (28,575) | (93,571) |
| Gross loss | (5,365) | (54,012) |
| Operating Expenses | | |
| Research and development | (8,280,442) | (4,924,267) |
| Selling, general and administrative | (1,903,016) | (2,640,726) |
| Total operating expenses | (10,183,458) | (7,564,993) |
| Loss From Operations | (10,188,823) | (7,619,005) |
| Other Income (Expense) | | |
| Interest income | 14,775 | 23,431 |
| Foreign exchange transaction loss | (9,197) | (1,286) |
| Interest expense | (1,873) | - |
| Total income | 3,705 | 22,145 |
| Net Loss | (10,185,118) | (7,596,860) |
| Other Comprehensive Income (Loss) | | |
| Unrealized gain from investment | - | 10,113 |
| Foreign currency translation loss | (1,425) | (992) |
| Total comprehensive income (loss) | (1,425) | 9,121 |
| Comprehensive Loss | \$(10,186,543) | \$(7,587,739) |
| Net Loss Per Common Share – Basic and Diluted | \$(0.14) | \$(0.19) |
| Weighted Average Common Shares Outstanding – Basic and Diluted | 75,356,388 | 40,624,920 |

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 C-2, Series C-3, Series D, Series E and Series F | | Accumulated Other Comprehensive Income | Additional Paid-in Capital | Accumulated Deficit | Total Stockholders' Equity |
|---|--------------|----------|--|--------|--|----------------------------|---------------------|----------------------------|
| | Shares | Amount | Shares | Amount | Income | Capital | Deficit | Equity |
| Balance at January 1, 2018 | 71,413,790 | \$71,414 | 419,585 | \$420 | \$98,433 | \$159,197,950 | \$(152,174,866) | \$7,193,351 |
| Proceeds from ATM sale of common stock, net | 10,202,099 | 10,202 | | | | 3,258,961 | | 3,269,163 |
| Issuance of vested restricted stock | 43,385 | 43 | | | | (43) | | - |
| Stock issued for payment of deferred fees | 127,628 | 128 | | | | 173,645 | | 173,773 |
| Stock-based compensation | | | | | | 373,293 | | 373,293 |
| Cumulative effect of adoption of ASC 606 (Note 1) | | | | | | | 17,655 | 17,655 |
| Other comprehensive income | | | | | (1,425) | | | (1,425) |
| Net loss | | | | | | | (10,185,118) | (10,185,118) |
| Balance at March 31, 2018 | 81,786,902 | \$81,787 | 419,585 | \$420 | \$97,008 | \$163,003,806 | \$(162,342,329) | \$840,692 |

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, | |
|---|---|--------------------|
| | 2018 | 2017 |
| CASH FLOWS FROM OPERATING ACTIVITIES: | | |
| Net loss | \$(10,185,118) | \$(7,596,860) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Stock-based compensation | 373,293 | 452,023 |
| Loss on foreign currency transactions | - | 210 |
| Depreciation | 19,381 | 8,773 |
| Changes in operating assets and liabilities: | | |
| (Increase) decrease in trade receivables | 57,182 | (63,509) |
| Decrease in inventory | 15,282 | 71,866 |
| (Increase) decrease in prepaid expenses and other current assets | (28,151) | 563,180 |
| Increase in accounts payable | 1,849,784 | 80,764 |
| Increase (decrease) in accrued expenses | 916,578 | (270,292) |
| Decrease in deferred revenue | (72,534) | (4,881) |
| Net cash used in operating activities | (7,054,303) | (6,758,726) |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | |
| Sale of short-term investments | 1,604,198 | 5,160,073 |
| Purchase of equipment | (38,226) | (1,998) |
| Net cash provided by investing activities | 1,565,972 | 5,158,075 |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | |
| Proceeds from sale of common stock from at-the-market program | 3,269,163 | 347,361 |
| Proceeds from exercise of stock options | - | 6,800 |
| Net cash provided by financing activities | 3,269,163 | 354,161 |
| Foreign exchange effect on cash | 1,473 | 668 |
| NET DECREASE IN CASH | (2,217,695) | (1,245,822) |
| CASH, CASH EQUIVALENTS AND RESTRICTED CASH – BEGINNING OF PERIOD | 10,551,282 | 8,236,043 |
| CASH, CASH EQUIVALENTS AND RESTRICTED CASH – END OF PERIOD | \$8,333,587 | \$6,990,221 |
| Cash paid for interest | \$1,873 | \$- |
| Supplemental Disclosure of Non-Cash Financing Activities: | | |
| Conversion of preferred stock to common stock | \$- | \$7 |
| Issuance of common stock for payment of deferred fees | \$173,773 | \$10,218 |
| Unrealized gain from investments | \$- | \$10,113 |
| Issuance of common stock for vested restricted stock units | \$43 | \$- |

See Notes to Unaudited Condensed Consolidated Financial Statements.

CORMEDIX INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 1 — Organization, Business and Basis of Presentation:

Organization and Business

CorMedix Inc. (“CorMedix” or the “Company”), a biopharmaceutical company focused on developing and commercializing therapeutic products for the prevention and treatment of infectious and inflammatory diseases, was incorporated in the State of Delaware on July 28, 2006. In 2013, the Company formed a wholly-owned subsidiary, CorMedix Europe GmbH.

The Company’s primary focus is to develop its lead product candidate, Neutrolin®, for potential commercialization in the United States (“U.S.”) and other key markets. The Company has in-licensed the worldwide rights to develop and commercialize Neutrolin, which is a novel anti-infective solution (a formulation of taurolidine, citrate and heparin 1000 u/ml) under development for the reduction and prevention of catheter-related infections and thrombosis in patients requiring central venous catheters in clinical settings such as dialysis, critical/intensive care, and oncology.

The Company launched its first Phase 3 clinical trial in hemodialysis patients with catheters in the U.S. in December 2015. The clinical trial, named Catheter Lock Solution Investigational Trial or LOCK-IT-100, is a prospective, multicenter, randomized, double-blind, active control trial which aims to demonstrate the efficacy and safety of Neutrolin in preventing catheter-related bloodstream infections, or CRBSI, in subjects receiving hemodialysis therapy as treatment for end stage renal disease. Two pivotal clinical trials to demonstrate safety and effectiveness of Neutrolin are required by the U.S. Food and Drug Administration (“FDA”) to secure marketing approval in the U.S. The design of the second Phase 3 clinical trial required for NDA submission has not been determined.

The Company received CE Mark approval for Neutrolin in 2013 and commercially launched Neutrolin in Germany for the prevention of catheter-related bloodstream infections and maintenance of catheter patency in hemodialysis patients using a tunneled, cuffed central venous catheter for vascular access. Neutrolin is registered and is being sold in certain European Union and Middle Eastern countries.

The completion of the Company’s ongoing LOCK-IT-100 clinical trial and the execution of the second Phase 3 clinical trial are dependent on the Company’s ability to raise sufficient additional funds through various potential sources, such as equity, debt financings, and/or strategic relationships (See Notes 2 and 5). The Company can provide no assurances that financing or strategic relationships will be available on acceptable terms, or at all, to complete its clinical development program for Neutrolin.

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 8 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, 2018 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 19, 2018. The accompanying condensed balance sheet as of December 31,

2017 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

Recently Adopted Accounting Pronouncements

The Financial Accounting Standards Board (“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 Company adopted the new revenue recognition standard as of January 1, 2018 using the modified retrospective method, which requires the cumulative effect of adoption to be recognized as an adjustment to opening retained earnings in the period of adoption. The majority of the Company’s revenue relates to the sale of finished products to various customers, and the adoption did not have a material impact on revenue recognized from these transactions. The Company accelerated the remaining deferred revenue under these agreements and recorded the reserve for returns and allowances as cumulative effect adjustments to opening retained earnings at January 1, 2018 in net amount of \$17,655.

The following table presents the Company’s revenue for the three months ended March 31, 2018 under the ASC 606 model as compared to revenue under the previous guidance:

| | Revenue As Reported | Revenue Under Previous Guidance | Difference |
|--|---------------------|---------------------------------|------------|
| Net revenue | \$21,004 | \$21,004 | \$- |
| Revenue recognized under agreement with warranty | - | 30,158 | 30,158 |
| Revenue recognized under Wonik Agreement | 2,206 | 2,206 | - |
| Total net revenue | \$23,210 | \$53,368 | \$30,158 |

In October 2015, the Company shipped product with less than 75% of its remaining shelf life to a customer and issued a guarantee that the specific product shipped would be replaced by the Company if the customer was not able to sell the product before it expired. As a result of this warranty, the Company may have an additional performance obligation (i.e. accept returned product and deliver new product to the customer) if the customer is unable to sell the short-dated product. As the result of the adoption of ASC 606, the Company accelerated the deferred revenue and related cost of sales in the net amount of \$70,500 and recorded the warranty obligation in the amount of \$52,900 upon adoption (see Note 1).

In January 2016, the FASB issued a new standard that modifies certain aspects of the recognition, measurement, presentation, and disclosure of financial instruments. The accounting standard update was effective for fiscal years, and interim periods within those years, beginning after December 15, 2017, and early adoption is permitted. The Company adopted this guidance on January 1, 2018, which did not have a material impact on the Company’s consolidated financial statements.

In August 2016, the FASB issued new guidance which clarifies how certain cash receipts and cash payments are presented and classified in the statement of cash flows in order to reduce diversity in practice. The guidance was effective for the Company beginning in the first quarter of fiscal year 2018. The Company adopted this guidance on January 1, 2018 and it did not have an impact on its consolidated financial statements.

In November 2016, the FASB issued new guidance which clarifies how restricted cash is presented and classified in the statement of cash flows. The guidance is effective for the Company beginning in the first quarter of fiscal year 2018. Early adoption is permitted. The Company adopted this guidance on January 1, 2018 and has included restricted cash in its beginning and ending cash balances on the statement of cash flows for the three months ended March 31, 2018 and 2017.

In May 2017, the FASB issued new guidance which clarifies the application of stock based accounting guidance when a change is made to the terms or conditions of a share-based payment award. The guidance was effective for the Company beginning in the first quarter of fiscal year 2018. The Company adopted this guidance on January 1, 2018 and it did not have an impact on its consolidated financial statements.

CORMEDIX INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 2 — Summary of Significant Accounting Policies:

Liquidity, Going Concern and Uncertainties

The financial statements have been prepared in conformity with GAAP which contemplate continuation of the Company as a going concern. To date, the Company's commercial operations have not generated sufficient revenues to enable profitability. As of March 31, 2018, the Company had an accumulated deficit of \$162.3 million, and had incurred losses from operations of \$10.2 million for the quarter then ended. Based on the current development plans for Neutrolin in both the U.S. and foreign markets (including the ongoing hemodialysis Phase 3 clinical trial in the U.S.) and the Company's other operating requirements, as well as the current status of the Company's negotiations with its contract research organization (CRO), management believes that the Company's existing cash and cash equivalents at March 31, 2018 are expected to fund its operations into the third quarter of 2018, subject to the outcome of the Company's assessment and negotiations with its CRO for the delay incurred in performing the interim efficacy analysis of the LOCK-IT-100 clinical trial (see Note 5). These factors raise substantial doubt regarding the Company's ability to continue as a going concern.

At March 31, 2018, approximately \$14.5 million remained available for sale under the Company's August 2016 At-the-Market Issuance Sales Agreement, as amended on December 8, 2017, (the "ATM program") with B. Riley FBR, Inc. ("B. Riley") (see Note 3 – Stockholders' Equity). This ATM program expired on April 16, 2018. On March 9, 2018, the Company entered into a new At-the-Market Issuance Sales Agreement with B. Riley for the sale of up to \$14.7 million of the Company's common stock, the registration statement for which was filed on March 9, 2018 and became effective on April 16, 2018. The company has not sold any shares under the new agreement as of the March 31, 2018 financial statement filing date.

The Company's continued operations will depend on its ability to raise additional capital through various potential sources, such as equity and/or debt financings, strategic relationships, or out-licensing of its products in order to complete its Phase 3 clinical trials and until it achieves profitability, if ever. Management is actively pursuing financing plans but can provide no assurances that such financing or strategic relationships will be available on acceptable terms, or at all. Without this funding, the Company could be required to delay, scale back or eliminate some or all of its research and development programs which would likely have a material adverse effect on the Company.

The financial statements do not include any adjustments relating to the recoverability and classification of asset carrying amounts or the amount and classification of liabilities that might result should the Company be unable to continue as a going concern.

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

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

Financial Instruments

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents and short-term investments. The Company maintains its cash and cash equivalents in bank deposit and other interest bearing accounts, the balances of which, at times, may exceed federally insured limits.

The following table is the reconciliation of the recently adopted new accounting standard that modifies certain aspects of the recognition, measurement, presentation and disclosure of financial instruments as shown on the Company's condensed consolidated statement of cash flows:

| | March 31, 2018 | March 31, 2017 |
|--|-------------------|-------------------|
| Cash and cash equivalents | \$8,162,034 | \$6,818,668 |
| Restricted cash | 171,553 | 171,553 |
| Total cash, cash equivalents and restricted cash | \$8,333,587 | \$6,990,221 |

The appropriate classification of marketable securities is determined at the time of purchase and reevaluated as of each balance sheet date. Investments in marketable debt and equity securities classified as available-for-sale are reported at fair value. Fair value is determined using quoted market prices in active markets for identical assets or liabilities or quoted prices for similar assets or liabilities or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. Changes in fair value that are considered temporary are reported in the condensed consolidated statement of operations. Realized gains and losses, amortization of premiums and discounts and interest and dividends earned are included in income (expense). For declines in the fair value of equity securities that are considered other-than-temporary, impairment losses are charged to other (income) expense, net. The Company considers available evidence in evaluating potential impairments of its investments, including the duration and extent to which fair value is less than cost. There were no deemed permanent impairments at March 31, 2018 or December 31, 2017.

CORMEDIX INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

The Company's marketable securities are highly liquid and consist of U.S. government agency securities, high-grade corporate obligations and commercial paper with original maturities of more than 90 days. As of March 31, 2018 and December 31, 2017, all of the Company's investments had contractual maturities of less than one year. The following table summarizes the amortized cost, unrealized gains and losses and the fair value at March 31, 2018 and December 31, 2017:

| March 31, 2018: | Amortized Cost | Gross Unrealized Losses | Gross Unrealized Gains | Fair Value |
|---|----------------|-------------------------|------------------------|-------------|
| Money Market Funds included in Cash Equivalents | \$3,658,011 | \$- | \$- | \$3,658,011 |
| Total March 31, 2018 | \$3,658,011 | \$- | \$- | \$3,658,011 |

December 31, 2017:

| | | | | |
|---|-------------|---------|-----|-------------|
| Money Market Funds included in Cash Equivalents | \$6,032,034 | \$- | \$- | \$6,032,034 |
| Corporate Securities | 905,625 | (112) | - | 905,516 |
| Commercial Paper | 698,682 | - | - | 698,682 |
| Subtotal | 1,604,307 | (112) | - | 1,604,198 |
| Total December 31, 2017 | \$7,636,341 | \$(112) | \$- | \$7,636,232 |

Fair Value Measurements

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

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

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

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

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

CORMEDIX INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

The following table provides the carrying value and fair value of the Company's financial assets measured at fair value on a recurring basis as of March 31, 2018 and December 31, 2017:

| March 31, 2018: | Carrying Value | Level 1 | Level 2 | Level 3 |
|-------------------------|----------------|-------------|-------------|---------|
| Money Market Funds | \$3,658,011 | \$3,658,011 | \$- | \$- |
| Total March 31, 2018 | \$3,658,011 | \$3,658,011 | \$- | \$- |
| December 31, 2017: | | | | |
| Money Market Funds | \$6,032,034 | \$6,032,034 | \$- | \$- |
| Corporate Securities | 905,516 | - | 905,516 | - |
| Commercial Paper | 698,682 | - | 698,682 | - |
| Subtotal | 1,604,198 | - | 1,604,198 | \$- |
| Total December 31, 2017 | \$7,636,232 | \$6,032,034 | \$1,604,198 | \$- |

Foreign Currency Translation and Transactions

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

The Company has intercompany loans between the parent company based in New Jersey and its German subsidiary. The intercompany loans outstanding are not expected to be repaid in the foreseeable future and unrealized foreign exchange movements related to long-term intercompany loans are recognized in other comprehensive income.

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.

Restricted Cash

As of March 31, 2018 and December 31, 2017, the Company has restricted cash in connection with the patent and utility model infringement proceedings against TauroPharm (see Note 5). 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 furthermore had to provide a deposit in the amount of \$40,000 in connection with the unfair competition proceedings in Cologne.

Prepaid Research and Development and Other 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.

CORMEDIX INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Inventories, net

Inventories are valued at the lower of cost or net realizable value 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, 2018 | December 31, 2017 |
|-------------------|-------------------|----------------------|
| Raw materials | \$140,691 | \$141,233 |
| Work in process | 532,583 | 526,067 |
| Finished goods | 8,638 | 29,894 |
| Inventory reserve | (103,000) | (103,000) |
| Total | \$578,912 | \$594,194 |

Accrued Expenses

Accrued expenses consist of the following:

| | March 31, 2018 | December 31, 2017 |
|--|-------------------|----------------------|
| Professional and consulting fees | \$515,349 | \$485,089 |
| Accrued payroll and payroll taxes | 417,712 | 755,221 |
| Clinical trial and manufacturing development | 3,866,000 | 2,884,924 |
| Product development | 80,001 | 80,001 |
| Market research | 116,466 | 116,466 |
| Other | 95,358 | 42,166 |
| Total | \$5,090,886 | \$4,363,867 |

Revenue Recognition

The Company adopted Accounting Standards Codification (“ASC”) 606, Revenue from Contracts with Customers, as of January 1, 2018 using the modified retrospective method. ASC 606 prescribes a five step model for recognizing revenue which includes (i) identifying contracts with customers; (ii) identifying performance obligations; (iii) determining the transaction price; (iv) allocating the transaction price and (v) recognizing revenue.

The Company recognizes net sales upon shipment of product to the dialysis centers and upon meeting the five step model prescribed by ASC 606 outlined above.

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 “Wonik 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 Wonik 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”). Product registration in the Territory is contingent upon the marketing approval of Neutrolin in the U.S. The term of the Wonik 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 is being recognized as revenue on a straight-line basis over the contractual term of the Agreement. The Company recognized \$2,200 revenue related to the Wonik agreement for each of the three months ended March 31, 2018 and 2017.

Deferred revenue related to this agreement at March 31, 2018 and December 31, 2017 amounted to approximately \$17,600 and \$19,800, respectively.

CORMEDIX INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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, | |
|---|---------------------------------|------------|
| | 2018 | 2017 |
| Series C non-voting convertible preferred stock | 2,540,000 | 2,790,000 |
| Series D non-voting convertible preferred stock | 1,479,240 | 1,479,240 |
| Series E non-voting convertible preferred stock | 1,959,759 | 1,959,759 |
| Series F non-voting convertible preferred stock | 3,157,561 | - |
| Shares underlying outstanding warrants | 23,017,891 | 4,006,468 |
| Shares underlying restricted stock units | 97,529 | 107,931 |
| Shares underlying outstanding stock options | 5,501,613 | 5,637,045 |
| Total | 37,753,593 | 15,980,443 |

Stock-Based Compensation

The Company accounts for stock options granted to employees, officers and directors according to ASC No. 718, “Compensation — Stock Compensation” (“ASC 718”). Share-based compensation cost is measured at grant date, based on the estimated fair value of the award using the Black-Scholes option pricing model for options with service or performance based conditions. Stock-based compensation is recognized as expense 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 No. 505-50, “Equity-Based Payments to Non-Employees”. The non-cash charge to operations for non-employee options with time-based vesting provisions is based on the fair value of the options remeasured each reporting period and amortized to expense over the related vesting period. The non-cash charge to operations for non-employee options with performance based vesting provisions is recorded when the achievement of the performance condition is probable and remeasured each reporting period until the performance condition is achieved.

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. As actual costs become known, the Company adjusts its accruals in the period when actual costs become known. 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.

CORMEDIX INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 3 — Stockholders' Equity:

Common Stock

At March 31, 2018, the Company had a sales agreement, as amended on December 8, 2017, with B. Riley (the "Sales Agreement") under which the Company may issue and sell up to an aggregate of \$60.0 million of shares of its common stock from time to time through B. Riley acting as agent, subject to limitations imposed by the Company and subject to B. Riley's acceptance, such as the number or dollar amount of shares registered under the registration statement to which the offering relates. When the Company wishes to issue and sell common stock under the Sales Agreement, it notifies B. Riley 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. B. Riley is entitled to a commission of up to 3% of the gross proceeds from the sale of common stock sold under the Sales Agreement. The shares of common stock to be sold under the Sales Agreement are registered under an effective registration statement filed with the SEC. The Sales Agreement expired on April 16, 2018. During the quarter ended March 31, 2018, the Company issued 10,202,099 shares of common stock under the Sales Agreement and realized net proceeds of approximately \$3,269,000.

On March 9, 2018, the Company entered into a new agreement with B. Riley for the sale of up to \$14.7 million of the Company's common stock, the registration statement for which was filed on March 9, 2018 and became effective on April 16, 2018. The registration statement is for an aggregate of \$70.0 million of the Company's securities, including the \$14.7 million of common stock allocated to the ATM program.

During the quarter ended March 31, 2018, the Company issued an aggregate of 43,385 shares of its common stock upon the vesting of restricted stock units issued to the Company's board of directors.

During the quarter ended March 31, 2018, the Company issued an aggregate of 127,628 shares of its common stock to its certain board members for payment of deferred fees.

Preferred Stock

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

| | As of March 31, 2018 | | | As of December 31, 2017 | | |
|------------|------------------------------|------------------------------------|------------------------------|------------------------------|------------------------------------|------------------------------|
| | Preferred Shares Outstanding | Liquidation Preference (Per Share) | Total Liquidation Preference | Preferred Shares Outstanding | Liquidation Preference (Per Share) | Total Liquidation Preference |
| Series C-2 | 150,000 | 10.0 | 1,500,000 | 150,000 | 10.0 | 1,500,000 |
| | 104,000 | 10.0 | 1,040,000 | 104,000 | 10.0 | 1,040,000 |

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| | | | | | | |
|------------|---------|-------|------------|---------|-------|------------|
| Series C-3 | | | | | | |
| Series D | 73,962 | 21.0 | 1,553,202 | 73,962 | 21.0 | 1,553,202 |
| Series E | 89,623 | 49.2 | 4,409,452 | 89,623 | 49.2 | 4,409,452 |
| Series F | 2,000 | 1,000 | 2,000,000 | 2,000 | 1,000 | 2,000,000 |
| Total | 419,585 | | 10,502,654 | 419,585 | | 10,502,654 |

CORMEDIX INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

On November 9, 2017, the Company entered into a securities purchase agreement with existing institutional investors (the “Buyers”), pursuant to which, on November 16, 2017, the Company sold \$2.0 million of its Series F convertible preferred stock (“Series F Stock”) at \$1,000 per share. Based on the terms of the Series F Stock, the conversion price was set at \$0.162 on April 2, 2018, currently convertible anytime at the Buyers' option. The conversion price of the Series F Stock is subject to anti-dilution adjustment for customary recapitalization events such as stock splits, as well as full ratchet anti-dilution protection in the event that the Company does not obtain the subordination of the Series C-3 preferred stock to that of the Series F Stock or obtain stockholder approval, if required by NYSE American rules, of the issuance of common stock that exceeds NYSE American rules. The Series F Stock became mandatorily convertible on April 2, 2018, subject to certain equity conditions, one of which was not met as of March 31, 2018. The last condition to be met is the subordination of the outstanding Series C-3 preferred stock to the Series F Stock. When and if that condition is met, the Series F Stock will be mandatorily convertible. Pursuant to the terms of the Series F Stock, a holder will be prohibited from converting shares of Series F Stock into shares of common stock if, as a result of such conversion, (i) such holder, together with its affiliates, would beneficially own more than 9.99% of the total number of shares of the Company’s common stock then issued and outstanding, or (ii) the Company would issue shares in an amount equal to or greater than 20% of the shares of common stock outstanding on November 9, 2017, unless the Company has received the approval of its stockholders for such overage.

Stock Options

During the three months ended March 31, 2018, the Company granted ten-year qualified and non-qualified stock options covering an aggregate of 588,000 shares of the Company’s common stock under the 2013 Stock Incentive Plan. The weighted average exercise price of these options is \$0.42 per share.

During the three months ended March 31, 2018, and 2017, total compensation expense for stock options issued to employees, directors, officers and consultants was \$350,000 and \$431,000, respectively.

As of March 31, 2018, there was \$2,606,000 in total unrecognized compensation expense related to stock options granted which expense will be recognized over an expected remaining weighted average period of 1.6 years.

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

| | Three Months Ended March 31, | |
|---|------------------------------|-------------------|
| | 2018 | 2017 |
| Expected Term | 5 years | 5 years |
| Volatility | 92.97% - 94.6% | 103.78% - 104.67% |
| Dividend yield | 0.0% | 0.0% |
| Risk-free interest rate | 2.63% - 2.65% | 1.93% - 1.99% |
| Weighted average grant date fair value of options granted during the period | \$0.31 | \$1.42 |

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. Beginning January 1, 2017, 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, with a lookback period equal to the expected term of the respective award. In 2016, the expected stock price volatility was calculated based on the historical volatility since the initial public offering, weighted between the period pre and post CE Mark approval in the European Union. 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 which is 5 years for employees and 10 years for non-employees.

CORMEDIX INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

The following table summarizes the Company's stock options activity and related information for the three months ended March 31, 2018:

| | Shares | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term (Years) | Aggregate Intrinsic Value |
|------------------------------------|-----------|---------------------------------------|--|------------------------------|
| Outstanding at beginning of period | 4,962,795 | \$2.04 | 7.5 | \$247,500 |
| Forfeited | (49,182) | \$1.41 | | \$0 |
| Granted | 588,000 | \$0.42 | | \$0 |
| Outstanding at end of period | 5,501,613 | \$1.87 | 7.4 | \$0 |
| Vested at end of period | 2,637,837 | \$1.89 | 6.0 | \$0 |

There were no stock option exercises during the quarter ended March 31, 2018 and during the quarter ended March 31, 2017, the total intrinsic value of stock options exercised was \$13,200. The aggregate intrinsic value was 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.

Restricted Stock Units

During the three months ended March 31, 2018, the Company granted an aggregate 74,500 restricted stock units ("RSUs") to its directors under its 2013 Stock Incentive Plan with a weighted average grant date fair value of \$0.57 per share. The fair value of each RSU was estimated to be the closing price of the Company's common stock on each date of grant. These RSUs will vest in full on the first anniversary of the grant date, subject to continued service on the board.

During the three months ended March 31, 2018 and 2017, compensation expense recorded for these RSUs was \$23,000 and \$21,000, respectively. Unrecognized compensation expense for these RSUs amounted to \$68,700. The expected weighted average period for the expense to be recognized is 0.82 years.

Warrants

As of March 31, 2018, there were 23,017,891 outstanding warrants with a weighted average exercise price of \$1.07 per share and a weighted average remaining contractual life of 3.2 years.

Note 4 — Related Party Transactions:

On March 19, 2018, the Company entered into a binding term sheet with Elliott Management Corporation for a proposed \$3.0 million backstop facility. The proposed backstop facility would be available for drawing between April 16, 2018 and July 31, 2018. In view of its ongoing negotiations with its CRO regarding certain remediation efforts and financial considerations for the delay incurred by the Company in performing the interim efficacy analysis of the LOCK-IT-100 study, the Company has determined to delay the finalization of this transaction.

CORMEDIX INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 5 — Commitments and Contingencies:

Contingency Matters

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

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

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

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

The opposition proceeding against the Prosl European Patent before the EPO is ongoing. The EPO held a hearing in the opposition proceeding on November 25, 2015. In its preliminary consideration of the matter, the EPO (and the German PTO) had regarded the patent as not inventive or novel due to publication of prior art. However, the EPO did not issue a decision at the end of the hearing but adjourned the matter due to the fact that the panel was of the view that Claus Herdeis, one of the managing directors of TauroPharm, has to be heard as a witness in a further hearing in order to close some gaps in the documentation presented by TauroPharm as regards the publication of the prior art.

CORMEDIX INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

The German PTO held a hearing in the validity proceedings relating to the Utility Model on June 29, 2016, at which the panel affirmed its preliminary finding that the Utility Model was invalid based upon prior publication of a reference to the benefits that may be associated with adding heparin to a taurolidine based solution. The decision has only a declaratory effect, as the Utility Model had expired in November 2015. Furthermore, it has no bearing on the ongoing consideration by the EPO of the validity and possible infringement of the Prosl European Patent. The Company filed an appeal against the ruling on September 7, 2016.

In October 2016, TauroPharm submitted a further writ to the EPO requesting a date for the hearing and bringing forward further arguments, in particular in view of the June 2016 decision of the German PTO on the invalidity of the utility model, which we have appealed. On November 22, 2017, the EPO in Munich, Germany held a further oral hearing in this matter. At the hearing, the panel held that the Prosl European Patent would be invalidated because it did not meet the requirements of novelty based on a technical aspect of the European intellectual property law. The Company disagrees with this decision and plans to appeal. The Company's appeal will be based, in part, on the written opinion to be issued by the Opposition Division, which is expected by the third quarter of 2018. The Company continues to believe that the Prosl European Patent is indeed novel and that its validity should be maintained. There can be no assurance that the Company will prevail in this matter with either the German PTO or the EPO. In addition, the ongoing Unfair Competition litigation brought by the Company against TauroPharm is not affected and will continue.

On January 16, 2015, the Company filed a complaint against TauroPharm GmbH and its managing directors in the District Court of Cologne, Germany. In the complaint, the Company alleges violation of the German Unfair Competition Act by TauroPharm for the unauthorized use of its proprietary information obtained in confidence by TauroPharm. The Company alleges that TauroPharm is improperly and unfairly using its proprietary information relating to the composition and manufacture of Neutrolin, in the manufacture and sale of TauroPharm's products TauroLock™, TauroLock-HEP100 and TauroLock-HEP500. The Company seeks a cease and desist order against TauroPharm from continuing to manufacture and sell any product containing taurolidine (the active pharmaceutical ingredient ("API") of Neutrolin) and citric acid in addition to possible other components, damages for any sales in the past and the removal of all such products from the market. An initial hearing in the District Court of Cologne, Germany was held on November 19, 2015 to consider the Company's claims. In this hearing, the presiding judge explained that the court needed more information with regard to several aspects of the case. As a consequence, the court issued an interim decision in the form of a court order outlining several issues of concern that relate primarily to the court's interest in clarifying the facts and reviewing any and all available documentation, in particular with regard to the question which specific know-how was provided to TauroPharm by whom and when. The Company's legal team has prepared the requested reply and produced the respective documentation. TauroPharm has also filed another writ within the same deadline and both parties have filed further writs at the end of April setting out their respective argumentation in more detail. A further oral hearing in this matter was held on November 15, 2016. In this hearing, the court heard arguments from CorMedix and TauroPharm concerning the allegations of unfair competition. The court made no rulings from the bench, and indicated that it is prepared to further examine the underlying facts of the Company's allegations. On March 7, 2017, the court issued another interim decision in the form of a court order outlining again several issues relating to the argumentation of both sides in the proceedings. In particular the court requested the Company to further specify its requests and to further substantiate in even more detail which know-how was provided by Biolink to TauroPharm by whom and when. The court also raised the question whether the know-how provided at the time to TauroPharm could still be considered to be secret know-how or may have become public in the meantime. The court granted both sides the opportunity to reply to this court order and provide additional facts and evidence until May 15, 2017. Both parties have submitted further writs in this matter and the court has now scheduled a further hearing on May 8, 2018. After having been rescheduled several times, the hearing will now take place on November 20, 2018. The Company intends to continue to pursue this matter, and to provide

additional supplemental documentary and other evidence as may be necessary to support its claims.

CORMEDIX INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

In connection with the aforementioned patent and utility model infringement proceedings against TauroPharm, the Company was required by the District Court Mannheim to provide a security deposit of approximately \$132,000 to cover legal fees in the event TauroPharm is entitled to reimbursement of these costs. The Company recorded the deposit as restricted cash for the year ended December 31, 2015. The Company furthermore had to provide a deposit in the amount of \$40,000 in connection with the unfair competition proceedings in Cologne. These amounts are shown as restricted cash on the condensed consolidated balance sheets.

Commitments

Manufacturing

The Company has developed a program aimed at reducing the cost of goods of Neutrolin through a more efficient, custom synthesis of the active ingredient taurolidine. As part of that program, on April 8, 2015, the Company entered into a Preliminary Services Agreement with [RC]2 Pharma Connect LLC (“RC2”), pursuant to which RC2 will coordinate certain manufacturing services related to taurolidine that the Company believes are necessary for the submission of its planned new drug application for Neutrolin to the FDA, as well as any foreign regulatory applications. The services related to this agreement were completed in the first quarter of 2017 at a total cost of \$1.8 million. The API produced under this agreement has been manufactured for future commercial sales in the EU and Middle East and used for the U.S. Phase 3 clinical trial.

The Company also has several service agreements with RC2 for the manufacture of clinical supplies to support its Phase 3 clinical trials for an aggregate amount of \$8.9 million at March 31, 2018. During the quarters ended March 31, 2018 and 2017, the Company recognized research and development expense of approximately \$129,000 and \$543,000, respectively, related to these agreements. The Company may terminate these agreements upon 30 days written notice and is only obligated for project costs and reasonable project shut down costs provided through the date of termination.

Clinical and Regulatory

In December 2015, the Company entered into a Master Service Agreement and Work Orders (the “Master Service Agreement”) with a CRO to help the Company conduct its Phase 3 multicenter, double-blind, randomized active control study to demonstrate the safety and effectiveness of Neutrolin in preventing catheter-related bloodstream infections and blood clotting in subjects receiving hemodialysis therapy as treatment for end stage renal disease. In May 2017, the Company signed a contract modification with its CRO for an additional cost of \$7.2 million to cover the extension of the estimated study timeline, incorporate several protocol amendments and take on several new tasks related to the enrollment sites. Given several changes to the study agreed with the FDA, the Company signed a second contract modification with its CRO for an additional \$6.3 million, to cover the continuation of trial enrollment which is anticipated to continue into the third quarter of 2018, the increased length of time in which patients are enrolled and additional activities related to the collection of retrospective data outside the treatment centers. At March 31, 2018, the total cost of the contract increased to \$33 million from its original amount of \$19.2 million. During the quarters ended March 31, 2018 and 2017, the Company recognized \$5,798,000 and \$2,555,000 in research and development expense related to this agreement, respectively. The remaining budget under this current contract is approximately \$12 million at March 31, 2018.

The Company has determined that issues in data quality have delayed the timing of the completion of the interim efficacy analysis and is in negotiations with its CRO regarding certain remediation efforts and financial considerations. The Company is assessing the impact of this delay and the possible outcomes of its discussions with

its CRO on its anticipated cash needs and future commitments. As such, the current contract is subject to further modifications as the clinical trial progresses.

CORMEDIX INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

In-Licensing

In 2008, the Company entered into a License and Assignment Agreement (the “NDP License Agreement”) with ND Partners, LLP (“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.

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. In 2014, a certain milestone was achieved resulting in the release of 36,386 shares held in escrow. The number of shares held in escrow as of March 31, 2018 and 2017 is 109,157 shares of common stock. The maximum aggregate amount of cash payments due upon achievement of milestones is \$3,000,000 with the balance of \$2,500,000 for the quarters ended March 31, 2018 and 2017. Events that trigger milestone payments include but are not limited to the reaching of various stages of regulatory approval and upon achieving certain worldwide net sales amounts. There were no milestones achieved during the quarters ended March 31, 2018 and 2017.

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.

Employment Agreements

On March 19, 2018, the Company entered into an employment agreement with Elizabeth Masson, its Executive Vice President and Head of Clinical Operations. Unless renewed pursuant to the terms thereof, the agreement will expire on March 18, 2021. After the initial three-year term of the employment agreement, the agreement will automatically renew for additional successive one-year periods, unless either party notifies the other in writing at least 90 days before the expiration of the then current term that the agreement will not be renewed. In connection with Ms. Masson’s employment, the Company granted her stock options to purchase 310,000 shares of common stock, 186,000 of which vest over four years and 124,000 of which vest upon the achievement of designated milestones.

If the Company terminates Ms. Masson’s employment other than for Cause (as defined in the agreement), death or disability, other than by notice of nonrenewal, or if she resigns for Good Reason (as defined in the agreement), Ms. Masson will receive her base salary and benefits for a period of nine months following the effective date of the termination of her employment, and all unvested stock options held by her will be accelerated and deemed to have vested as of the termination date, provided that any milestone option whose vesting requirements have not been met as of the termination date will not be accelerated.

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NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 6 — Concentrations:

At March 31, 2018, approximately 70% of net accounts receivable was due from two customers (45% and 25%). During the quarter ended March 31, 2018, the Company had revenue from two customers that each exceeded 10% of its total sales (45% and 17%).

At December 31, 2017, approximately 81% of net accounts receivable was due from two customers (57% and 24%). During the year ended December 31, 2017 and 2016, the Company had revenue from two customers that each exceeded 10% of its total sales (25% and 19%) and (24% and 12%), respectively.

Note 7 — Subsequent Event:

The Company intends to ask its stockholders to approve a reverse split of the Company's common stock and grant to the Board the authority to set the ratio for the reverse split in the range of 1-for-5 and 1-for-10, as determined by the Board of Directors, at any time before June 26, 2019, if and as determined by the Board of Directors (the "Reverse Stock Split"). A special stockholders' meeting is planned to be held on June 26, 2018. If the proposal is approved by the stockholders, the Board will have authority to effect the Reverse Stock Split, if and at such time and in such ratio as it determines to be appropriate within that range and time period. Currently, if approved by the stockholders, the Company expects to effect the Reverse Stock Split shortly after such approval.

On April 2, 2018, pursuant to its terms, the conversion price of the Company's Series F Stock was set at \$0.162 and the Series F Stock also became mandatorily convertible, subject to certain equity conditions, one of which has not been met as of the date of this report. The last condition to be met is the subordination of the Company's outstanding Series C-3 preferred stock to the Series F Stock. When and if that condition is met, the Series F Stock will be mandatorily convertible.

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 2017 Annual Report on Form 10-K, filed with the Securities and Exchange Commission, or the SEC, on March 19, 2018.

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," "s," "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 in Part II. Item 1A of this report, 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 biopharmaceutical company focused on developing and commercializing therapeutic products for the prevention and treatment of infectious and inflammatory diseases.

Our primary focus is to develop our lead product candidate, Neutrolin®, for potential commercialization in the U.S. and other key markets. We have in-licensed the worldwide rights to develop and commercialize Neutrolin, which is a novel anti-infective solution (a formulation of taurolidine, citrate and heparin 1000 u/ml) under development in the U.S. for the reduction and prevention of catheter-related infections and thrombosis in patients requiring central venous catheters in clinical settings such as dialysis, critical/intensive care, and oncology. 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, the need for IV antibiotic treatment, long-term anticoagulation therapy, removal/replacement of the central venous catheter, related treatment costs and increased mortality. We believe Neutrolin has the potential to address a significant unmet medical need and represents a significant market opportunity.

In July 2013, we received CE Mark approval for Neutrolin. In December 2013, we commercially launched Neutrolin in Germany for the prevention of catheter-related bloodstream infections and maintenance of catheter patency in hemodialysis patients using a tunneled, cuffed central venous catheter for vascular access. To date, Neutrolin is registered and may be sold in certain European Union and Middle Eastern countries for such treatment. In April 2017, we entered into a commercial collaboration with Hemotech SAS covering France and French overseas territories.

We initiated a Phase 3 clinical trial in hemodialysis patients with a central venous catheter (“LOCK-IT-100”) in December 2015. Two successful pivotal trials to demonstrate the safety and effectiveness of Neutrolin are required by the U.S. Food and Drug Administration (“FDA”) to secure marketing approval in the United States.

In April 2017, a safety review by an independent Data Safety Monitoring Board, or DSMB was completed. The DSMB unanimously concluded that it is safe to continue the LOCK-IT-100 clinical trial as designed based on its evaluation of data from the first 279 patients randomized into the trial.

On August 2, 2017, we announced that the FDA had agreed to key changes to the LOCK-IT-100 clinical trial. We believe that the changes endorsed by the FDA will facilitate our ability to complete patient enrollment of our ongoing Phase 3 clinical trial in hemodialysis patients with central venous catheters by the third quarter of 2018, and to complete the trial once we have accumulated the requisite number of CRBSI events. We sought guidance from the FDA to address, in part, the apparent overall lower rate of catheter-related blood stream infection (CRBSI) events from patients in the study, as announced in April 2017. Changes to the study included 1) the utilization of a Clinical Adjudication Committee (CAC) to assess suspected CRBSIs; 2) the use of the CAC to critically and independently assess suspected CRBSIs in a blinded fashion based on a single positive blood culture and supporting documentation, rather than two positive blood cultures as required per protocol; 3) the ability to capture cases occurring outside of dialysis centers to facilitate more complete capture of CRBSI events in the study, particularly when patients present with CRBSI events outside of the dialysis center setting, e.g. emergency rooms or urgent care centers; and 4) a revision of the design of the study to detect a treatment effect of 55% or greater when comparing the Neutrolin and heparin control arms. The FDA agreed that cases adjudicated by the CAC to be CRBSI events and the per protocol definition of CRBSI events will be included in the primary analysis of the primary efficacy endpoint of the LOCK-IT-100 study. The amended study assumptions including a reduction in statistical power have resulted in a reduction in the total number of CRBSI events required from 161 events to 56 events to complete the study.

We recently announced that we are in negotiations with our contract research organization (CRO) regarding certain remediation efforts and financial considerations for the ongoing delay we incurred in performing the interim efficacy analysis of the LOCK-IT-100 study. We are currently anticipating that the DSMB will review the interim analysis and make its recommendations in July 2018, assuming no further significant delays in obtaining the additional data needed to assess secondary endpoints and severe adverse events (SAEs) to complete the review process are encountered. We are assessing the impact of this delay and the possible outcomes of our CRO negotiations on our anticipated cash needs.

We are sponsoring a pre-clinical research collaboration for the use of taurolidine as a possible combination treatment for rare orphan pediatric tumors. In February 2018, the FDA granted orphan drug designation to taurolidine for the treatment of neuroblastoma. We are seeking one or more strategic partners or other sources of capital to help us develop and commercialize taurolidine for the treatment of neuroblastoma.

We are also evaluating opportunities for the possible expansion of taurolidine as a platform compound for use in certain medical devices. Patent applications have been filed in wound closure, surgical meshes, wound management, and osteoarthritis, including visco-supplementation. Based on initial feasibility work, we are advancing pre-clinical studies for taurolidine-infused surgical meshes, suture materials, and hydrogels. We will seek to establish development/commercial partnerships as these programs advance.

In August 2017, the Company secured a research grant from the National Institutes of Health (NIH) to expand the Company's antimicrobial hydrogel medical device program. In addition to our ongoing development of taurolidine-incorporated hydrogels to reduce infections in common burns, this funding will finance the development of an advanced hydrogel formulation that is designed to reduce the risk of potentially life-threatening infection and promote healing of more severe burn injuries, for which there is significant need.

The FDA recently informed us that it regards taurolidine as a new chemical entity and therefore an unapproved drug. Consequently, there is no appropriate predicate device currently marketed in the U.S. on which a 510k approval process could be based. As a result, we will be required to submit a premarket approval application for marketing authorization for these indications. In the event that the New Drug Application for Neutrolin is approved by the FDA, the regulatory pathway can be revisited with the FDA. Although there will presumably still be no appropriate predicate, de novo Class II designation can be proposed, based on a risk assessment and a reasonable assurance of safety and effectiveness.

Since our inception, we have not generated sufficient revenue from product sales to be profitable. Our operations to date have been primarily limited to conducting clinical trials and establishing manufacturing for our product candidates, licensing product candidates, business and financial planning, research and development, seeking regulatory approval for our products, initial commercialization activities for Neutrolin in the European Union and other foreign markets, and maintaining and improving our patent portfolio. We have funded our operations primarily through debt and equity financings. We have generated significant losses to date, and we expect to use substantial amounts of cash for our operations as we continue to conduct our ongoing Phase 3 clinical trial in hemodialysis patients with catheters, plan a second Phase 3 clinical trial for Neutrolin, commercialize Neutrolin in the European Union and other foreign markets, pursue 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, 2018, we had an accumulated deficit of approximately \$162.3 million. We are unable to predict the extent of any future losses or when we will become profitable, if ever.

Financial Operations Overview

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 expect to incur higher R&D expenses for the foreseeable future in order to complete development of Neutrolin in the U.S., especially the ongoing LOCK-IT-100 clinical trial and an anticipated second Phase 3 trial.

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. We are currently focused on clinical development in the U.S. and optimization of sales in foreign markets where Neutrolin is approved. In December 2015, we contracted with our CRO to help us conduct our multicenter, double-blind, randomized, active control Phase 3 clinical trial in hemodialysis patients with central venous catheters to demonstrate the efficacy and safety of Neutrolin in preventing catheter-related bloodstream infections and blood clotting in subjects receiving hemodialysis therapy as treatment for end stage renal disease. In May 2017 and again in November 2017 we modified the original contract to cover various changes in cost due to timeline extensions, protocol changes, and additional activities related to the collection of retrospective data outside the treatment centers. In April 2018 we announced that we brought in-house and assumed direct responsibility for several aspects of the study, among them site management and review of SAE's for the remainder of the study. Our CRO is currently working cooperatively with us on the other operational aspects of the study. At March 31, 2018, the total cost of the contract had increased to \$33 million from its original amount of \$19.2 million, of which approximately \$26.5 million has been accrued through March 31, 2018. An additional contract modification is currently expected to be executed to reflect the impact of the recent changes in timeline and reduced CRO activity.

We are pursuing additional opportunities to generate value based on taurolidine, an active component of Neutrolin. Based on initial feasibility work, we have completed an initial round of pre-clinical studies for taurolidine-infused surgical meshes, suture materials, and hydrogels, which will require a PMA regulatory pathway for approval. We are also involved in a pre-clinical research collaboration for the use of taurolidine as a possible treatment for rare orphan pediatric tumors. In February 2018, the FDA granted orphan drug designation to taurolidine for the treatment of neuroblastoma. We are seeking one or more strategic partners or other sources of capital to help us develop and commercialize taurolidine for the treatment of neuroblastoma.

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.

Foreign Currency Exchange Transaction Gain (Loss)

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

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 expenditures.

Results of Operations

Three months ended March 31, 2018 compared to three months ended March 31, 2017

The following is a tabular presentation of our consolidated operating results (in thousands):

| | For the Three Months Ended March 31, | | % of Change Increase |
|-------------------------------------|--|-----------|-------------------------|
| | 2018 | 2017 | (Decrease) |
| Revenue | \$23 | \$40 | 41% |
| Cost of sales | (29) | (94) | (69)% |
| Gross profit (loss) | (6) | (54) | (90)% |
| Operating Expenses: | | | |
| Research and development | (8,280) | (4,924) | 68% |
| Selling, general and administrative | (1,903) | (2,641) | (28)% |
| Total operating expenses | (10,183) | (7,565) | 35% |
| Loss from operations | (10,189) | (7,619) | 34% |
| Interest income | 15 | 23 | (37)% |
| Foreign exchange transaction loss | (9) | (1) | 615% |
| Interest expense | (2) | - | N/A |
| Net loss | (10,185) | (7,597) | 34% |
| Other comprehensive income | (1) | 9 | (114)% |
| Comprehensive loss | \$(10,186) | \$(7,588) | 34% |

Revenue. Revenue was \$23,000 for the three months ended March 31, 2018 as compared to \$40,000 in the same period last year, a decrease of \$17,000. The decrease was primarily due to the adoption of ASC 606 at January 1, 2018 of which, no deferred revenue for the products sold with warranty was recognized for the three months ended March 31, 2018 as compared to the \$30,000 deferred revenue recognized for the same period last year. This decrease was offset by an increase in product sales in the amount of \$13,000 for the three months ended March 31, 2018.

Cost of Sales. Cost of sales was approximately \$29,000 for the three months ended March 31, 2018 compared to \$94,000 in the same period last year, a decrease of \$65,000. The decrease was primarily due to the stability studies initiated in 2017 and recognition of cost of sales associated with deferred revenue. The decrease was primarily due to the adoption of ASC 606 at January 1, 2018 of which, no deferred revenue for the products sold with warranty was recognized for the three months ended March 31, 2018 as compared to the \$30,000 deferred revenue recognized for the same period last year. This decrease was offset by an increase in product sales in the amount of \$13,000 for the three months ended March 31, 2018.

Research and Development Expense. R&D expense was approximately \$8,280,000 for the three months ended March 31, 2018, an increase of \$3,356,000, from \$4,924,000 for the three months ended March 31, 2017. The increase was primarily attributable to increased expenses related to the LOCK-IT-100 trial of \$3,880,000, due to increased number of patients enrolled, and an increase in personnel costs mainly due to conversion of several consultants into employee status of \$152,000, including the chief medical officer, partially offset by a decrease in costs to support the U.S.

clinical trial drug supply consisting of manufacturing process development activities of \$538,000, reduced cost of studies related to wound closure, wound management and surgical meshes of \$130,000, and a decrease in consulting fees of \$32,000.

Selling, General and Administrative Expense. SG&A expense was \$1,903,000 for the three months ended March 31, 2018, a decrease of \$738,000 from \$2,641,000 for the three months ended March 31, 2017. The decrease was primarily attributable to reductions in consulting fees of \$492,000, mainly due to executive search fees that were incurred in 2017, a decrease in marketing research studies of \$175,000, and a decrease in non-cash charge for stock-based compensation expense of \$96,000. These decreases, among others of lesser significance, were partially offset by an increase in investor relations expense of \$44,000.

Interest Income. Interest income was \$15,000 for the three months ended March 31, 2018 compared to \$23,000 for the same period last year, a decrease of \$8,000. The decrease was attributable to lower average interest-bearing cash balances and short-term investments during 2018 as compared to the same period in 2017.

Other Comprehensive Income (Loss). Unrealized foreign exchange movements related to long-term intercompany loans and the translation of the foreign affiliate financial statements to U.S. dollars and unrealized movements related to short-term investment are recorded in other comprehensive income (loss) totaling a \$1,000 loss and \$9,000 gain for the three months ended March 31, 2018 and 2017, respectively.

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 our incorporation. During the three months ended March 31, 2018, we received net proceeds of \$3,269,000 from the issuance of 10,202,099 shares of common stock under our then current at-the-market-issuance sales agreement.

Net Cash Used in Operating Activities

Net cash used in operating activities for the three months ended March 31, 2018 was \$7,054,000 as compared to \$6,759,000 for the same period in 2016, an increase in net cash use of \$295,000. The increase was primarily attributable to an increase in net loss of \$2,588,000 driven by increased research and development expenses. The net loss of \$10,185,000 for the quarter ended March 31, 2018 was higher than cash used in operating activities by \$3,131,000. The difference is primarily attributable to increases in accounts payable and accrued expenses of \$1,850,000 and \$917,000, respectively, non-cash stock-based compensation of \$373,000, and decreases in prepaid expenses, trade receivables and inventory of \$87,000, \$57,000 and \$15,000, respectively, partially offset by a decrease in deferred revenue of \$73,000.

Net Cash Provided by Investing Activities

Cash provided by investing activities for the three months ended March 31, 2018 was \$1,566,000 as compared to \$5,158,000 for the same period in 2017, both of which are mainly attributable to the proceeds on the sale of short-term investments.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the three months ended March 31, 2018 was \$3,269,000 as compared to \$354,000 for the same period in 2017. During the quarter ended March 31, 2018, we generated net proceeds of \$3,269,000 from the sale of our common stock in our then current at-the-market program. During the same period in 2017, we generated \$347,000 from the sale of our common stock in the current at-the-market program and received net proceeds of \$7,000 from the exercise of stock options.

Funding Requirements and Liquidity

Our total cash on hand and short-term investments as of March 31, 2018 was \$8.2 million, excluding restricted cash of \$0.2 million, compared with \$12 million at December 31, 2017. As of the date of this report, we have \$14.7 million available under our at-the-market program. On March 9, 2018, we entered into a new ATM agreement for the sale of up to \$14.7 million of our common stock, for which the registration statement was filed on March 9, 2018 and became

effective on April 16, 2018. This ATM agreement and registration statement is for an aggregate of \$70.0 million of our securities, including the \$14.7 million of common stock allocated to the ATM program, and replaced the prior ATM and related registration statement, both of which expired on April 16, 2018.

Because our business has not generated positive operating cash flow, we will need to raise additional capital in order to continue to fund our research and development activities, as well as to fund operations generally. Our continued operations and specifically the completion of our ongoing LOCK-IT-100 clinical trial for Neutrolin in the U.S., which was initiated in December 2015, will depend on our ability to raise sufficient additional funds through various potential sources, such as equity, debt financings, and/or strategic relationships. We can provide no assurances that financing or strategic relationships will be available on acceptable terms, or at all, that may enable us to complete our LOCK-IT-100 clinical trial and a second Phase 3 trial that is currently required in order to receive FDA marketing approval.

We expect to continue to fund operations from cash on hand and through capital raising sources as previously described, which may be dilutive to existing stockholders, through revenues from the licensing of our products, or through strategic alliances. We may utilize our new at-the-market program, if conditions allow, to support our ongoing funding requirements. Additionally, we may seek to sell additional equity or debt securities through one or more discrete transactions, or enter into a strategic alliance arrangement, but can provide no assurances that any such financing or strategic alliance arrangement will be available on acceptable terms, or at all. Moreover, the incurrence of indebtedness would result in increased fixed obligations and could contain covenants that would restrict our operations. Raising additional funds through strategic alliance arrangements with third parties may require significant time to complete and could force 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 due to 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, the 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.

We intend to hold a special meeting of stockholders to seek approval to amend our certificate of incorporation to effect a reverse stock split at a ratio of any whole number between 1-for-5 and to 1-for-10, as determined by our board, at any time before June 26, 2019, if and as determined by our board of directors. Such approval may not be obtained. If approved, following the implementation of a reverse stock split, and as a critical part of our ongoing efforts to finance our ongoing LOCK-IT-100 clinical trial, we anticipate conducting a rights offering whereby our stockholders as of a record date to be selected by our board of directors would receive rights to purchase shares of common stock and possibly other securities. The rights offering would be dependent upon having a sufficient number of authorized but unissued shares of common stock needed to complete the transaction, which our board of directors believe is vital and in our best interests. This report does not constitute an offer of any of our securities for sale or the solicitation of an offer to buy any of our securities. Any such rights offering can be made only by a prospectus that we would make available to our stockholders upon the effectiveness of the registration statement for the securities to be offered in the rights offering.

While we expect to grow product sales, we do not anticipate that we will generate significant product revenues in the foreseeable future. In the absence of such revenue, we are likely to continue generating operating cash flow deficits. We expect to incur increases in our cash used in operations as we continue our Phase 3 clinical trials, pursue 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, 2018, the expected timing and cost of the ongoing LOCK-IT-100 clinical trial in the U.S., and the current status of our negotiations with our CRO, we believe that our existing cash and cash equivalents will fund our operations into the third quarter of 2018. If we are unable to raise additional funds when needed, we may be forced to slow or discontinue our Neutrolin Phase 3 program, including our ongoing LOCK-IT-100 clinical trial. We could also be required to delay, scale back or eliminate some or all of our research

and development programs. Each of these alternatives would likely have a material adverse effect on our business. These factors raise substantial doubt regarding 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 Note 2 to our financial statements included with this report, 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 over the employee's requisite service period on a straight-line basis.

We account for stock options granted to non-employees on a fair value basis using the Black-Scholes option pricing model in accordance with ASC 718 and ASC No. 505-50, "Equity-Based Payments to Non-Employees". For the purpose of valuing options and warrants granted to our directors, officers, employees and consultants, we use the Black-Scholes option pricing model. The non-cash charge to operations for non-employee options with time based vesting provisions is based on the fair value of the options re-measured each reporting period and amortized to expense over the related vesting period, and the non-cash charge to operations for non-employee options with performance based vesting provisions is recorded when the achievement of the performance condition is probable.

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. 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.

Revenue Recognition

We adopted ASC 606, Revenue from Contracts with Customers, as of January 1, 2018. ASC 606 prescribes a five step model for recognizing revenue which includes (i) identifying the contract; (ii) identifying performance obligations; (iii) determining the transaction price; (iv) allocating the transaction price; and (v) recognizing revenue.

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 ASC 606, we recognize revenue from product sales based on the five-step model. As such, we recognize revenue upon shipment of product to the dialysis centers.

For our exclusive distribution agreements in which we received upfront payments, revenue is recognized based on the five-step model.

In October 2015, we shipped product with less than 75% of its remaining shelf life to a customer and issued a guarantee that the specific product shipped would be replaced by us if the customer was not able to sell the product before it expired. As a result of this warranty, we may have an additional performance obligation (i.e. accept returned product and deliver new product to the customer) if the customer is unable to sell the short-dated product. As the result of the adoption of ASC 606, we accelerated the deferred revenue and related cost of sales associated with the shipment of this product in the net amount of \$70,500 and recorded the warranty obligation in the amount of \$52,900.

In August 2014, we entered into an exclusive distribution agreement (the “Wonik 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 Wonik Agreement, Wonik paid to us a non-refundable \$50,000 payment and will pay an additional \$50,000 upon receipt of the product registration necessary to sell Neutrolin in the Republic of Korea (the “Territory”). Product registration in the Territory is contingent upon the marketing approval of Neutrolin in the U.S. The term of the Wonik 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. We recognized \$2,200 revenue related to the Wonik agreement for each of the three months ended March 31, 2018 and 2017.

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 net realizable value with cost determined on a first-in, first-out basis. Inventories are reviewed periodically to identify slow-moving or obsolete inventory based on sales activity, both projected and historical, as well as product shelf-life. In evaluating the recoverability of our inventories, we consider the probability that revenue will be obtained from the future sale of the related inventory and, if required, will write down inventory quantities in excess of expected requirements. Expired inventory is disposed of and the related costs are recognized as cost of product sales in our consolidated statements of operations.

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

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

Short-Term Investments

We determine the appropriate classification of marketable securities at the time of purchase and reevaluate such designation as of each balance sheet date. Investments in marketable debt and equity securities classified as available-for-sale are reported at fair value. Fair values of our investments are determined using quoted market prices in active markets for identical assets or liabilities or quoted prices for similar assets or liabilities or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. Our marketable securities are highly liquid and consist of U.S. government agency securities, high-grade corporate obligations and commercial paper with maturities of more than 90 days but less than 12 months. Changes in fair value that are considered temporary are reported net of tax in other comprehensive income (loss). Realized gains and losses, amortization of premiums and discounts and interest and dividends earned are included in income (expense) on the condensed consolidated statements of operations and comprehensive income (loss). The cost of investments for purposes of computing realized and unrealized gains and losses is based on the specific identification method. Investments with maturities beyond one year, if any, are classified as short-term based on management's intent to fund current operations with these securities or to make them available for current operations. For declines, if any, in the fair value of equity securities that are considered other-than-temporary, impairment losses are charged to other (income) expense, net. We consider available evidence in evaluating potential impairments of our investments, including the duration and extent to which fair value is less than cost and, for equity securities, our ability and intent to hold the investments.

Fair Value Measurements

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

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

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

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

Recent Authoritative Pronouncements

In February 2016, the FASB issued new guidance related to how an entity should lease assets and lease liabilities. The guidance specifies that an entity who is a lessee under lease agreements should recognize lease assets and lease liabilities for those leases classified as operating leases under previous FASB guidance. Accounting for leases by lessors is largely unchanged under the new guidance. The guidance is effective for us beginning in the first quarter of

2019. Early adoption is permitted. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. We are evaluating the impact of adopting this guidance on our consolidated financial statements.

In June 2016, the FASB issued new guidance which replaces the incurred loss impairment methodology in current GAAP with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The guidance is effective for us beginning in the first quarter of fiscal year 2020. Early adoption is permitted beginning in the first quarter of fiscal year 2019. We are evaluating the impact of adopting this guidance on our consolidated financial statements.

In July 2017, the FASB issued new guidance which changes the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features and recharacterizes the indefinite deferral of certain provisions within the guidance for distinguishing liabilities from equity. The guidance is effective for us beginning in the first quarter of fiscal year 2019. Early adoption is permitted. We are evaluating the impact of adopting this guidance on our consolidated financial statements.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Item 3.

Quantitative and Qualitative Disclosure about Market Risk.

None.

Item 4.

Controls and Procedures.

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. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we carried out an evaluation of the effectiveness of the design and operation 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, 2018. Based on the foregoing evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures are effective 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 rules and forms of the SEC, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosures.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended March 31, 2018, or in other factors that could significantly affect these controls, that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II
OTHER INFORMATION

Item 1.
Legal Proceedings.

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

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

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

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

The opposition proceeding against the Prosl European Patent before the EPO is ongoing. In its preliminary consideration of the matter, the EPO (and the German PTO) regarded the patent as not inventive or novel due to publication of prior art. Oral proceedings before the Opposition Division at the EPO were held on November 25, 2015, at which the three judge patent examiner panel considered arguments related to the validity of the Prosl European Patent. The hearing was adjourned due to the fact that the panel was of the view that Claus Herdeis, one of the managing directors of TauroPharm, has to be heard as a witness in a further hearing in order to close some gaps in the documentation presented by TauroPharm as regards the publication of prior art.

The German PTO held a hearing in the validity proceedings relating to the Utility Model on June 29, 2016, at which the panel affirmed its preliminary finding that the Utility Model was invalid based upon prior publication of a reference to the benefits that may be associated with adding heparin to a taurolidine based solution. The decision has only a declaratory effect, as the Utility Model had expired in November 2015. Furthermore, it has no bearing on the ongoing consideration by the EPO of the validity and possible infringement of the Prosl European Patent. We filed an appeal against the ruling on September 7, 2016.

In October 2016, TauroPharm submitted a further writ to the EPO requesting a date for the hearing and bringing forward further arguments, in particular in view of the June 2016 decision of the German PTO on the invalidity of the utility model, which we have appealed. On November 22, 2017, the EPO in Munich, Germany held a further oral hearing in this matter. At the hearing, the panel held that the Prosl European Patent would be invalidated because it did not meet the requirements of novelty based on a technical aspect of the European intellectual property law. We disagree with this decision and plan to appeal. Our appeal will be based, in part, on the written opinion to be issued by the Opposition Division, which is expected by the third quarter of 2018. We continue to believe that the Prosl European Patent is indeed novel and that its validity should be maintained. There can be no assurance that we will prevail in this matter with either the German PTO or the EPO. In addition, the ongoing Unfair Competition litigation against TauroPharm is not affected and will continue.

On January 16, 2015, we filed a complaint against TauroPharm GmbH and its managing directors in the District Court of Cologne, Germany. In the complaint, we allege violation of the German Unfair Competition Act by TauroPharm for the unauthorized use of its proprietary information obtained in confidence by TauroPharm. We allege that TauroPharm is improperly and unfairly using its proprietary information relating to the composition and manufacture of Neutrolin, in the manufacture and sale of TauroPharm's products TauroLock™, TauroLock-HEP100 and TauroLock-HEP500. We seek a cease and desist order against TauroPharm from continuing to manufacture and sell any product containing taurolidine (the active pharmaceutical ingredient ("API") of Neutrolin) and citric acid in addition to possible other components, damages for any sales in the past and the removal of all such products from the market. An initial hearing in the District Court of Cologne, Germany was held on November 19, 2015 to consider our claims. The judge made no decision on the merits of our complaint. On January 14, 2016, the court issued an interim decision in the form of a court order outlining several issues of concern that relate primarily to court's interest in clarifying the facts and reviewing any and all available documentation, in particular with regard to the question which specific know-how was provided to TauroPharm by whom and when. We have prepared the requested reply and produced the respective documentation. TauroPharm has also filed another writ within the same deadline and both parties have filed further writs at the end of April setting out their respective argumentation in more detail. A further oral hearing in this matter was held on November 15, 2016. In this hearing, the court heard arguments from CorMedix and TauroPharm concerning the allegations of unfair competition. The court made no rulings from the bench, and indicated that it is prepared to further examine the underlying facts of our allegations. On March 7, 2017, the court issued another interim decision in the form of a court order outlining again several issues relating to the argumentation of both sides in the proceedings. In particular the court requested us to further specify our requests and to further substantiate in even more detail which know know-how was provided by Biolink to TauroPharm by whom and when. The court also raised the question whether the know-how provided at the time to TauroPharm could still be considered to be secret know-how or may have become public in the meantime. The court granted both sides the opportunity to reply to this court order and provide additional facts and evidence until May 15, 2017. Both parties have submitted further writs in this matter and the court had scheduled a further hearing for May 8, 2018. After having been rescheduled several times, the hearing is now scheduled to take place on November 20, 2018. The Company intends to continue to pursue this matter, and to provide additional supplemental documentary and other evidence as may be necessary to support its claims.

Item 1A.

Risk Factors.

There have been no material changes to the risk factors previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2017 except the additional detailed risk as set forth below.

We will need to finance our future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. Any additional funds that we obtain may not be on terms favorable to us or our stockholders and may require us to relinquish valuable rights.

We have launched Neutrolin in certain European Union and Middle East countries, but to date have no other approved product on the market and have not generated significant product revenue from Neutrolin to date. Unless and until we receive applicable regulatory approval for Neutrolin in the U.S., we cannot sell Neutrolin in the U.S. Therefore, for the foreseeable future, we will have to fund all of our operations and capital expenditures from Neutrolin sales in Europe and other foreign markets, if approved, cash on hand, additional financings, licensing fees and grants.

Based on our cash resources at March 31, 2018, the expected timing and cost of the ongoing LOCK-IT-100 clinical trial in the U.S., and the current status of our negotiations with our CRO, we believe that our existing cash and short-term investments will fund operations into the third quarter of 2018. We will need additional funding thereafter to complete our ongoing and anticipated Phase 3 clinical trials in the U.S., and to continue the Neutrolin development program through to NDA filing and approval. If we are unable to raise additional funds when needed, we may not be able to complete our ongoing Phase 3 clinical trial, to complete the Neutrolin development program through to NDA filing and marketing approval or commercialize Neutrolin and we could be required to delay, scale back or eliminate some or all of our research and development programs. We can provide no assurances that any financing or strategic relationships will be available to us on acceptable terms, or at all. We expect to incur increases in our cash used in operations as we continue to conduct our ongoing Phase 3 clinical trial and prepare for additional Phase 3 clinical trials, seek FDA approval of Neutrolin in the U.S., commercialize Neutrolin in Europe and other markets, pursue development of our medical devices and other business development activities, and incur additional legal costs to defend our intellectual property.

To raise needed capital, we may sell additional equity or debt securities, obtain a bank credit facility, or enter into a corporate collaboration or licensing arrangement. The sale of additional equity or debt securities, if convertible, could result in dilution to our stockholders. The incurrence of indebtedness would result in 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.

At the time that we may need additional financing, we may not have sufficient authorized shares of common stock available, depending on the amount of the financing, the price of our common stock and our obligations to reserve shares for our outstanding convertible preferred stock, warrants and options. We currently have 160,000,000 shares of common stock authorized and at May 11, 2018, we had 81,903,027 shares outstanding and 47,901,830 shares reserved for issuance upon the exercise and conversion of our outstanding convertible preferred stock, warrants and options. To increase our authorized common stock, we would need stockholder approval to amend our certificate of incorporation, which approval may not be obtained. We intend to seek stockholder approval at a special meeting of stockholders to amend our certificate of incorporation to effect a reverse stock split at a ratio of any whole number between 1-for-5 and to 1-for-10, as determined by our board, at any time before June 26, 2019, if and as determined by our board. A reverse stock split would increase the shares available for issuance without increasing our authorized shares.

Until the date that none of the shares of common stock or warrants that we issued to Elliott Associates, L.P. and Elliott International, L.P in November 2017 as part of the backstop financing are outstanding, we are prohibited from issuing or selling any securities convertible into common stock on terms more favorable than the backstop financing terms and with a conversion, exchange or exercise price that is based upon and/or varies with the trading prices of or quotations for the shares of our common stock or that is subject to being reset at some future date or upon the occurrence of specified or contingent events directly or indirectly related to our business (other than pursuant to a customary “weighted average” anti-dilution provision) or the market for our common stock or enter into any agreement to sell securities at a future determined price (other than standard and customary “preemptive” or “participation” rights and other than pursuant to an at-the-market offering through a registered broker-dealer). This restriction could make raising capital through the sale of equity securities very difficult and could have a material adverse impact on our business, financial condition and prospects.

Item 6.
Exhibits.

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

| Exhibit Number | Description |
|----------------|---|
| <u>10.1</u> | Employment Agreement, effective March 19, 2018, between CorMedix Inc. and Elizabeth Masson.* + |
| <u>31.1</u> | Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.* |
| <u>31.2</u> | Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.* |
| <u>32.1</u> | Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.* |
| <u>32.2</u> | Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.* |
| 101 | The following materials from CorMedix Inc. Form 10-Q for the quarter ended March 31, 2018, formatted in Extensible Business Reporting Language (XBRL): (i) Condensed Consolidated Balance Sheets at March 31, 2018 and December 31, 2017, (ii) Condensed Consolidated Statements of Operations for the three months ended March 31, 2018 and 2017, (iii) Condensed Consolidated Statements of Changes in Stockholders' Equity for the three months ended March 31, 2018, (iv) Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2018 and 2017, 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.

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Confidential treatment has been requested with respect to certain portions of this exhibit. The 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 15, 2018 | By: | /s/ Khoso Baluch |
| | Name: | Khoso Baluch Chief Executive Officer |
| | Title: | (Principal Executive Officer) |

EXHIBIT INDEX

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