CorMedix Inc.
Form 10-Q
August 14, 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 June 30, 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 (State or Other Jurisdiction of Incorporation or Organization)	20-5894890 (I.R.S. Employer Identification No.)

400 Connell Drive, Suite 5000, Berkeley Heights, NJ (Address of Principal Executive Offices)	07922 (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

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

Large accelerated filer	Accelerated filer
Non-accelerated filer	Smaller reporting company
Emerging Growth Company	
(Do not check if a smaller reporting 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 August 10, 2018 was 97,844,285.

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)

	June 30, 2018	December 31, 2017
ASSETS		
Current assets		
Cash and cash equivalents	$4,701,978	$10,379,729
Restricted cash	171,553	171,553
Short-term investments	-	1,604,198
Trade receivables	3,478	64,148
Inventories, net	672,937	594,194
Prepaid research and development expenses	22,613	86,652
Other prepaid expenses and current assets	168,188	367,177
Total current assets	5,740,747	13,267,651
Property and equipment, net	185,802	186,282
TOTAL ASSETS	$5,926,549	$13,453,933
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$7,308,823	$1,808,311
Accrued expenses	5,080,302	4,363,867
Deferred revenue	15,441	88,404
Total current liabilities	12,404,566	6,260,582
TOTAL LIABILITIES	12,404,566	6,260,582
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY (DEFICIT)		
Preferred stock - $0.001 par value: 2,000,000 shares authorized; 419,585 shares issued and outstanding at June 30, 2018 and December 31, 2017	420	420
Common stock - $0.001 par value: 160,000,000 shares authorized; 85,019,240 and 71,413,790 shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively	85,019	71,414
Accumulated other comprehensive income	97,403	98,433

Additional paid-in capital	164,239,299	159,197,950
Accumulated deficit	(170,900,158)	(152,174,866)
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	(6,478,017)	7,193,351
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	$5,926,549	$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 June 30,		For the Six Months Ended June 30,	
	2018	2017	2018	2017
Revenue:				
Net sales	$7,551	$136,168	$30,760	$175,727
Cost of sales	(33,663)	(18,052)	(62,238)	(111,624)
Gross profit (loss)	(26,112)	118,116	(31,478)	64,103
Operating Expenses:				
Research and development	(6,600,215)	(5,089,624)	(14,880,657)	(10,013,891)
Selling, general and administrative	(1,945,825)	(2,051,093)	(3,848,838)	(4,691,819)
Total Operating Expenses	(8,546,040)	(7,140,717)	(18,729,495)	(14,705,710)
Loss From Operations	(8,572,152)	(7,022,601)	(18,760,973)	(14,641,607)
Other Income (Expense):				
Interest income	10,196	28,578	24,971	52,009
Foreign exchange transactions gain (loss)	5,043	(5,537)	(4,154)	(6,823)
Change in fair value of derivative liability	-	1,853,365	-	1,853,365
Interest expense	-	-	(1,873)	-
Total Other Income (Expense)	15,239	1,876,406	18,944	1,898,551
Net Loss	(8,556,913)	(5,146,195)	(18,742,029)	(12,743,056)
Other Comprehensive Income (Loss):				
Unrealized gain from investments	-	300	-	10,413
Foreign currency translation gain (loss)	394	6,077	(1,030)	5,085
Total Other Comprehensive Income (Loss)	394	6,377	(1,030)	15,498
Comprehensive Loss	(8,556,519)	(5,139,818)	(18,743,059)	(12,727,558)
Net Loss Per Common Share – Basic and Diluted	$(0.10)	$(0.10)	$(0.24)	$(0.27)
Weighted Average Common Shares Outstanding – Basic and Diluted	82,354,273	52,583,177	78,692,987	46,637,083

See Notes to Unaudited Condensed Consolidated Financial Statements.

CORMEDIX INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)
For the Six Months Ended June 30, 2018
(Unaudited)

	Common Stock		Non-Voting Preferred Stock – Series C-2, Series C-3, Series D, Series E and Series F					
	Shares	Amount	Shares	Amount	Accumulated Other Comprehensive Income	Additional Paid-inCapital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
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	13,434,437	13,434				4,136,279		4,149,713
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						731,468		731,468
Cumulative effect of adoption of ASC 606 (Note 1)							16,737	16,737
Other comprehensive income					(1,030)			(1,030)
Net loss							(18,742,029)	(18,742,029)
Balance at June 30, 2018	85,019,240	$85,019	419,585	$420	$97,403	$164,239,299	$(170,900,058)	$(6,478,017)

See Notes to Unaudited Condensed Consolidated Financial Statements.

CORMEDIX INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	For the Six Months Ended June 30, 2018	For the Six Months Ended June 30, 2017
Cash Flows From Operating Activities:		
Net loss	$(18,742,029)	$(12,743,056)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	731,468	849,643
Change in fair value of derivative liability	-	(1,853,365)
Inventory reserve decrease	-	(187,000)
Depreciation	38,734	17,671
Non-cash interest expense	-	2,020
Changes in operating assets and liabilities:		
Decrease (increase) in trade receivables	61,220	(133,119)
(Increase) decrease in inventory	(78,743)	40,598
Decrease (increase) in prepaid expenses and other current assets	263,151	(400,152)
Increase in accounts payable	5,498,465	117,509
Increase (decrease) in accrued expenses	911,636	(212,061)
Decrease in deferred revenue	(73,686)	(8,599)
Net cash used in operating activities	(11,389,784)	(14,509,911)
Cash Flows From Investing Activities:		
Purchase of short-term investments	-	(9,279,217)
Sale of short-term investments	1,604,198	10,504,355
Purchase of equipment	(38,225)	(3,922)
Net cash provided by investing activities	1,565,973	1,221,216
Cash Flows From Financing Activities:		
Proceeds from sale of common stock from at-the-market program	4,149,713	347,361
Proceeds from the public offering of common stock and warrants	-	12,798,325
Proceeds from exercise of stock options	-	6,800
Net cash provided by financing activities	4,149,713	13,152,486
Foreign exchange effect on cash	(3,653)	9,107
Net Decrease In Cash	(5,677,751)	(127,102)
Cash – Beginning of Period	10,551,282	8,236,043
Cash – End of Period	$4,873,531	$8,108,941
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 vested restricted stock units	$43	
Unrealized gain from investments	$-	$10,413
Issuance of common stock for payment of deferred fees	$173,773	$10,218

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 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.

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 designed 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. On July 25, 2018, the Company announced that the independent Data Safety Monitoring Board (“DSMB”) had completed its review of the interim analysis of the data from the LOCK-IT-100 study and, because the pre-specified level of statistical significance was reached and efficacy had been demonstrated, the DSMB recommended the study be terminated early. No safety concerns were reported by the DSMB based on the interim analysis. The Company will initiate dialogue with the U.S. Food and Drug Administration (“FDA”) on the appropriate next steps for the development of Neutrolin based on the results of the interim analysis.

Although two pivotal clinical trials to demonstrate safety and effectiveness of Neutrolin generally are required by the FDA to secure marketing approval in the U.S., in light of the interim analysis results and the DSMB recommendation, the Company plans to meet with the FDA as soon as possible to seek agreement on the required next steps to file a new drug application (“NDA”) for Neutrolin.

The necessary activities for the submission of an NDA for Neutrolin are dependent on the Company’s ability to raise sufficient 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 the FDA will not require a second clinical trial for an NDA for Neutrolin, or that financing or strategic relationships will be available on acceptable terms, or at all, to complete its clinical development program for Neutrolin.

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.

CORMEDIX INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") for interim financial information and with the instructions for Form 10-Q and Article 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.

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.

The following table presents the Company's revenue for the three months ended June 30, 2018 under the ASC 606 model as compared to revenue under the previous guidance:

	Revenue As Reported	Revenue Under Previous Guidance	Difference
Net sales	$5,345	$5,345	$-
Revenue recognized under agreement with warranty	-	7,511	7,511
Revenue recognized under Wonik Agreement	2,206	2,206	-
Total net sales	$7,551	$15,062	$7,511

The following table presents the Company's revenue for the six months ended June 30, 2018 under the ASC 606 model as compared to revenue under the previous guidance:

	Revenue As Reported	Difference

		Revenue Under Previous Guidance	
Net sales	$26,348	$26,348	$-
Revenue recognized under agreement with warranty	-	37,669	37,669
Revenue recognized under Wonik Agreement	4,412	4,412	-
Total net sales	$30,760	$68,429	$37,669

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 recognition of 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.

CORMEDIX INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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. 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 six months ended June 30, 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.

Recent Authoritative Accounting 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. In July 2018, the FASB issued new guidance with targeted improvements which include a new transition method and a practical expedient for separating components of a contract intended to reduce costs and ease implementation of the lease standard. The guidance is effective for the Company 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. The Company is evaluating the impact of adopting this guidance on its consolidated financial statements.

In June 2018, the FASB issued a new guidance which expands the scope of ASC 718 to include share-based payment transactions for acquiring goods and services from nonemployees. The guidance is effective for the Company beginning in the first quarter of fiscal year 2019. Early adoption is permitted. The Company is evaluating the impact of adopting this guidance on its consolidated financial statements.

Note 2 — Summary of Significant Accounting Policies:

Liquidity, Going Concern and Uncertainties

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; the 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

Management has evaluated whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within a year after the date the consolidated financial statements contained in this Report are issued. As of June 30, 2018, the Company had an accumulated deficit of $170.9 million, and had incurred losses from operations of $8.6 million and $18.8 million for the three and six months ended June 30, 2018, respectively, and its cash position decreased from $10.6 million at December 31, 2017 to $4.9 million at June 30, 2018. These factors raise substantial doubt regarding the Company's ability to continue as a going concern. Based on the current development plans for Neutrolin and the Company's other operating requirements, as well as the current status of its negotiations with its contract research organization ("CRO"), management believes that the existing cash and cash equivalents at June 30, 2018, plus the funds raised under the at-the-market common stock issuance program (the "ATM Program") through August 10, 2018, will be adequate to fund the costs of closing the LOCK-IT-100 study and to hold its planned meeting with the FDA with respect to Neutrolin's proposed development path. A successful outcome of the Company's negotiations with its CRO may enable the Company to continue its operations into 2019; or if no such agreement is reached, additional financing may be required during the fourth quarter of 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 same date on which the prior At-the-Market Issuance Sales Agreement with B. Riley entered into in 2016 expired. Under the ATM Program, the Company sold 3,116,213 shares of common stock and realized net proceeds of approximately $929,000 during the quarter ended June 30, 2018 and 13,434,437 shares and realized $4.1 million of net proceeds for the six months ended June 30, 2018.

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 the development and commercialization of Neutrolin, 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.

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.

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.

CORMEDIX INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

The following table is the reconciliation under the aforementioned 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:

	June 30, 2018	June 30, 2017
Cash and cash equivalents	$4,701,978	$7,937,388
Restricted cash	171,553	171,553
Total cash, cash equivalents and restricted cash	$4,873,531	$8,108,941

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 June 30, 2018 or December 31, 2017.

The Company's marketable securities are highly liquid and consist of U.S. government agency securities, high-grade corporate obligations and commercial paper with original maturities of more than 90 days. As of June 30, 2018, the Company has no marketable securities and at 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 June 30, 2018 and December 31, 2017:

June 30, 2018:	Amortized Cost	Gross Unrealized Losses	Gross Unrealized Gains	Fair Value
Money Market Funds included in Cash Equivalents	$-	$-	$-	$-
Total June 30, 2018	$-	$-	$-	$-
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

CORMEDIX INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Fair Value Measurements

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

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

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

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

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

The following table provides the carrying value and fair value of the Company's financial assets measured at fair value on a recurring basis as of June 30, 2018 and December 31, 2017:

June 30, 2018:	Carrying Value	Level 1	Level 2	Level 3
Money Market Funds	$-	$-	$-	$-
Total June 30, 2018	$-	$-	$-	$-
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.

CORMEDIX INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

The Company has intercompany loans between the parent company based in New Jersey and its German subsidiary. 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 June 30, 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.

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:

	June 30, 2018	December 31, 2017
Raw materials	$93,716	$141,233
Work in process	294,267	526,067
Finished goods	387,954	29,894
Inventory reserve	(103,000)	(103,000)
Total	$672,937	$594,194

Accounts Payable

Accounts payable consist of invoices received from vendors. At June 30, 2018, the balance increased by approximately $5,500,000 from $1,808,000 balance at December 31, 2017, due to the suspension of payments to the CRO while negotiations regarding financial considerations for the interim analysis continue.

Accrued Expenses

Accrued expenses consist of the following:

	June 30, 2018	December 31, 2017
Professional and consulting fees	$324,286	$485,089
Accrued payroll and payroll taxes	775,222	755,221
Clinical trial and manufacturing development	3,756,595	2,884,924
Product development	80,001	80,001
Market research	-	116,466
Other	144,198	42,166
Total	$5,080,302	$4,363,867

CORMEDIX INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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.

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 June 30,2018 and 2017, and $4,400 each for the six months ended June 30, 2018 and 2017.

Deferred revenue related to the Wonik Agreement at June 30, 2018 and December 31, 2017 amounted to approximately $15,400 and $19,800, respectively.

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.

	Six Months Ended June 30,	
	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	12,345,679	-

Shares underlying outstanding warrants	22,892,891	33,052,578
Shares underlying restricted stock units	97,529	61,414
Shares underlying outstanding stock options	5,505,795	5,709,545
Total	46,820,893	45,052,536

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NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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.

Note 3 — Stockholders’ Equity:

Common Stock

The Company had a prior sales agreement with B. Riley for its ATM Program, which agreement expired on April 16, 2018, and under which the Company could issue and sell up to an aggregate of $60.0 million of shares of its common stock. 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 under the ATM Program, 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. Under the ATM Program, the Company may issue and sell 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. B. Riley is entitled to a commission of up to 3% of the gross proceeds from the sale of common stock sold under the ATM Program. During the three and six months ended June 30, 2018, the Company sold 3,116,213 and 13,434,437 shares of common stock, respectively, under the ATM Program and realized net proceeds of approximately $929,000 and $4.1 million for the three and six months ended June 30, 2018, respectively.

CORMEDIX INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

During the six months ended June 30, 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 six months ended June 30, 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 June 30, 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
Series C-3	104,000	10.0	1,040,000	104,000	10.0	1,040,000
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

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 will be mandatorily convertible if certain equity conditions are met. As of June 30, 2018, the last condition has not been met, which condition is the subordination of the outstanding Series C-3 preferred stock to the Series F Stock, therefore, the Series F Stock is not mandatorily convertible as of June 30, 2018. 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.

CORMEDIX INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Stock Options

During the six months ended June 30, 2018, the Company granted ten-year qualified and non-qualified stock options covering an aggregate of 623,000 shares of the Company's common stock under the 2013 Stock Incentive Plan. The weighted average exercise price of these options is $0.41 per share.

During the three and six months ended June 30, 2018, total compensation expense for stock options issued to employees, directors, officers and consultants was $337,000 and $687,000, respectively, and $383,000 and $814,000 for the three and six months ended June 30, 2017, respectively.

As of June 30, 2018, there was $2,275,000 in total unrecognized compensation expense related to stock options granted which expense will be recognized over an expected remaining weighted average period of 1.5 years.

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

	Six Months Ended June 30,	
	2018	2017
Expected Term	5 years	5 years
Volatility	92.97% - 95.51%	101.69% - 105.07%
Dividend yield	0.0%	0.0%
Risk-free interest rate	2.63% - 2.92%	1.77% - 1.99%
Weighted average grant date fair value of options granted during the period	$0.30	$1.27

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. 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. 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.

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NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

The following table summarizes the Company's stock options activity and related information for the six months ended June 30, 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
Expired	(30,818)	$1.17		$0
Granted	623,000	$0.41		$500
Outstanding at end of period	5,505,795	$1.86	7.3	$500
Vested at end of period	2,777,265	$1.86	5.9	$21

There were no stock option exercises during the six months ended June 30, 2018 and during the six months ended June 30, 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 six months ended June 30, 2018, the Company granted an aggregate of 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 and six months ended June 30, 2018, compensation expense recorded for the RSUs was $21,000 and $44,000, respectively, and $15,000 and $36,000 for the three and six months ended June 30, 2017. Unrecognized compensation expense for these RSUs amounted to $48,000. The expected weighted average period for the expense to be recognized is 0.57 years.

Warrants

As of June 30, 2018, there were 22,892,891 outstanding warrants with a weighted average exercise price of $1.07 per share and a weighted average remaining contractual life of 2.9 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 the DSMB recommendation to terminate the LOCK-IT-100 study for efficacy and the Company's ongoing negotiations with its CRO regarding financial considerations for the interim efficacy analysis of the LOCK-IT-100 study, the Company has determined to not draw down on this facility.

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NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Pursuant to the November 2017 consulting agreement between the Company and Gary Gelbfish, a director, in June 2018 the Company accrued $160,000 in fees submitted by Dr. Gelbfish under the consulting agreement for his work in the data quality review for the interim analysis of the Company's LOCK-IT-100 clinical trial for Neutrolin. Under the terms of the consulting agreement, Dr. Gelbfish is compensated at the rate of $800 per hour.

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.

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CORMEDIX INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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.

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 TauroLockTM, TauroLock-HEP100 and TauroLock-HEP500. The Company seeks a cease and desist order against TauroPharm from continuing to manufacture and sell any product containing taurolidine (the active pharmaceutical ingredient (“API”) of Neutrolin) and citric acid in addition to possible other components, damages for any sales in the past and the removal of all such products from the market. 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 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 June 30, 2018. During the three and six months ended June 30, 2018, the Company recognized research and development expense of approximately $56,000 and $159,000, respectively, related to these agreements and approximately $349,000 and $896,000 for the three and six months ended June 30, 2017, respectively. The Company may terminate these agreements upon 30 days written notice and is only obligated for project costs and reasonable project shut down costs provided through the date of termination.

Clinical and Regulatory

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 budgeted 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 the changes to the study agreed with the FDA, the Company signed a second contract modification with its CRO increasing the budget by $6.3 million, to cover the continuation of trial enrollment, the increased length of time in which patients are enrolled and additional activities related to the collection of retrospective data outside the treatment centers. During the three and six months ended June 30, 2018, the Company recognized $3,242,000 and $9,040,000 in research and development expense related to this agreement, respectively, and $2,811,000 and $5,365,000 during the three and six months ended June 30, 2017, respectively.

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NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

At June 30, 2018, the total CRO contract was $33 million, increasing from its original amount of $19.2 million. The Company determined that certain issues delayed the completion of the interim efficacy analysis, and it is in negotiations with its CRO regarding financial considerations. The Company is assessing 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.

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 June 30, 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 being $2,500,000 as of June 30, 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 six month periods ending June 30, 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.

Note 6 — Concentrations:

At June 30, 2018, approximately 89% of net accounts receivable was due from two customers (53% and 26%). During the three months and six months ended June 30, 2018, the Company had revenue from two customers that each exceeded 10% of its total sales (34% and 28%) and (36% and 14%), respectively. During the three and six months ended June 30, 2017, two customers also exceeded 10% of the Company’s total sales (48% and 36%) and (50% and 33%), respectively.

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.

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NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 7 — Subsequent Event:

During July 2018 through August 10, 2018, the Company issued an aggregate of 13,807,818 shares under its ATM Program with a weighted average sale price of $0.51 per share, resulting in net proceeds of approximately $6.9 million.

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," "sl "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.

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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 was 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 July 25, 2018, we announced that the DSMB had completed its review of the interim analysis of the data from the LOCK-IT-100 study and, because the pre-specified level of statistical significance was reached and efficacy had been demonstrated, the DSMB recommended the study be terminated early.

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.

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.

In August 2017, we secured a research grant from the National Institutes of Health (NIH) to expand our antimicrobial hydrogel medical device program. In addition to our ongoing development of taurolidine-incorporated hydrogels to reduce infections in common burns, this funding will be applied toward 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.

Since our inception, 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 terminate our LOCK-IT-100 Phase 3 clinical trial in hemodialysis patients with catheters, possibly plan a second Phase 3 clinical trial for Neutrolin, if required by the FDA, prepare and submit a new drug application for Neutrolin to the FDA, 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 June 30, 2018, we had an accumulated deficit of approximately $170.9 million. We are unable to predict the extent of any future losses or when we will become profitable, if ever.

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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 would expect to incur higher R&D expenses for the foreseeable future if we are required to conduct a second Phase 3 clinical trial in order to submit a new drug application to complete development of Neutrolin in the U.S.

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 of Neutrolin in the U.S. and optimization of sales in foreign markets where Neutrolin is approved. In December 2015, we contracted with our contract research organization, or 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 severe adverse events, or 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 June 30, 2018, approximately $29.7 million has been incurred related to the CRO contract. We continue our negotiations with our CRO regarding financial considerations related to the delay and additional costs we incurred in performing the interim efficacy analysis of the LOCK-IT-100 study. Our CRO is continuing to provide services for the LOCK-IT-100 trial to close down study sites in light of the DSMB recommendation to terminate the trial for efficacy.

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 and six months ended June 30, 2018 compared to three and six months ended June 30, 2017

The following is a tabular presentation of our consolidated operating results:

	For the Three Months Ended June 30,		% Increase	For the Six Months Ended June 30,		% Increase
	2018	2017	(Decrease)	2018	2017	(Decrease)
Revenue	$7,551	$136,168	(94)%	$30,760	$175,727	(82)%
Cost of sales	(33,663)	(18,052)	86%	(62,238)	(111,624)	(44)%
Gross profit (loss)	(26,112)	118,116	(122)%	(31,478)	(31,478)	(149)%
Operating Expenses:						
Research and development	(6,600,215)	(5,089,624)	30%	(14,880,657)	(10,013,891)	49%
Selling, general and administrative	(1,945,825)	(2,051,093)	(5)%	(3,848,838)	(4,691,819)	(18)%
Total operating expenses	(8,546,040)	(7,140,717)	20%	(18,729,495)	(14,705,710)	27%

Loss from operations	(8,572,152)	(7,022,601)	22%	(18,760,973)	(14,641,607)	28%
Interest income	10,196	28,578	(64)%	24,971	52,009	(52)%
Foreign exchange transaction gain (loss)	5,043	(5,537)	(191)%	(4,154)	(6,823)	(39)%
Value of warrants issued in connection with public offering	-	1,853,365	(100)%	-	1,853,365	(100)%
Interest expense	-	-		(1,873)	-	-
Total Other Income	15,239	1,876,406	(99)%	18,944	1,898,551	(99)%
Net loss	(8,556,913)	(5,146,195)	66%	(18,742,029)	(12,743,056)	47%
Other comprehensive income (loss)	394	6,377	(94)%	(1,030)	15,498	(107)%
Comprehensive loss	$(8,556,519)	$(5,139,818)	66%	(18,743,059)	(12,727,558)	47%

Revenue. Revenue was $8,000 for the three months ended June 30, 2018 as compared to $136,000 in the same period last year, a decrease of $128,000. The decrease was primarily due to decreased sales in the European Union of $94,000 and the adoption of ASC 606 at January 1, 2018, which caused no deferred revenue to be recognized for the products sold with warranty for the three months ended June 30, 2018 as compared to the $35,000 recognized for the same period last year.

Revenue for the six months ended June 30, 2018 was $31,000 as compared to $176,000 for the same period last year, a decrease of $145,000. The decrease was primarily due to decreased sales in the European Union of $81,000 and the adoption of ASC 606 at January 1, 2018, which caused no deferred revenue to be recognized for the products sold with warranty for the six months ended June 30, 2018 as compared to the $64,000 recognized for the same period last year.

Cost of Sales. Cost of sales was approximately $34,000 for the three months ended June 30, 2018 compared to $18,000 in the same period last year, an increase of $16,000. The increase was due to a reduction of inventory reserve in 2017 for $187,000, partially offset by a $155,000 decrease in cost of materials and packaging due to lower sales in the European Union during the three months ended June 30, 2018, and a decrease in stability studies of $17,000.

Cost of sales for the six months ended June 30, 2018 was $62,000 compared to $112,000 in the same period last year, a decrease of $50,000. The decrease is attributed to a $180,000 decrease in cost of materials and packaging due lower sales in the European Union during the six months ended June 30, 2017, and a decrease in stability studies of $57,000, partially offset by a reduction in inventory reserve during the six months ended June 30, 2017 in the amount of $187,000.

Research and Development Expense. R&D expense was approximately $6,600,000 for the three months ended June 30, 2018, an increase of $1,510,000, from $5,090,000 for the three months ended June 30, 2017. The increase was primarily attributable to increased expenses related to the LOCK-IT-100 trial of $1,207,000, due to increased number of patients enrolled. Consulting fees and personnel expenses also increased by $386,000 and $271,000, respectively. Increase in consulting fees was due to increased regulatory activities and increase in personnel expenses was mainly due to hiring of new staff supporting the LOCK-IT-100 trial and the conversion of several consultants into employee status. These increases were partially offset by a decrease in costs to support the U.S. clinical trial drug supply consisting of manufacturing process development activities of $191,000, reduced cost of studies related to wound closure, wound management and surgical meshes of $135,000, and a decrease in non-cash stock-based compensation of $27,000.

R&D expense for the six months ended June 30, 2018 was $14,881,000, compared to $10,014,000 for the same period last year, an increase of $4,867,000. The increase was primarily attributable to a $5,481,000 increase in expenses related to the LOCK-IT-100 clinical trial in the U.S. Personnel expenses also increased by $423,000, due to the hiring of new staff supporting the LOCK-IT-100 trial and the conversion of several consultants to employee status. These increases were partially offset by decreases in costs related to manufacturing process development activities of $774,000 and cost of new studies related to antimicrobial sutures, nanofiber webs, wound management and osteoarthritis and visco-supplementation of $265,000.

Selling, General and Administrative Expense. SG&A expense was $1,946,000 for the three months ended June 30, 2018, a decrease of $105,000 from $2,051,000 for the three months ended June 30, 2017. The decrease was primarily attributable to reductions in selling and distribution cost in the EU of $119,000, decreases in marketing research studies and consulting fees of $100,000 and $61,000, respectively. These decreases, among others of lesser significance, were partially offset by an increase in legal fees of $182,000 mainly due to fees related to the ongoing discussions with our CRO.

SG&A expense for the six months ended June 30, 2018 was $3,849,000 compared to $4,692,000 for the same period last year, a decrease of $843,000. The decrease was primarily attributable to a decrease in consulting fees of $553,000, mainly due to executive search fees that were incurred in 2017, a decrease in marketing research studies of $275,000, and a decrease in non-cash charge for stock-based compensation expense of $108,000. These decreases among others of lesser significance, were partially offset by a $115,000 increase in legal fees, mainly due to fees related to the ongoing discussions with our CRO.

Interest Income. Interest income was $10,000 for the three months ended June 30, 2018 compared to $29,000 for the same period last year, a decrease of $19,000. 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.

Interest income for the six months ended June 30, 2018 was $25,000 as compared to $52,000 for the same period last year, a decrease of $27,000. The decrease was attributable to lower interest-bearing cash balance during the first six months of 2018 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 $400 and $6,000 gain for the three months ended June 30, 2018 and 2017, respectively.

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 a $15,000 gain for the six months ended June 30, 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 six months ended June 30, 2018, we received net proceeds of $4,150,000 from the issuance of 13,434,437 shares of common stock under our at-the-market-issuance sales program.

Net Cash Used in Operating Activities

Net cash used in operating activities for the six months ended June 30, 2018 was $11,390,000 as compared to $14,510,000 for the same period in 2017, a decrease in net cash use of $3,120,000. The decrease was primarily attributable to an increase in net loss of $5,795,000 driven by increased research and development expenses. The net loss of $18,742,000 for the six months ended June 30, 2018 was higher than cash used in operating activities by $7,352,000. The difference is primarily attributable to increases in accounts payable and accrued expenses of $5,498,000 and $912,000, respectively, primarily due to the suspension of payments to our CRO while negotiations continue. Additionally, there is also an increase in non-cash stock-based compensation of $731,000, and decreases in prepaid expenses and trade receivables of $263,000 and $61,000, respectively, partially offset by an increase in inventory and a decrease in deferred revenue of $79,000 and $74,000, respectively.

Net Cash Provided by Investing Activities

Cash provided by investing activities for the six months ended June 30, 2018 was $1,566,000 as compared to $1,221,000 for the same period in 2017, both of which are mainly attributable to the proceeds received on the sale of short-term investments.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the six months ended June 30, 2018 was $4,150,000 as compared to $13,152,000 for the same period in 2017. During the six months ended June 30, 2018, we generated net proceeds of

$4,150,000 from the sale of our common stock in our at-the-market program. During the same period in 2017, we generated $12,798,000 from the public offering of our common stock and warrants, $347,000 from the sale of our common stock in the 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 June 30, 2018 was $4.7 million, excluding restricted cash of $0.2 million, compared with $12 million at December 31, 2017, excluding restricted cash of $0.2 million.

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 are focused in activities leading to the preparation and submission of a new drug application for Neutrolin to the FDA will depend on our ability to raise sufficient 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.

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 continue to utilize our ATM 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.

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 will continue to use cash as we terminate our Phase 3 clinical trial, and increase other activities leading to the preparation and submission of a new drug application to seek marketing approval of Neutrolin in the U.S., pursue business development activities, and incur additional legal costs to defend our intellectual property.

Based on our cash resources at June 30, 2018, the proceeds received under our ATM Program through August 10, 2018, and the current status of our negotiations with our CRO, we believe we have sufficient resources to fund the costs of closing the LOCK-IT-100 study and to hold its planned meeting with the FDA with respect to Neutrolin's proposed development path. A successful outcome of our negotiations with our CRO may enable us to continue our operations into 2019; or if no such agreement is reached, additional financing may be required during the fourth 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. We may 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.

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.

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. We accrue 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, we adjust our 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.

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 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 and $4,400 revenue related to the Wonik Agreement for each of the three and six months ended June 30, 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.

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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. In July 2018, the FASB issued new guidance with targeted

improvements which include a new transition method and a practical expedient for separating components of a contract intended to reduce costs and ease implementation of the lease standard. 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.

In June 2018, the FASB issued a new guidance which expands the scope of ASC 718 to include share-based payment transactions for acquiring goods and services from nonemployees. 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 reports filed pursuant to the Securities Exchange Act of 1934, as amended, or the Exchange Act, 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 Exchange Act) as of June 30, 2018. Based on the foregoing evaluation, our Chief Executive Officer and Chief 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 Chief Executive Officer and Chief 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 June 30, 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.

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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 TauroLockTM, 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.

If we fail to comply with the continued listing standards of the NYSE American, it may result in a delisting of our common stock from the exchange.

Our common stock is currently listed for trading on the NYSE American, and the continued listing of our common stock on the NYSE American is subject to our compliance with a number of listing standards. These listing standards include the requirement for avoiding sustained losses and maintaining a minimum level of stockholders' equity. In 2012, 2014, and 2018 we received notices from the NYSE American that we did not meet continued listing standards of the NYSE American as set forth in Part 10 of the Company Guide. Specifically, we were not in compliance with Section 1003(a)(i), Section 1003(a)(ii) or Section 1003(iii) of the Company Guide because we reported stockholders' equity of less than the required amounts.

On June 14, 2018, we received a notice from the NYSE American that, based on our Form 10-Q for the quarter ended March 31, 2018, filed on May 15, 2018, we do not meet a continued listing standard of the NYSE American as set forth in Part 10 of the NYSE American Company Guide because we reported stockholders' equity of less than the required amounts. As a result, we have become subject to the procedures and requirements of Section 1009 of the Company Guide. We submitted to the NYSE American on July 16, 2018 a plan of compliance to address how we intend to regain compliance with Section 1003(a)(i), Section 1003(a)(ii) or Section 1003(a)(iii) of the Company Guide by December 16, 2019. If the plan is accepted by the NYSE American, we may be able to continue our listing during the Sections 1003(a)(i)-(iii) Plan Period, during which time we will be subject to periodic review to determine whether we are making progress consistent with the plan.

If our common stock were no longer listed on the NYSE American, investors might only be able to trade on one of the over-the-counter markets, including the OTC Bulletin Board ® or in the Pink Sheets ® (a quotation medium operated by Pink Sheets LLC). This would impair the liquidity of our common stock not only in the number of shares that could be bought and sold at a given price, which might be depressed by the relative illiquidity, but also through delays in the timing of transactions and reduction in media coverage.

Item 6.
Exhibits.

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

Exhibit Number	Description
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
101	The following materials from CorMedix Inc. Form 10-Q for the quarter ended June 30, 2018, formatted in Extensible Business Reporting Language (XBRL): (i) Condensed Consolidated Balance Sheets at June 30, 2018 and December 31, 2017, (ii) Condensed Consolidated Statements of Operations and Comprehensive Income (Loss) for the three and six months ended June 30, 2018 and 2017, (iii) Condensed Consolidated Statements of Changes in Stockholders' Equity (Deficit) for the six months ended June 30, 2018, (iv) Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2018 and 2017, and (v) Notes to the Unaudited Condensed Consolidated Financial Statements.**

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Filed herewith.

**
Pursuant to Rule 406T of Regulation S-T, the Interactive Data Files in Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended,

are deemed not filed for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended and otherwise are not subject to liability under those sections.

SIGNATURES

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

CORMEDIX INC.

Date: August 14, 2018	By:	/s/ Khoso Baluch Name: Khoso Baluch Title: Chief Executive Officer (Principal Executive Officer)

EXHIBIT INDEX

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