REFINITIV

DELTA REPORT

10-Q

CRMD - CORMEDIX INC.

10-Q - JUNE 30, 2024 COMPARED TO 10-Q - MARCH 31, 2024

The following comparison report has been automatically generated

TOTAL DELTAS	587
CHANGES	110
DELETIONS	194
ADDITIONS	283

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, June 30, 2024

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

For the transition period from _____ to _____

Commission file number 001-34673

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

Delaware	20-5894890
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
300 Connell Drive, Suite 4200, Berkeley Heights, NJ	07922
(Address of Principal Executive Offices)	(Zip Code)

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, $0.001 par value	CRMD	Nasdaq Global Market

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 every Interactive Data File required to be submitted 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 such files). Yes ☒ No ☐

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging Growth Company	☐		

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

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

The number of shares outstanding of the issuer's common stock, as of March 31, 2024 August 12, 2024 was 54,959,270. 55,859,964.

CORMEDIX INC. AND SUBSIDIARIES

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PART I
FINANCIAL INFORMATION

Item 1. Unaudited Condensed Consolidated Financial Statements.

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

	March 31, 2024	December 31, 2023	June 30, 2024 (Unaudited)	December 31, 2023
ASSETS				
Current assets				
Cash and cash equivalents	$ 35,180,529	$ 43,642,684	$ 28,540,633	$ 43,642,684
Restricted cash	75,540	77,453	-	77,453
Short-term investments	23,370,989	32,388,130	17,069,660	32,388,130
Trade receivables			206,337	-
Inventories	2,320,396	2,106,345	4,011,560	2,106,345
Prepaid research and development expenses	295,845	353,574	227,167	353,574
Other prepaid expenses and current assets	2,166,267	882,214	3,139,022	882,214
Total current assets	63,409,566	79,450,400	53,194,379	79,450,400
Property and equipment, net	1,905,704	1,866,224	1,915,569	1,866,224
License intangible asset	2,000,000	-		
License intangible asset, net			1,948,052	-
Restricted cash, long-term	103,838	103,055	104,426	103,055
Operating lease right-of-use asset	604,634	640,278	568,168	640,278
TOTAL ASSETS	$ 68,023,742	$ 82,059,957	$ 57,730,594	$ 82,059,957
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities				
Accounts payable	$ 2,826,322	$ 4,279,679	$ 3,344,803	$ 4,279,679
Accrued expenses	6,553,311	6,970,217	7,607,537	6,970,217
Operating lease liability, short-term	154,801	150,619	159,077	150,619
Total current liabilities	9,534,434	11,400,515	11,111,417	11,400,515
Operating lease liability, net of current portion	476,588	517,013	435,246	517,013
TOTAL LIABILITIES	10,011,022	11,917,528	11,546,663	11,917,528
COMMITMENTS AND CONTINGENCIES (Note 4)				
COMMITMENTS AND CONTINGENCIES (Note 5)				
STOCKHOLDERS' EQUITY				
Preferred stock - $0.001 par value: 2,000,000 shares authorized; 181,622 shares issued and outstanding at March 31, 2024 and December 31, 2023	182	182		
Common stock - $0.001 par value: 160,000,000 shares authorized; 54,959,270 and 54,938,258 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	54,959	54,938		
Preferred stock - $0.001 par value: 2,000,000 shares authorized; 181,622 shares issued and outstanding at June 30, 2024 and December 31, 2023			182	182
Common stock - $0.001 par value: 160,000,000 shares authorized; 55,274,791 and 54,938,258 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively			55,274	54,938
Accumulated other comprehensive gain	83,461	94,108	85,731	94,108
Additional paid-in capital	394,040,254	391,693,214	396,360,369	391,693,214
Accumulated deficit	(336,166,136)	(321,700,013)	(350,317,625)	(321,700,013)
TOTAL STOCKHOLDERS' EQUITY	58,012,720	70,142,429	46,183,931	70,142,429
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 68,023,742	$ 82,059,957	$ 57,730,594	$ 82,059,957

See Accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

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

	For the Three Months Ended March 31,	
	2024	**2023**
Revenues, net	$ -	$ -
Cost of revenues	(818,539)	-
Gross loss	(818,539)	-
Operating Expenses		
Research and development	(837,445)	(3,407,502)
Selling, general and administrative	(15,048,252)	(7,609,677)
Total operating expenses	(15,885,697)	(11,017,179)
Loss From Operations	(16,704,236)	(11,017,179)
Other Income (Expense)		
Interest income	857,186	446,384
Foreign exchange transaction (loss) gain	(4,008)	12,345
Interest expense	(9,835)	(8,776)
Total other income	843,343	449,953
Net Loss Before Income Taxes	(15,860,893)	(10,567,226)
Tax benefit	1,394,770	-
Net Loss	(14,466,123)	(10,567,226)
Other Comprehensive (Loss) Income		
Unrealized (loss) gain from investment	(10,903)	16,393
Foreign currency translation gain	256	2,096
Total other comprehensive (loss) income	(10,647)	18,489
Other Comprehensive Loss	$ (14,476,770)	$ (10,548,737)
Net Loss Per Common Share - Basic and Diluted	$ (0.25)	$ (0.24)
Weighted Average Common Shares Outstanding - Basic and Diluted	57,503,154	44,090,998

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
Revenue:				
Net sales	$ 806,119	$ -	$ 806,119	$ -
Cost of sales	(509,839)	-	(1,328,377)	-
Gross profit (loss)	296,280	-	(522,258)	-
Operating Expenses:				
Research and development	(650,988)	(4,794,758)	(1,488,432)	(8,202,260)
Selling and marketing	(7,386,841)	(3,256,047)	(13,724,061)	(5,897,223)
General and administrative	(7,559,277)	(3,753,777)	(16,270,310)	(8,722,278)
Total Operating Expenses	(15,597,106)	(11,804,582)	(31,482,803)	(22,821,761)
Loss From Operations	(15,300,826)	(11,804,582)	(32,005,061)	(22,821,761)
Other Income (Expense):				
Interest income	657,366	550,183	1,514,551	996,567
Foreign exchange transaction loss	(1,473)	(13,368)	(5,481)	(1,023)
Other income	500,000	-	500,000	-
Interest expense	(6,556)	(5,851)	(16,391)	(14,627)
Total Other Income	1,149,337	530,964	1,992,679	980,917
Loss before income taxes	(14,151,489)	(11,273,618)	(30,012,382)	(21,840,844)
Tax benefit	-	-	1,394,770	-
Net Loss	(14,151,489)	(11,273,618)	(28,617,612)	(21,840,844)
Other Comprehensive Income (Loss):				
Unrealized income (loss) from investments	2,030	(10,732)	(8,872)	5,661
Foreign currency translation gain	240	197	495	2,293
Total Other Comprehensive Income (Loss)	2,270	(10,535)	(8,377)	7,954
Comprehensive Loss	$ (14,149,219)	$ (11,284,153)	$ (28,625,989)	$ (21,832,890)
Net Loss Per Common Share – Basic and Diluted	$ (0.25)	$ (0.25)	$ (0.50)	$ (0.49)
Weighted Average Common Shares Outstanding – Basic and Diluted	57,620,974	45,365,635	57,562,064	44,731,838

See Accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

CORMEDIX INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(Unaudited)

For the three months ended March 31, 2024 June 30, 2024

	Common Stock		Preferred Stock-Series C-3, Series E and Series G		Accumulated Other Comprehensive	Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Income	Capital	Deficit	Equity
Balance at December 31, 2023	54,938,258	$ 54,938	181,622	$ 182	$ 94,108	$ 391,693,214	$ (321,700,013)	$ 70,142,429
Issuance of vested restricted stock, net of shares withheld for employee withholding taxes	42,844	43	-	-	-	(97,161)	-	(97,118)
Cancellation of shares held in escrow	(21,832)	(22)	-	-	-	22	-	-
Stock-based compensation	-	-	-	-	-	2,444,179	-	2,444,179
Other comprehensive loss	-	-	-	-	(10,647)	-	-	(10,647)
Net loss	-	-	-	-	-	-	(14,466,123)	(14,466,123)
Balance at March 31, 2024	**54,959,270**	**$ 54,959**	**181,622**	**$ 182**	**$ 83,461**	**$ 394,040,254**	**$ (336,166,136)**	**$ 58,012,720**

	Common Stock		Preferred Stock-Series C-3, Series E and Series G		Accumulated Other Comprehensive	Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Income	Capital	Deficit	Equity
Balance at March 31, 2024	54,959,270	$ 54,959	181,622	$ 182	$ 83,461	$ 394,040,254	$ (336,166,136)	$ 58,012,720
Stock issued in connection with ATM sale of common stock, net	231,097	231	-	-	-	1,009,369	-	1,009,600
Stock issued in connection with options exercised	49,165	49	-	-	-	186,433	-	186,482
Issuance of vested restricted stock, net of shares withheld for employee withholding taxes	35,259	35				(139,532)		(139,497)
Stock-based compensation	-	-	-	-	-	1,263,845	-	1,263,845
Other comprehensive gain	-	-	-	-	2,270	-	-	2,270
Net loss	-	-	-	-	-	-	(14,151,489)	(14,151,489)
Balance at June 30, 2024	**55,274,791**	**$ 55,274**	**181,622**	**$ 182**	**$ 85,731**	**$ 396,360,369**	**$ (350,317,625)**	**$ 46,183,931**

For the three six months ended March 31, 2023 June 30, 2024

	Common Stock		Preferred Stock-Series C-3, Series E and Series G		Accumulated Other Comprehensive	Additional Paid-in	Accumulated	Total Stockholders'	Common Stock		Preferred Stock-Series C-3, Series E and Series G		Ac Co
	Shares	Amount	Shares	Amount	Income	Capital	Deficit	Equity	Shares	Amount	Shares	Amount	
Balance at December 31, 2022	42,815,196	$ 42,815	181,622	$ 182	$ 82,743	$ 330,294,782	$ (275,360,786)	$ 55,059,736					
Balance at January 1, 2024									54,938,258	$ 54,938	181,622	$ 182	$
Stock issued in connection with ATM sale of common stock, net	1,684,592	1,685	-	-	-	7,198,721	-	7,200,406	231,097	231	-	-	
Stock issued in connection with options exercised									49,165	49	-	-	

Issuance of vested restricted stock, net of shares withheld for employee withholding taxes									78,103	78			
Cancellation of shares held in escrow									(21,832)	(22)			
Stock-based compensation	-	-	-	-	-	2,216,349	-	2,216,349	-	-	-	-	
Other comprehensive gain	-	-	-	-	18,489	-	-	18,489					
Other comprehensive loss									-	-	-	-	
Net loss	-	-	-	-	-	-	(10,567,226)	(10,567,226)	-	-	-	-	
Balance at March 31, 2023	**44,499,788**	**$ 44,500**	**181,622**	**$ 182**	**$ 101,232**	**$ 339,709,852**	**$ (285,928,012)**	**$ 53,927,754**					
Balance at June 30, 2024									**55,274,791**	**$ 55,274**	**181,622**	**$ 182**	**$**

See Accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

CORMEDIX INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(Unaudited)

For the three months ended June 30, 2023

	Common Stock		Preferred Stock – Series C-3, Series E and Series G		Accumulated Other Comprehensive	Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Income (Loss)	Capital	Deficit	Equity
Balance at March 31, 2023	44,499,788	$ 44,500	181,622	$ 182	$ 101,232	$ 339,709,852	$ (285,928,012)	$ 53,927,754
Stock issued in connection with ATM sale of common stock, net	1,181,829	1,182	-	-	-	5,313,621	-	5,314,803
Stock issued in connection with options exercised	57,375	57	-	-	-	233,799	-	233,856
Issuance of vested restricted stock, net of shares withheld for employee withholding taxes	66,291	67	-	-	-	(198,509)	-	(198,442)
Stock-based compensation	-	-	-	-	-	1,057,291	-	1,057,291
Other comprehensive loss	-	-	-	-	(10,535)	-	-	(10,535)
Net loss	-	-	-	-	-	-	(11,273,618)	(11,273,618)
Balance at June 30, 2023	**45,805,283**	**$ 45,806**	**181,622**	**$ 182**	**$ 90,697**	**$ 346,116,054**	**$ (297,201,630)**	**$ 49,051,109**

For the six months ended June 30, 2023

	Common Stock		Preferred Stock – Series C-3, Series E and Series G		Accumulated Other Comprehensive	Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Income (Loss)	Capital	Deficit	Equity
Balance at January 1, 2023	42,815,196	$ 42,815	181,622	$ 182	$ 82,743	$ 330,294,782	$ (275,360,786)	$ 55,059,736
Stock issued in connection with ATM sale of common stock, net	2,866,421	2,867	-	-	-	12,512,342	-	12,515,209
Stock issued in connection with options exercised	57,375	57	-	-	-	233,799	-	233,856
Issuance of vested restricted stock, net of shares withheld for employee withholding taxes	66,291	67	-	-	-	(198,509)	-	(198,442)
Stock-based compensation	-	-	-	-	-	3,273,640	-	3,273,640
Other comprehensive gain	-	-	-	-	7,954	-	-	7,954
Net loss	-	-	-	-	-	-	(21,840,844)	(21,840,844)
Balance at June 30, 2023	**45,805,283**	**$ 45,806**	**181,622**	**$ 182**	**$ 90,697**	**$ 346,116,054**	**$ (297,201,630)**	**$ 49,051,109**

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

	For the Three Months Ended March 31,		For the Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
CASH FLOWS FROM OPERATING ACTIVITIES:				
Net loss	$ (14,466,123)	$ (10,567,226)	$ (28,617,612)	$ (21,840,844)
Adjustments to reconcile net loss to net cash used in operating activities:				
Stock-based compensation	2,444,179	2,216,349	3,708,024	3,273,640
Change in right-of-use assets	35,644	32,582	72,110	65,901
Depreciation	21,826	16,863	46,750	34,292
Amortization of intangible			51,948	-
Changes in operating assets and liabilities:				
Increase in trade receivables			(206,337)	-
Increase in inventory	(214,051)	-	(1,905,215)	-
Increase in prepaid expenses and other current assets	(1,226,454)	(419,578)	(2,130,587)	(1,502,179)
Decrease in accounts payable	(1,453,352)	(755,582)		
Decrease in accrued expenses	(2,415,719)	(884,872)		
(Decrease) Increase in accounts payable			(934,870)	698,353
(Decrease) Increase in accrued expenses			(1,361,111)	370,099
Decrease in operating lease liabilities	(36,244)	(32,422)	(73,310)	(65,578)
Net cash used in operating activities	(17,310,294)	(10,393,886)	(31,350,210)	(18,966,316)
CASH FLOWS FROM INVESTING ACTIVITIES:				
Purchase of short-term investments	(7,693,762)	(25,422,039)	(19,806,594)	(42,901,487)
Maturity of short-term investments	16,700,000	10,750,000	35,116,192	25,850,000
Purchase of equipment	(61,306)	(14,766)	(96,095)	(21,124)
Net cash provided by (used in) investing activities	8,944,932	(14,686,805)	15,213,503	(17,072,611)
CASH FLOWS FROM FINANCING ACTIVITIES:				
Proceeds from sale of common stock from at-the-market program, net			1,009,600	12,515,209
Payment of employee withholding taxes on vested restricted stock units	(97,118)	-	(236,615)	(198,442)
Proceeds from sale of common stock from at-the-market program, net	-	7,200,406		
Net cash (used in) provided by financing activities	(97,118)	7,200,406		
Proceeds from exercise of stock options			186,482	233,856
Net cash provided by financing activities			959,467	12,550,623
Foreign exchange effect on cash	(893)	2,531		
NET DECREASE IN CASH AND CASH EQUIVALENTS	(8,463,285)	(17,878,001)	(15,178,133)	(23,485,773)
CASH, CASH EQUIVALENTS AND RESTRICTED CASH - BEGINNING OF PERIOD	43,823,192	43,374,745	43,823,192	43,374,745
CASH, CASH EQUIVALENTS AND RESTRICTED CASH - END OF PERIOD	$ 35,359,907	$ 25,496,744	$ 28,645,059	$ 19,888,972
Cash paid for interest	$ 9,835	$ 8,776	$ 16,391	$ 14,627
Supplemental Disclosure of Non-Cash Investing Activities:				
Liability related to license agreement	$ 2,000,000	-	$ 2,000,000	-
Unrealized gain (loss) from investments	$ 10,903	$ (16,393)		
Unrealized (loss) gain from investments			$ (8,872)	$ 5,661

See Accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

Note 1 - Organization, Business and Basis of Presentation:

Organization and Business

CorMedix Inc. ("CorMedix" or the "Company") was incorporated in the State of Delaware on July 28, 2006. The Company is a biopharmaceutical company focused on developing and commercializing therapeutic products for life-threatening diseases and conditions.

The Company's primary focus is on the commercialization of its lead product, DefenCath® in the United States, or U.S. The Company has in-licensed the worldwide rights to develop and commercialize DefenCath. The name DefenCath is the U.S. proprietary name approved by the U.S. Food and Drug Administration, or FDA.

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, or GAAP, for interim financial information and with the instructions for Quarterly Reports on 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 to fairly state the interim results. Interim operating results are not necessarily indicative of results that may be expected for the full year ending December 31, 2024 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, or SEC, on March 12, 2024. The accompanying consolidated balance sheet as of December 31, 2023 has been derived from the audited financial statements included in such Annual Report on Form 10-K.

Note 2 - Summary of Significant Accounting Policies and Liquidity and Uncertainties:

Liquidity and Uncertainties

The condensed consolidated financial statements have been prepared in conformity with GAAP which contemplate continuation of the Company as a going concern. To date, the Company's commercial operations have not generated sufficient revenues to enable profitability. Based on the Company's current commercial plans and development plans for DefenCath and its other operating requirements, the Company's existing cash, cash equivalents and short-term investments at March 31, 2024 June 30, 2024 are expected to fund its operations for at least twelve months from the issuance of this Quarterly Report on Form 10-Q.

In March 2024, the Company received $1,395,000, net of expenses, from the sale of its unused New Jersey net operating losses ("NOL"), that was eligible for sale under the State of New Jersey's Economic Development Authority's New Jersey Technology Business Tax Certificate Transfer program ("NJEDA Program"). The NJEDA Program allowed the Company to sell its available NOL tax benefits for the state fiscal year 2023 in the amount of approximately $1,529,000.

The Company may raise additional capital through various potential sources, such as equity and/or debt financings, strategic relationships, potential strategic transactions and/or out-licensing. Management can provide no assurances that such financing or strategic relationships will be available on acceptable terms, or at all. As of March 31, 2024 June 30, 2024, approximately $48,800,000 of the Company has $104,400,000 Company's common stock remains available for sale under its current shelf registration the 2024 ATM program, with $100,000,000 of remaining capacity under the 2024 Shelf Registration Statement for the issuance of equity, debt or equity-linked Company securities (see Note 5) 6).

The Company's operations are subject to a number of other factors that can affect its operating results and cash flow projections over the next twelve months from the issuance of these financial statements. Such factors include, but are not limited to: the ability to market DefenCath and generate necessary revenue in the time periods required; ability to manufacture successfully; competition from products manufactured and sold or being developed by other companies; the price of, and demand for, Company products; the Company's ability to negotiate favorable licensing or other manufacturing and marketing agreements for its products; and the Company's ability to raise capital to support its operations.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. The Company bases its estimates and judgments on historical experience and various other assumptions that it believes are reasonable under the circumstances. The amounts of assets and liabilities and disclosure of contingent assets and liabilities in the Company's consolidated balance sheets and the reported amounts of revenue and expenses reported for each of the periods presented are affected by estimates and assumptions. As future events and their effects cannot be determined with precision, actual results could differ significantly from those estimates.

Reclassifications

Certain reclassifications were made to the prior year's amounts to conform to the 2024 presentation.

Basis of Consolidation

The condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation.

Trade Accounts Receivable and Allowances

The Company complies with ASU 2016-13, *Measurement of Credit Losses on Financial Instruments*, which requires the Company to recognize an allowance that reflects a current estimate of credit losses expected to be incurred over the life of a financial asset, including trade receivables. The Company continuously monitors collections and payments from its customers and maintains a provision for estimated credit losses. The Company determines its allowance for credit losses by considering a number of factors, including the length of time balances are past due, the customer's current ability to pay its obligations to the Company and the expected condition of the general economy and the industry as a whole. The Company writes off accounts receivable when they are determined to be uncollectible. There was no allowance for credit losses as of June 30, 2024.

Major Customers

The major customers of the Company are defined as those constituting greater than 10% of its total revenue. In the three and six months ended June 30, 2024, the Company had sales to one customer that accounted for 100% of its total revenue of $806,119. This customer also accounts for 100% of the Company's accounts receivable as of June 30, 2024.

Financial Instruments

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

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

			June 30,	
	March 31, 2024	**March 31, 2023**	**2024**	**2023**
Cash and cash equivalents	$ 35,180,529	$ 25,268,225	$ 28,540,633	$ 19,699,565
Restricted cash	179,378	228,519	104,426	189,407
Total cash, cash equivalents and restricted cash	$ 35,359,907	$ 25,496,744	$ 28,645,059	$ 19,888,972

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 classified as available-for-sale and equity securities 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 other comprehensive income. Realized gains and losses, amortization of premiums and discounts and interest and dividends earned are included in other income (expense). The Company considers available evidence in evaluating potential impairments of its investments, including the duration and extent to which fair value is less than cost. There were no deemed permanent impairments at March 31, 2024 June 30, 2024 or December 31, 2023.

The Company's marketable securities are highly liquid and consist of U.S. government agency securities, high-grade corporate obligations and commercial paper with original maturities of more than 90 days. As of March 31, 2024 June 30, 2024 and December 31, 2023, all of the Company's investments had contractual maturities of less than one year. The following table summarizes the amortized cost, unrealized gains and losses and the fair value at March 31, 2024 June 30, 2024 and December 31, 2023:

	Amortized Cost	Gross Unrealized Losses	Gross Unrealized Gains	Fair Value	Amortized Cost	Gross Unrealized Losses	Gross Unrealized Gains	Fair Value
March 31, 2024:								
June 30, 2024:								
Money Market Funds included in Cash Equivalents	$ 28,343,324	$ -	$ -	$ 28,343,324	$ 21,230,822	$ -	$ 22	$ 21,230,844
U.S. Government Agency Securities	20,690,147	(480)	315	20,689,982	15,898,364	(320)	524	15,898,568
Commercial Paper	2,682,664	(1,657)	-	2,681,007	1,171,108	(46)	30	1,171,092
Subtotal	23,372,811	(2,137)	315	23,370,989	17,069,472	(366)	554	17,069,660
Total March 31, 2024	$ 51,716,135	$ (2,137)	$ 315	$ 51,714,313				
Total June 30, 2024					$ 38,300,294	$ (366)	$ 576	$ 38,300,504
December 31, 2023:								
Money Market Funds included in Cash Equivalents	$ 32,541,230	$ -	$ -	$ 32,541,230	$ 32,541,230	$ -	$ -	$ 32,541,230
U.S. Government Agency Securities	29,701,677	-	10,506	29,712,183	29,701,677	-	10,506	29,712,183
Commercial Paper	2,677,372	(1,425)	-	2,675,947	2,677,372	(1,425)	-	2,675,947
Subtotal	32,379,049	(1,425)	10,506	32,388,130	32,379,049	(1,425)	10,506	32,388,130
Total December 31, 2023	$ 64,920,279	$ (1,425)	$ 10,506	$ 64,929,360	$ 64,920,279	$ (1,425)	$ 10,506	$ 64,929,360

Fair Value Measurements

In accordance with Accounting Standards Codification ("ASC") 825, *Financial Instruments*, disclosures of fair value information about financial instruments is required, whether or not recognized in the consolidated balance sheet, for which it is practicable to estimate that value. 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 reoccurring basis as of March 31, 2024 June 30, 2024 and December 31, 2023:

	Carrying Value	Level 1	Level 2	Level 3	Carrying Value	Level 1	Level 2	Level 3
March 31, 2024:								
June 30, 2024:								
Money Market Funds and Cash Equivalents	$ 28,343,324	$ 28,343,324	$ -	$ -	$ 21,230,844	$ 21,230,844	$ -	$ -
U.S. Government Agency Securities	20,689,982	20,689,982	-	-	15,898,568	15,898,568	-	-
Commercial Paper	2,681,007	-	2,681,007	-	1,171,092	-	1,171,092	-
Subtotal	23,370,989	20,689,982	2,681,007	$ -	17,069,660	15,898,568	1,171,092	$ -
Total March 31, 2024	$ 51,714,313	$ 49,033,306	$ 2,681,007	$ -				
Total June 30, 2024					$ 38,300,504	$ 37,129,412	$ 1,171,092	$ -
December 31, 2023:								
Money Market Funds and Cash Equivalents	$ 32,541,230	$ 32,541,230	$ -	$ -	$ 32,541,230	$ 32,541,230	$ -	$ -
U.S. Government Agency Securities	29,712,183	29,712,183	-	-	29,712,183	29,712,183	-	-
Commercial Paper	2,675,947	-	2,675,947	-	2,675,947	-	2,675,947	-
Subtotal	32,388,130	29,712,183	2,675,947	-	32,388,130	29,712,183	2,675,947	-
Total December 31, 2023	$ 64,929,360	$ 62,253,413	$ 2,675,947	$ -	$ 64,929,360	$ 62,253,413	$ 2,675,947	$ -

Inventories

The Company engages third parties to manufacture and package inventory held for sale and warehouse such goods until packaged for final distribution and sale. Costs related to the manufacturing of DefenCath incurred prior to FDA approval in order to support the preparation for commercial launch of its product were expensed as research and development expenses ("R&D") as incurred. Upon FDA approval, costs related to the manufacturing of inventory are stated at the lower of cost or net realizable value with cost determined on a first-in, first-out basis. Inventories expensed as R&D prior to FDA approval that can be used for commercial purposes amounted to approximately $6,388,000. $6,359,000.

Inventory is valued utilizing the standard cost method, which approximates costs determined on the first-in first-out basis. The Company records an inventory reserve for losses associated with dated, expired, excess or obsolete items. This reserve is based on management's current knowledge with respect to inventory levels, planned production and sales volume assumptions. As of March 31, 2024 June 30, 2024 and December 31, 2023, no reserves were deemed necessary.

Inventories consist of raw materials (including labeling and packaging), work-in-process, and finished goods for DefenCath. Inventories consist of the following:

	March 31, 2024	December 31, 2023	June 30, 2024	December 31, 2023
Raw materials	$ 1,424,409	$ 1,525,420	$ 919,801	$ 1,525,420
Work in progress	471,415	580,925	2,014,921	580,925
Finished goods	424,572	-	1,076,838	-
Total	$ 2,320,396	$ 2,106,345	$ 4,011,560	$ 2,106,345

Revenue Recognition

The Company recognizes revenue from the sale of its product, DefenCath, in accordance with ASC 606, *Revenue from Contracts with Customers* (ASC 606). The provisions of ASC 606 require the following steps to determine revenue recognition: (1) identify the contract(s) with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when (or as) the entity satisfies a performance obligation.

The Company recognizes revenue when it believes that it is probable that it will collect the consideration to which it is entitled in exchange for the goods or services that will be transferred to the customer. The Company's product revenue is recognized at a point in time when the performance obligation is satisfied by transferring control of the promised goods or services to a customer. In accordance with the Company's contracts with customers, control of the product is transferred upon the conveyance of title, which occurs when the product is received by a customer. The Company's customers are located in the United States and consist primarily of wholesale distributors and outpatient service providers.

Variable Consideration

The Company includes an estimate of variable consideration in its transaction price at the time of sale when control of the product transfers to the customer. Variable consideration includes:

- Distribution service fees;
- Prompt pay and other discounts;
- Product returns;
- Chargebacks;
- Rebates;
- Volume incentive rebates;

The Company assesses whether or not an estimate of variable consideration is constrained based on the probability that a significant reversal in the amount of cumulative revenue may occur in the future when the uncertainty associated with the variable consideration is subsequently resolved. Actual amounts of consideration ultimately received may vary from our estimates. If actual results in the future vary from estimates, the Company adjusts these estimates, which would affect product sales and earnings in the period such variances become known.

The specific considerations that the Company uses in estimating these amounts related to variable considerations are as follows:

Distribution services fees – The Company pays distribution service fees primarily to its wholesale distributors. The Company reserves these fees based on actual net sales and the contractual fee rates negotiated with the customers in the distribution channel. The Company records these fees as contra accounts receivable on the balance sheet.

Prompt pay and other discounts – The Company provides customers with prompt pay discounts. The specific prompt pay terms vary by customer and are contractually fixed. Prompt pay discounts are expected to be taken by the Company's customers, so an estimate of the discount is recorded at the time of sale based on the invoice price. Prompt pay discount estimates are recorded as contra accounts receivable on the balance sheet.

Product returns – Customers have the right to return product that is within six months or less of the labeled expiration date or that is past the expiration date by no more than six months. The Company determines its estimate for product returns based on: (i) data provided to the Company by its distributors (including weekly reporting of distributors' sales and inventory held by distributors that provided the Company with visibility into the distribution channel in order to determine what quantities were sold to both inpatient and outpatient facilities), and (ii) the estimated remaining shelf life of DefenCath held by the wholesale distributors and outpatient service providers. Since the returns primarily consist of expired and short dated products that will not be resold, the Company does not record a return asset for the right to recover the goods returned by the customer at the time of the initial sale (when recognition of revenue is deferred due to the anticipated return). Estimated product returns are recorded as accrued expenses on the balance sheet.

Chargebacks – Certain covered entities, group purchasing organizations (GPO) and government entities will be able to purchase the product at a price discounted below WAC. The difference between the GPO, government or covered entity purchase price and the wholesale distributor purchase price of WAC will be charged back to the Company. The Company estimates the amount in chargebacks based on the expected number of claims and related cost that is associated with the revenue being recognized for product that remains in the distribution channel at the end of each reporting period. Estimated chargebacks are recorded as contra accounts receivable on the balance sheet.

Rebates – The Company is subject to negotiated discount obligations to different prescription benefit managers (PBM), other commercial organizations or government programs. The rebate amounts for these programs are determined by statutory requirements or contractual arrangements. Rebates are owed after the product has been dispensed to an end user and the Company has been invoiced. Rebates are typically invoiced in arrears. The Company's liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter based on expected product utilization, and estimated future claims that will be made for product that has been recognized as revenue, but remains in the distribution channel at the end of each reporting period. Rebate estimates are recorded as accrued expenses on the balance sheet.

Volume Incentive Rebates – The Company is subject to negotiated volume incentive rebates with certain direct customers (primarily outpatient service providers). Rebates are owed based on predetermined volume levels and payable per the terms in the customer contracts. The Company estimates and records volume incentive rebates based on anticipated purchase volume with specific customers based on communications with the customer. Volume incentive rebates are recorded as accrued expenses on the balance sheet.

Provisions for the revenue reserves described above totaled $194,000 for the three and six months ended June 30, 2024. As of June 30, 2024, reserves on the balance sheet associated with variable consideration were $194,000.

License Agreement

The Company's rights under the License and Assignment Agreement with ND Partners, LLP are capitalized and stated at cost and will amortize using the straight-line method over estimated economic life of the intangible asset. The Company will amortize the intangible asset over its useful life, based on its assessment of various factors impacting estimated useful lives and cash flows of the acquired rights. Such factors include the launch date of DefenCath, the strength of the intellectual property protection of DefenCath and various other competitive, developmental and regulatory considerations, and contractual terms. See Note 45 – Commitments and Contingencies for further discussion.

Leases

The Company determines if an arrangement is a lease at inception. Operating leases are included in operating lease right-of-use ("ROU") assets, current portion of operating lease liabilities, (included in accrued expenses), and operating lease liabilities, net of current portion, on the consolidated balance sheet (see Note 6) 7).

Operating lease ROU assets and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. As the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at commencement date in determining the present value of future payments. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term.

The Company has elected, as an accounting policy, not to apply the recognition requirements in ASC 842 to short-term leases. Short-term leases are leases that have a term of 12 months or less and do not include an option to purchase the underlying asset that the Company is reasonably certain to exercise. The Company recognizes the lease payments for short-term leases on a straight-line basis over the lease term.

The Company has also elected, as a practical expedient, by underlying class of asset, not to separate lease components from non-lease components and, instead, account for them as a single component.

Loss Per Common Share

Basic loss per common share excludes dilution and is computed by dividing net loss by the weighted average number of common shares outstanding during the period. The weighted average number of common shares outstanding during the period included 2,500,625 shares underlying outstanding pre-funded warrants. 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 Company.

The Company's outstanding shares of Series E preferred stock entitle the holders to receive dividends on a basis equivalent to the dividends paid to holders of common stock. As a result, the Series E preferred stock meet the definition of participating securities requiring the application of the two-class method. Under the two-class method, earnings available to common shareholders, including both distributed and undistributed earnings, are allocated to each class of common stock and participating securities according to dividends declared and participating rights in undistributed earnings, which may cause diluted earnings per share to be more dilutive than the calculation using the treasury stock method. No loss has been allocated to these participating securities since they do not have contractual obligations that require participation in the Company's losses.

Since the Company has only incurred losses, potentially dilutive securities are excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive, and therefore basic and diluted loss per share are the same for all periods presented. The shares outstanding at the end of the respective periods presented below were excluded from the calculation of diluted net loss per share due to their anti-dilutive effect:

	Three Months Ended March 31,		Six Months Ended June 30,	
	2024	2023	2024	2023
	(Number of Shares of Common Stock Issuable)		(Number of Shares of Common Stock Issuable)	
Series C-3 non-voting preferred stock	4,000	4,000	4,000	4,000
Series E non-voting preferred stock	391,953	391,953	391,953	391,953
Series G non-voting preferred stock	5,004,069	5,004,069	5,004,069	5,004,069
Shares issuable for payment of deferred board compensation	48,909	48,909	48,909	48,909
Shares underlying outstanding stock options	7,996,361	6,126,080	8,048,134	5,929,143
Shares underlying restricted stock units	366,235	207,469	303,994	103,735
Total potentially dilutive shares	13,811,527	11,782,480	13,801,059	11,481,809

Stock-Based Compensation

Share-based Stock-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 requisite service period on a straight-line basis or when the achievement of the performance condition is probable.

Research and Development

Research and development costs are charged to expense as incurred. Research and development include 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.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies that the Company adopts as of the specified effective date. Unless otherwise discussed below, the Company does not believe the adoption of recently issued standards have or may have a material impact on its consolidated financial statements or disclosures.

ASU No. 2023-09

In December 2023, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2023-09, *Income Taxes - Improvements to Income Tax Disclosures* (Topic 740). The standard requires disaggregation of the effective rate reconciliation into standard categories, enhances disclosure of income taxes paid, and modifies other income tax-related disclosures. The standard will be effective for CorMedix beginning in annual reporting period ending December 31, 2025, with early adoption permitted. CorMedix is currently assessing the impact of adopting this guidance on its consolidated financial statements.

ASU No. 2023-07

In November 2023, the FASB issued ASU No. 2023-07 *Segment Reporting - Improving Reportable Segment Disclosures* (Topic 280). The standard requires disclosures to include significant segment expenses that are regularly provided to the chief operating decision maker (CODM), a description of other segment items by reportable segment, and any additional measures of a segment's profit or loss used by the CODM when deciding how to allocate resources. The ASU also requires all annual disclosures currently required by Topic 280 to be included in interim periods. The standard is effective for CorMedix beginning in annual reporting period ending December 31, 2024 and interim periods beginning in fiscal year 2025, with early adoption permitted and requires retrospective application to all prior periods presented in the financial statements. CorMedix is currently assessing the impact of adopting this guidance on its consolidated financial statements.

Note 3 – Other Prepaid Expenses and Current Assets:

Other Prepaid Expenses and Current Assets

Other prepaid expenses and current assets consist of the following:

	June 30, 2024	December 31, 2023
Manufacturing	$ 994,481	$ -
Commercial	595,484	171,393
Vendor settlement receivable	500,000	-
Subscriptions	471,325	466,114
Medical affairs	259,145	-
Insurance	107,078	126,616
Other	211,509	118,091
Total	$ 3,139,022	$ 882,214

Note 4 - Accrued Expenses:

Accrued Expenses

Accrued expenses consist of the following:

	March 31, 2024	December 31, 2023	June 30, 2024	December 31, 2023
Professional and consulting fees	$ 1,340,502	$ 2,270,022	$ 1,192,682	$ 2,270,022
Accrued payroll and payroll taxes	2,636,726	2,718,770	3,438,384	2,718,770
License agreement payable (see Note 4 – Commitments and Contingencies)	2,000,000	-		
License agreement payable (see Note 5 – Commitments and Contingencies)			2,000,000	-
Manufacturing related	349,421	1,835,101	389,993	1,835,101
Accrued gross-to-net deductions			150,188	-
Other	226,662	146,324	436,290	146,324
Total	$ 6,553,311	$ 6,970,217	$ 7,607,537	$ 6,970,217

Note 4 5 - Commitments and Contingencies:

Contingency Matters

In re CorMedix Inc. Securities Litigation, *Case No. 2:21-cv-14020 (D.N.J.)*

On October 13, 2021, the United States District Court for the District of New Jersey consolidated into In re CorMedix Inc. Securities Litigation, Case No. 2:21-cv 14020-JXN-CLW, two putative class action lawsuits filed on or about July 22, 2021 and September 13, 2021, respectively, and appointed lead counsel and lead plaintiff, a purported stockholder of the Company. The lead plaintiff filed a consolidated amended class action complaint on December 14, 2021, alleging violations of Sections 10(b) and 20(a) of the Exchange Act, along with Rule 10b-5 promulgated thereunder, and Sections 11 and 15 of the Securities Act of 1933. On October 10, 2022, the lead plaintiff filed a second amended consolidated complaint that superseded the original complaints in In re CorMedix Securities Litigation. On March 21, 2024, the court denied Defendant's motion to dismiss without prejudice and granted lead plaintiff leave to amend the complaint. On April 22, 2024, lead plaintiff filed a third amended consolidated complaint that superseded the second amended consolidated complaint. In the third amended complaint, the lead plaintiff seeks to represent a class of shareholders who purchased or otherwise acquired CorMedix securities between October 16, 2019 and August 8, 2022, inclusive. The third amended complaint names as defendants the Company and six (6) current and former officers of CorMedix, namely Khoso Baluch, Robert Cook, Matthew David, Phoebe Mounts, John L. Armstrong, and Joseph Todisco (the "Officer Defendants" and collectively with CorMedix, the "CorMedix Defendants"). The third amended complaint alleges that the CorMedix Defendants violated Section 10(b) of the Exchange Act (and Rule 10b-5) and that the Officer Defendants violated Section 20(a). In general, the purported bases for these claims are allegedly false and misleading statements and omissions related to the NDA submissions to the FDA for DefenCath, subsequent complete response letters, as well as communications from the FDA related and directed to the Company's contract manufacturing organization and heparin supplier. The Company intends to vigorously contest such claims. Defendants' The Company filed its motion to dismiss the third amended complaint is due on or before June 6, 2024. Lead plaintiff's, and received from Plaintiffs their opposition is due to the Company's motion to dismiss on or before July 22, 2024. Defendants' reply is due The Company will be filing its response on or before August 21, 2024.

In re CorMedix Inc. Derivative Litigation, *Case No. 2:21-cv-18493-JXN-LDW (D.N.J.)*

On or about October 13, 2021, a purported shareholder, derivatively and on behalf of the Company, filed a shareholder derivative complaint in the United States District Court for the District of New Jersey, in a case entitled Voter v. Baluch, et al., Case No. 2:21-cv-18493-JXN-LDW (the "Derivative Litigation"). The complaint names as defendants Khoso Baluch, Janet Dillione, Alan W. Dunton, Myron Kaplan, Steven Lefkowitz, Paulo F. Costa, Greg Duncan, Matthew David, Phoebe Mounts and Joseph Todisco along with the Company as Nominal Defendant. The complaint alleges breaches of fiduciary duties, abuse of control, and waste of corporate assets against the defendants and a claim for contribution for purported violations of Sections 10(b) and 21D of the Exchange Act against certain defendants. The individual defendants intend to vigorously contest such claims. On January 21, 2022, pursuant to a stipulation between the parties, the Court entered an order staying the case while the motion to dismiss the class action lawsuit described in the foregoing paragraph is pending. The stay may be terminated before the motion to dismiss is resolved according to certain circumstances described in the stipulation available on the Court's public docket.

On or about January 13, 2023, another purported shareholder, derivatively and on behalf of the Company, filed a shareholder derivative complaint in the United States District Court for the District of New Jersey, in a case entitled *DeSalvo v. Costa, et al.*, Case No. 2:23-cv-00150-JXN-CLW. Defendants Paulo F. Costa, Janet D. Dillione, Greg Duncan, Alan Dunton, Myron Kaplan, Steven Lefkowitz, Joseph Todisco, Khoso Baluch, Robert Cook, Matthew David, Phoebe Mounts, and John L. Armstrong along with the Company as Nominal Defendant. The complaint alleges breaches of fiduciary duty and unjust enrichment against the individual defendants.

On or about January 25, 2023, another purported shareholder, derivatively and on behalf of the Company, filed a shareholder derivative complaint in the United States District Court for the District of New Jersey, in a case entitled *Scullion v. Baluch, et al.*, Case No. 2:23-cv-00406-ES-ESK. Defendants Khoso Baluch, Janet Dillione, Alan W. Dunton, Myron Kaplan, Steven Lefkowitz, Paulo F. Costa, Gregory Duncan, Matthew David, and Phoebe Mounts, along with the Company as Nominal Defendant. The complaint alleges breaches of fiduciary duties.

On or about April 18, 2023, the Court entered an order consolidating the above-mentioned shareholder derivative complaints for all purposes, including pretrial proceedings, trial and appeal. The consolidated derivative action is entitled, *In re CorMedix Inc. Derivative Litigation*, C.A. No. 2:21-cv-18493-JXN-LDW. The individual defendants intend to vigorously contest the claims set forth in the consolidated derivative action. The provisions of the Order to Stay entered in the *Voter* Action on January 21, 2022, apply to the consolidated derivative action. On April 20, 2023, the consolidated derivative action was administratively terminated and removed from the Court's docket until the motion to dismiss the class action is resolved and the Private Securities Litigation Reform Act, or PSLRA, stay is lifted. As noted above, on On April 22, 2024, the lead plaintiff in the class action filed a third amended complaint. The class action remains stayed under the PSLRA.

Demand Letter

On or about June 23, 2022, the Company's Board received a letter demanding it investigate and pursue causes of action, purportedly on behalf of Company, against certain current and former directors, officers, and/or other employees of the Company (the "Letter"), which the Board believes are duplicative of the claims already asserted in the Derivative Litigation. As set forth in the Board's response to the Letter, the Board will consider the Letter at an appropriate time, as circumstances warrant, as it continues to monitor the progress of the Derivative Litigation.

License and Assignment Agreement

In 2008, the Company entered into a License and Assignment Agreement (the "ND License Agreement") with ND Partners, LLP ("NDP"). Pursuant to the ND 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"). As consideration in part for the rights to the NDP Technology, upon execution of the ND License Agreement, the Company paid NDP an initial licensing fee of $325,000 and granted NDP a 5% equity interest in the Company, consisting of 7,996 shares of the Company's common stock.

Under the ND License Agreement, the Company is required to make cash and equity payments to NDP upon the achievement of certain milestones. In 2014, a certain milestone was achieved resulting in the release of 7,277 shares held in escrow. As of December 31, 2022, the shares remaining in escrow were cancelled in accordance with the terms of the escrow agreement. Under the ND License Agreement, the maximum aggregate amount of cash payments due upon achievement of milestones was $3,000,000, with the balance being $2,000,000 as of March 31, 2024 June 30, 2024 and December 31, 2023. The initial licensing fee of $325,000, the fair value of the 5% equity interest (7,996 shares of the Company's common stock) and an additional $500,000, as a result of the achievement of one milestone, were recognized on the Company's statement of operations in R&D in prior periods, as the related milestones were achieved by the Company prior to the FDA approval. During the three six months ended March 31, 2024 June 30, 2024, the Company determined it was probable that the net sales milestones will be achieved in future periods and, as a result, the Company recorded a license intangible asset of $2,000,000 and a license agreement liability of $2,000,000, which is included within accrued expenses in the Company's condensed consolidated balance sheet as of March 31, 2024 June 30, 2024.

The Beginning in the second quarter of 2024, the license intangible asset will be is amortized as cost of goods sold over its estimated economic life beginning in the second quarter of 2024, correlating approximately 10 years. The amortization start period correlates with the product launch of DefenCath and the first period in which revenue will be recognized. Amortization expense of approximately $52,000 was recorded during the three and six month periods ending June 30, 2024.

The ND License Agreement will expire on a country-by-country basis upon the earlier of (i) the expiration of the last patent claim under the ND License Agreement in a given country, or (ii) the payment of all milestone payments. Upon the expiration of the ND License Agreement in each country, we will have an irrevocable, perpetual, fully paid-up, royalty-free exclusive license to the NDP Technology in such country. The ND License Agreement also may be terminated by NDP if the Company materially breaches or defaults under the ND License Agreement and that breach is not cured within 60 days following the delivery of written notice to the Company, or by the Company on a country-by-country basis upon 60 days prior written notice in the event the Company's Board determines not to proceed with the development of the NDP Technology. If the ND License Agreement is terminated by either party, the Company's rights to the NDP Technology will revert back to NDP.

Note 5 6 - Stockholders' Equity:

Common Stock

On August 12, 2021, the Company filed a shelf registration statement (the "2021 Shelf Registration Statement") for the issuance of up to $150,000,000. As of March 31, 2024, the Company has $104,000,000 available under the 2021 Shelf Registration Statement.

On June 28, 2023, the Company entered into an underwriting agreement (the "Underwriting Agreement") with RBC Capital Markets, LLC and Truist Securities, Inc., as representatives of the several underwriters named therein, relating to the issuance and sale of an aggregate of 7,500,000 shares of the Company's common stock, and in lieu of common stock to certain investors, pre-funded warrants to purchase 2,500,625 shares of common stock to the underwriters. Pursuant to the Underwriting Agreement, the Company also granted the underwriters a 30-day option to purchase up to 1,500,093 additional shares of common stock.

The offering pursuant to the 2021 Shelf Registration Statement closed on July 3, 2023. Upon closing, the Company issued and sold an aggregate of 7,500,000 shares of its common stock at a public offering price of $4.00 per share and, in lieu of common stock to certain investors, pre-funded warrants to purchase up to an aggregate of 2,500,625 shares of its commons stock at a price of $3.999 per pre-funded warrant (see Pre-Funded Warrants below). The Company realized net proceeds of approximately $37,300,000 from the sale of its common stock and the pre-funded warrants. On July 26, 2023, the underwriters' representatives fully exercised the option to purchase additional shares of the Company's common stock, and on July 28, 2023, the Company issued and sold an aggregate of 1,500,093 shares of its common stock at the public offering price of $4.00 per share, less underwriting discounts and commissions, and the Company realized net proceeds of approximately $5,600,000.

On May 9, 2024, the Company filed a shelf registration statement (the "2024 Shelf Registration Statement") for the issuance of up to $150,000,000 of Company securities. Also on May 9, 2024, the Company entered into an At-The-Market Issuance Sales Agreement with Leerink Partners LLC, as sales agent, pursuant to which the Company may sell, from time to time, an aggregate of up to $50,000,000 of its common stock through the sales agents under the 2024 Shelf Registration Statement, subject to limitations imposed by the Company and subject to the sales agent's acceptance (the "2024 ATM program "). The sales agent is entitled to a commission of up to 3% of the gross proceeds from the sale of common stock sold under the 2024 ATM program. As of June 30, 2024, approximately $48,800,000 of the Company's common stock remains available for sale under its 2024 ATM program, with $100,000,000 of capacity remaining under its 2024 Shelf Registration Statement for the issuance of Company securities.

During the quarter three and six months ended March 31, 2023 June 30, 2024, the Company sold an aggregate of 1,684,592 231,097 shares of its common stock, respectively, under the previous 2024 ATM program and realized net proceeds of $7,200,000.

The approximately $1,010,000. For the three and six months ended June 30, 2023, the Company did not sell any sold under its previous at-the-market program, an aggregate of 1,181,829 and 2,866,421 shares of its common stock, during the quarter ended March 31, 2024. respectively, and realized net proceeds of $5,315,000 and $12,515,000, respectively.

Restricted Stock Units

In January 2024, the Company granted 283,333 restricted stock units ("RSUs") to its executive officers under its Amended and Restated 2019 Omnibus Stock Incentive Plan with a weighted average grant date fair value of $3.47 per share. The fair market value of the RSUs was estimated to be the closing price of the Company's common stock on the date of grant. These RSUs vest 25% on the grant date and 25% each on the first, second and third anniversaries of the grant date, subject to continued service as an employee or consultant through the applicable vesting date. The During the six months ended June 30, 2024, the Company issued 42,844 shares upon the vesting of 25% of these RSUs on the grant date and 27,989 shares were withheld in lieu of withholding taxes.

In May 2024 and 2023, 62,241 and 103,734 RSUs vested, respectively, pursuant to a grant made to the Company's chief executive officer, of which 35,259 and 66,291 shares of common stock were issued by the Company, respectively, and 26,982 and 37,443 shares, respectively, were withheld in lieu of withholding taxes.

As of March 31, 2024 and 2023, June 30, 2024, the Company has 366,235 and 207,469 303,994 outstanding RSUs, respectively, for which the RSUs. The Company recorded $362,000 $114,000 and $86,000 $476,000 compensation expense for the quarter three and six months ended March 31, 2024 June 30, 2024, respectively, and 2023, $68,000 and $154,000 for the three and six months ended June 30, 2023, respectively. As of March 31, 2024 June 30, 2024, unrecognized compensation expense related for these RSUs amounted to unvested RSUs is $999,000, will $886,000 and the expected weighted average period for the expense to be recognized over a weighted average remaining period of 1.8 at March 31, 2024. is 1.7 years.

Preferred Stock

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

	As of March 31, 2024 and December 31, 2023			As of June 30, 2024 and December 31, 2023		
	Preferred Shares Outstanding	Liquidation Preference (Per Share)	Total Liquidation Preference	Preferred Shares Outstanding	Liquidation Preference (Per Share)	Total Liquidation Preference
Series C-3	2,000	$ 10.00	$ 20,000	2,000	$ 10.00	$ 20,000
Series E	89,623	$ 49.20	$ 4,409,452	89,623	$ 49.20	$ 4,409,452
Series G	89,999	$ 187.36	$ 16,862,213	89,999	$ 187.36	$ 16,862,213
Total	181,622		$ 21,291,665	181,622		$ 21,291,665

Stock Options

During the three six months ended March 31, 2024 June 30, 2024 and 2023, the Company granted ten-year qualified and non-qualified stock options covering an aggregate of 1,911,167 2,043,667 and 1,747,000 1,901,200 shares, respectively, of the Company's common stock under the Amended and Restated 2019 Omnibus Stock Incentive Plan. The weighted average exercise price of these options is $3.52 $3.62 and $4.36 $4.43 per share, respectively.

During the three and six months ended March 31, 2024 and 2023, June 30, 2024, stock-based compensation expense for stock options issued to employees, directors, officers and consultants was $2,082,000 $1,150,000 and $2,130,000, $3,232,000, respectively, and $989,000 and $3,119,000 for the three and six months ended June 30, 2023, respectively.

As of March 31, 2024 June 30, 2024, there was approximately $9,132,000 $8,464,000 in total unrecognized compensation expense related to stock options granted, which will be recognized over an expected remaining weighted average period of 1.6 1.5 years.

The fair value of each stock option award estimated on the grant date is determined using the Black-Scholes option pricing model. The following assumptions were used for the Black-Scholes option pricing model for the stock options granted during the three six months ended March 31, 2024 June 30, 2024:

Expected term (in years)	5.96	5.98
Volatility weighted average	98.98 %	98.95 %
Dividend yield weighted average	0 %	0 %
Risk-free interest rate weighted average	4.13 %	4.15 %
Weighted average grant date fair value of options granted during the period	$ 2.82	$ 2.90

During the three months ended March 31, 2024, the The Company uses the simplified method to calculate the expected term which takes into account the vesting term and the expiration date of the stock options. The expected term of the stock options granted to consultants, if any, 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 of the Company's stock price for the expected term. The expected dividend yield of 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.

Note 6 7 - Leases:

The Company entered into a seven-year operating lease agreement in March 2020 for an office space at 300 Connell Drive, Berkeley Heights, New Jersey 07922. The lease agreement, with a monthly average cost of approximately $17,000, commenced on September 16, 2020.

The Company entered into an operating lease for its office space in Germany that began in July 2017 that is set to expire and terminated in June 2024. The rental agreement has a three-month term which automatically renews and includes had a monthly cost of 400 Euros. The Company elected to apply the short-term practical expedient to the office lease.

Operating lease expense in the Company's condensed consolidated statements of operations and comprehensive loss for each of the three and six months ended March 31, 2024 and 2023 June 30, 2024 was approximately $52,000 and $104,000, respectively, and $52,000 and $104,000 for the three and six months ended June 30, 2023, respectively, which includes costs associated with leases for which ROU assets have been recognized as well as short-term leases.

At March 31, 2024 June 30, 2024, the Company has a total operating lease liability of $632,000, $594,000, of which approximately $155,000 and $477,000 were $159,000 was classified as operating lease liabilities, short-term and $435,000 was classified as operating lease liabilities, net of current portion, respectively, on the condensed consolidated balance sheet. At December 31, 2023, the Company's total operating lease liability was $668,000, of which $151,000 was classified as operating lease liabilities, short-term and $517,000 was classified as operating lease liabilities, net of current portion, on the condensed consolidated balance sheet. Operating ROU assets as of March 31, 2024 June 30, 2024 and December 31, 2023 were $605,000 $568,000 and $640,000, respectively.

For each of the three and six months ended March 31, 2024 and 2023, June 30, 2024, cash paid for amounts included in the measurement of lease liabilities in operating cash flows from operating leases was $51,000 and $102,000, respectively, and $50,000 and $100,000 for the three and six months ended June 30, 2023, respectively.

The weighted average remaining lease term as of March 31, 2024 June 30, 2024 and 2023 were 3.6 was 3.3 and 4.6 4.3 years, respectively, and the weighted average discount rate for operating leases was 9% at March 31, 2024 June 30, 2024 and 2023.

As of March 31, 2024 June 30, 2024, maturities of lease liabilities were as follows:

2024 (excluding the three months ended March 31, 2024)	$ 154,000	
2024 (excluding the six months ended June 30, 2024)		$ 102,000
2025	208,000	208,000
2026	211,000	211,000
2027	169,000	169,000
Total future minimum lease payments	742,000	690,000
Less imputed interest	(110,000)	(96,000)
Total	$ 632,000	$ 594,000

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 the unaudited financial information and the notes thereto included in this Quarterly Report on Form 10-Q and our audited 2023 Annual Report on Form 10-K, filed with the Securities and Exchange Commission, or the SEC, on March 12, 2024.

Forward Looking Statements

This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that are subject to risks and uncertainties. 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," "should," "target," "will," "would," and similar expressions or variations intended to identify forward-looking statements. All statements, other than statements of historical facts, regarding management's expectations, beliefs, goals, plans or CorMedix's prospects should be considered forward-looking statements. Readers are cautioned that actual results may differ materially from projections or estimates due to a variety of important factors, and readers are directed to the Risk Factors identified in CorMedix's filings with the SEC, including its most recent Annual Report on Form 10-K, copies of which are available free of charge at the SEC's website at www.sec.gov or upon request from CorMedix. CorMedix, and a summary of which is copied below. CorMedix may not actually achieve the goals or plans described in its forward-looking statements, and such forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q. Investors should not place undue reliance on these statements. CorMedix assumes no obligation and does not intend to update these forward-looking statements, except as required by law.

Risks Related to our Financial Position and Need for Additional Capital

- We have a history of operating losses, expect to incur additional operating losses in the future and may never be profitable
- We may need to finance our future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements, which may not be on terms favorable to us or our stockholders and may require us to relinquish valuable rights

Risks Related to the Commercialization of DefenCath

- We are highly dependent on the successful commercialization of our only approved product, DefenCath
- The successful commercialization of DefenCath will depend on obtaining coverage and reimbursement for use of DefenCath from third-party payors
- The expected outpatient demand for DefenCath is highly concentrated, with two large customers accounting for more than 70% of total expected market volume. The failure of one or both of these large dialysis providers to utilize DefenCath is likely to adversely impact the commercial launch of DefenCath
- If we are unable to effectively recruit, train, retain and equip our sales force, our ability to successfully commercialize DefenCath will be harmed

Risks Related to the Development and Commercialization of our Other Products

- Successful development and commercialization of our product candidates is uncertain
- Final approval by regulatory authorities of our product candidates for commercial use may be delayed, limited or prevented, any of which would adversely affect our ability to generate operating revenues

Risks Related to Healthcare Regulatory and Legal Compliance Matters

- DefenCath, and our product candidates (if approved), will be subject to extensive post-approval regulation
- Current healthcare laws and regulations in the U.S. and future legislative or regulatory reforms to the U.S. healthcare system may affect our ability to commercialize DefenCath and future marketed products profitably
- We are subject to laws and regulations relating to privacy, data protection and the collection and processing of personal data. Failure to maintain compliance with these regulations could create additional liabilities for us
- Clinical trials required for our new product candidates or for expanded uses of DefenCath will be expensive and time-consuming, and their outcome is uncertain

Risks Related to Our Business and Industry

- Healthcare institutions, physicians and patients may not accept or use our products
- Competition and technological change may make our products and technologies less attractive or obsolete
- Healthcare policy changes, including reimbursement policies for drugs and medical devices, may have an adverse effect on our business, financial condition and results of operations
- If we lose key management or scientific personnel, cannot recruit qualified employees, directors, officers, or other personnel or experience increases in compensation costs, our business may materially suffer
- Changes in funding for the FDA and other government agencies or future government shutdowns or disruptions could cause delays in the submission and regulatory review of marketing applications, including supplements, which could negatively impact our business or prospects
- If we are unable to hire additional qualified personnel, our ability to grow our business may be harmed
- We may not successfully manage our growth
- We face the risk of product liability claims and the amount of insurance coverage we hold now or in the future may not be adequate to cover all liabilities we might incur
- We may be exposed to liability claims associated with the use of hazardous materials and chemicals
- If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business
- Negative U.S. and global economic conditions may pose challenges to our business strategy, which relies on funding from the financial markets or collaborators

Risks Related to Our Intellectual Property

- If we materially breach or default under the ND License Agreement with NDP, NDP would have the right to terminate the ND License Agreement, which would materially harm our business
- If we do not obtain protection for and successfully defend our respective intellectual property rights, competitors may be able to take advantage of our research and development efforts to develop competing products
- Intellectual property disputes could require us to spend time and money to address such disputes and could limit our intellectual property rights
- If we infringe the rights of third parties, we could be prevented from selling products and forced to pay damages and defend against litigation

Risks Related to Dependence on Third Parties

- If we or our collaborators are unable to manufacture our products in sufficient quantities or experience quality or manufacturing problems, we may be unable to meet demand for our products and we may lose potential revenues
- We depend on third party suppliers and contract manufacturers for the manufacturing of DefenCath and all key active pharmaceutical ingredients ("APIs"), which subjects us to potential cost increases and manufacturing delays that are not within our control
- We currently have one FDA approved supplier for each of our key APIs, taurolidine and heparin, respectively, as well as one currently FDA approved manufacturing site for DefenCath finished dosage. We are actively working to qualify an alternative manufacturing site for finished dosage as well as making preparations to qualify alternative sources of both APIs. There is no guarantee we will be successful in these endeavors.
- Corporate and academic collaborators may take actions that delay, prevent, or undermine the success of new development products or expanded uses of DefenCath
- Data provided by collaborators and others upon which we rely that has not been independently verified could turn out to be false, misleading or incomplete
- We may rely on third parties to conduct our clinical trials and pre-clinical studies. If those parties do not successfully carry out their contractual duties or meet expected deadlines, our product candidates may not advance in a timely manner or at all

Risks Related to Our Common Stock

- Our executive officers and directors may sell shares of their stock, and these sales could adversely affect our stock price
- Our common stock price has fluctuated considerably and is likely to remain volatile, and you could lose all or a part of your investment
- A significant number of additional shares of our common stock may be issued at a later date, and their sale could depress the market price of our common stock
- Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult
- If we fail to comply with the continued listing standards of the Nasdaq Global Market, it may result in a delisting of our common stock from the exchange
- Laws, rules and regulations relating to public companies may be costly and impact our ability to attract and retain directors and executive officers
- Our internal control over financial reporting and our disclosure controls and procedures may not prevent all possible errors that could occur
- Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer
- We do not currently pay dividends on our common stock so any returns on our common stock may be limited to the value of our common stock
- We are a "smaller reporting company" and we cannot be certain if the reduced reporting requirements applicable to such companies could make our common stock less attractive to investors.

Overview

CorMedix Inc. (collectively, with our wholly owned subsidiaries, referred to herein as “we,” “us,” “our” or the “Company”) is a biopharmaceutical company focused on developing and commercializing therapeutic products of life-threatening diseases and conditions.

Our primary focus is on the commercialization of our lead product, DefenCath, in the U.S. The name DefenCath is the U.S. proprietary name that was approved by the FDA.

DefenCath is an antimicrobial catheter lock solution (“CLS”) (a formulation of taurolidine 13.5 mg/mL, and heparin 1000 USP Units/mL) indicated to reduce the incidence of catheter-related bloodstream infections (“CRBSI”) in adult patients with kidney failure receiving chronic hemodialysis through a central venous catheter (“CVC”). It is indicated for use in a limited and specific population of patients. CRBSIs can lead to treatment delays and increased costs to the healthcare system when they occur due to hospitalizations, need for IV antibiotic treatment, long-term anticoagulation therapy, removal/replacement of the CVC, related treatment costs, as well as increased mortality. We believe DefenCath can address a significant unmet medical need.

On November 15, 2023, we announced that the FDA approved the NDA for DefenCath to reduce the incidence of CRBSI in adult patients with kidney failure receiving chronic hemodialysis through a CVC. DefenCath is indicated for use in a limited and specific population of patients. DefenCath is the first and only FDA-approved antimicrobial CLS in the U.S. and was shown to reduce the risk of CRBSI by up to 71% in a Phase 3 clinical study. As a result of the November 2023 FDA approval, CorMedix is launched the product commercially in April in the process of launching inpatient setting and July in the product commercially. outpatient hemodialysis setting.

DefenCath is listed in the Orange Book as having NCE exclusivity (5 years) expiring on November 15, 2028, and the Generating Antibiotic Incentives Now or GAIN exclusivity extension of the NCE exclusivity (an additional 5 years) expiring on November 15, 2033. The GAIN exclusivity extension of 5 years is the result of the January 2015 designation of DefenCath as a Qualified Infectious Disease Product (“QIDP”).

We announced on April 26, 2023 that following the submission of a duplicate New Technology Add-On Payment (“NTAP”) application in the fourth quarter of 2022 to Centers for Medicare and Medicaid Services (“CMS”), CMS has subsequently issued the Inpatient Prospective Payment System (“IPPS”) 2024 proposed rule that includes a NTAP of up to $17,111 per hospital stay for DefenCath. This NTAP represents reimbursement to inpatient facilities of 75% of the anticipated wholesaler acquisition cost price of $1,170 per 3 mL vial, and an average utilization of 19.5 vials per hospital stay. The final IPPS rule was published in early August 2023 and confirmed this payment amount in that final rule. This NTAP was conditioned upon the DefenCath NDA obtaining final FDA approval prior to July 1, 2024. As the NTAP was calculated by CMS based upon an anticipated wholesale acquisition price (“WAC”) of $1,170, and following FDA approval of the DefenCath NDA, an actual WAC of $249.99 per 3ml vial was established, we anticipate that CMS will revise the amount of the NTAP payment to reflect the actual WAC price in the next IPPS rulemaking, effective October 1, 2024. Upon the listing in the compendia of the actual WAC price of $249.99 per 3ml vial, the Company notified CMS of the new lower WAC pricing and recommended that CMS make an off-cycle adjustment to the NTAP to reflect the current lower WAC pricing amount. CMS subsequently communicated to the Company that they do not intend to update the NTAP reimbursement amount until the next review cycle in October 2024.

On January 25, 2024, CMS determined that DefenCath should be classified as a renal dialysis service that is subject to the Medicare end-stage renal disease prospective payment system (“ESRD PPS”). The ESRD PPS provides bundled payment for renal dialysis services, but also affords a transitional drug add-on payment adjustment, or TDAPA, which provides temporary, additional payments for certain new drugs and biologicals. We submitted an application for TDAPA on January 26, 2024, and received confirmation that our application was approved on April 18, 2024. We also submitted a HCPCS application for a J-code to CMS on December 8, 2023, for DefenCath, which is relevant to billing and the TDAPA application. The HCPCS J-code for DefenCath was published by CMS on April 2, 2024. TDAPA reimbursement is calculated based on 100 percent ASP (or 100 percent of wholesale acquisition price or else manufacturers’ list price, respectively, if such data is unavailable). TDAPA and post-TDAPA add-on payment adjustments for DefenCath apply for five years (with such add-on payments applying to all ESRD PPS payments for years three through five). CMS confirmed a July 1, 2024 implementation date for HCPCS and TDAPA as described below. TDAPA.

We announced on June 6, 2024 that the Center for Medicare & Medicaid Services (CMS) has determined that DefenCath® qualified for pass-through status under the hospital Out-Patient Prospective Payment System (OPPS). Pass-through status provides for separate payment under Medicare Part B for the utilization of DefenCath in the outpatient ambulatory setting for a period of at least two years, and up to a maximum of three years. While vascular access for hemodialysis can be initiated in an inpatient setting, ambulatory surgical centers or vascular access centers offer a less-invasive, outpatient-based alternative for patients. We estimate that up to 100,000 HD-CVC placements occur each year, and pass-through status ensures that providers are reimbursed separately for administration of DefenCath in this setting of care.

In May 2024, we announced that we have entered into a multi-year commercial supply contract with a top tier midsized dialysis provider, for the supply of DefenCath® (taurolidine and heparin). While on a no requirements basis, this agreement will allow for patients to have access to DefenCath at more than 500 dialysis facilities located nationally. We also announced previously a 5-year commercial no requirements supply contract with Florida-based dialysis provider, ARC Dialysis, LLC for the supply of DefenCath® (taurolidine and heparin). ARC Dialysis, a Miami-based medium-sized dialysis organization, provides inpatient dialysis services to approximately 100 inpatient facilities, and is the operator of 18 outpatient dialysis units throughout Florida. In addition, we secured agreements with group purchasing organizations (GPOs) that are relevant to our ongoing launch in the hospital inpatient setting. We are committed to building meaningful long-term relationships with dialysis providers that are dedicated to innovation and infection reduction.

We may pursue additional indications for DefenCath use as a CLS in populations with unmet medical needs that may also represent potentially significant market opportunities. While we are continuing to assess these areas, potential future indications may include use as a CLS to reduce CRBSIs in total parenteral nutrition patients using a central venous catheter and in certain oncology patients using a central venous catheter. In June 2024, CorMedix announced that the U.S. Food and Drug Administration (FDA) provided feedback to the Company's request to discuss development plans for additional indications for DefenCath. The FDA provided supportive feedback regarding the Company's plans to pursue an expanded indication in adult Total Parenteral Nutrition (TPN) patients. CorMedix expects to submit a complete clinical protocol to FDA in the 3rd quarter of 2024 with a goal of gaining further alignment and initiating the program by year-end 2024. In addition, the FDA confirmed its requirement that the Company anticipates discussing with conduct a study in pediatric hemodialysis (HD) patients under the FDA potential pathways for expanded indications. Pediatric Research Equity Act (PREA).

We currently have one FDA approved source for each of our two key APIs for DefenCath, taurolidine and heparin sodium, respectively. With regards to taurolidine, we have a DMF filed with the FDA. There is a master commercial supply agreement between a third-party manufacturer and us in place from August 2018. We are currently in the process of identifying and qualifying an alternate third-party manufacturer for taurolidine under our existing DMF. With respect to heparin sodium API, we have identified an alternate third-party supplier and intend to qualify such supplier under the DefenCath NDA over the next twelve months.

We received FDA approval of DefenCath with finished dosage production from our European based CMO Rovi Pharma Industrial Services. We believe this CMO has adequate capacity to produce the volumes needed to meet near-term projected demand for the commercial launch of DefenCath.

We previously announced a commercial arrangement with Siegfried Hameln to qualify their site as an additional finished dosage manufacturing site for DefenCath. The Company submitted the NDA supplement to FDA on May 7, 2024 as described below.

We announced on May 1, 2023 that the USPTO allowed our patent application directed to a locking solution composition for treating and reducing infection and flow reduction in central venous catheters. This application was granted on August 29, 2023 as U.S. Patent No. 11,738,120. Our newly granted U.S. Patent reflects the unique and proprietary formulation of our product, DefenCath, for which we received FDA approval on November 15, 2023. This patent supplements the coverage of our existing licensed U.S. Patent No. 7,696,182, and has the potential to provide an additional layer of patent protection for DefenCath through 2042.

As part of the DefenCath approval letter, the FDA communicated the existence of a required pediatric assessment under the Pediatric Research Equity Act, or PREA. PREA requires sponsors to conduct pediatric studies for, among other things, NDAs for a new active ingredient, such as taurolidine in DefenCath, unless a waiver or deferral is obtained from the FDA. A deferral acknowledges that a pediatric assessment is required but permits the applicant to submit the pediatric assessment after the submission of an NDA. FDA deferred submission of the pediatric study for DefenCath because the product is ready for approval for use in adults and the pediatric study has not been completed. We are currently obligated to conduct the study communicated in the approval letter: an open-label, two-arm (DefenCath vs. standard of care) study to assess safety and time to CRBSI in subjects from birth to less than 18 years of age with kidney failure receiving hemodialysis via a central venous catheter. CorMedix intends to address the design and requirements for the pediatric study during our Type C meeting with announced in June 2024 that the FDA during 2024. confirmed its requirement that the Company conduct a study in pediatric hemodialysis (HD) patients under the Pediatric Research Equity Act (PREA). Because this is a required post-marketing study, we would be required to make annual reports to the FDA. Pediatric studies for an approved product conducted under PREA may qualify for pediatric exclusivity, which, if granted, provides an additional six months of exclusivity that attaches to the end of existing marketing exclusivity and patent periods for DefenCath. Depending on the timing of final report submission, DefenCath could potentially receive a total marketing exclusivity period of 10.5 years. However, there are factors that could affect whether this exclusivity is received or the duration of exclusivity, and DefenCath may or may not ultimately be eligible for the additional 0.5 years of exclusivity associated with this pediatric study.

The Company We previously marketed and sold Neutrolin, a CLS product where we received CE-Mark approval for commercial distribution in the EU and other territories. The Company We previously elected to discontinue sales of Neutrolin for lack of commercial viability. The winding down of our operations in the EU is nearly complete and Neutrolin sales in both the EU and the Middle East have been discontinued since 2022.

In addition, the following events have occurred subsequent to March 31, 2024:

- *CMS HCPCS Determination*. CMS published its HCPCS coding decision for DefenCath on April 2, 2024, establishing a new HCPCS Level II code for DefenCath.
- *DefenCath Development Plan*. The FDA granted the Company's Type C meeting request to discuss an updated development plan for DefenCath and pediatric study requirements. The Company expects to receive feedback from the FDA by the end of the second quarter of 2024.
- *First Customer Announcement*. On April 8, 2024, the Company announced it had entered into a 5-year commercial supply contract with ARC Dialysis, LLC, a Florida-based dialysis provider, for the supply of DefenCath.
- *Inpatient Commercial Launch.* On April 15, 2024, the Company announced that DefenCath is commercially available for U.S. inpatient use.
- *Outpatient Reimbursement*. On April 18, 2024, CMS notified the Company of its determination that DefenCath meets the criteria for a Transitional Drug Add-On Payment (referred to herein as "TDAPA") and will be effective July 1, 2024. The TDAPA program currently provides for five years of additional payment reimbursement beyond the ESRD bundled rate to outpatient providers.
- *PAS Submission for Alternate Manufacturing*. On May 7, 2024 the Company submitted to FDA a supplement to the CorMedix NDA adding Siegfried Hameln as an alternate finished dosage manufacturing site for DefenCath. Pending FDA review and approval, the Company anticipates approval of the supplement by the end of 2024.

Financial Operations Overview

Revenues

We have not generated substantial revenue since our inception. Our ability to generate future revenue and become profitable depends on our ability to successfully commercialize DefenCath beginning in the second quarter of 2024 and any product candidates that we may advance in the future. If we fail to successfully commercialize DefenCath, or any other product candidates we advance in a timely manner or obtain regulatory approval for them, our ability to generate future revenue, and our results of operations and financial position, could be adversely affected. Through March 31, 2024 June 30, 2024, we have funded our operations primarily through debt and equity financings.

Cost of Revenues

Cost of revenues include direct and indirect costs related to the manufacturing and distribution of DefenCath, including product cost, packaging services, freight, amortization of the license intangible asset and an allocation of overhead costs that are primarily fixed such as salaries, benefits and insurance.

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 pre-clinical studies and clinical trials; (vii) facilities and other allocated expenses, which include direct and allocated expenses for rent, facility maintenance, as well as laboratory and other supplies; and (viii) manufacturing-related costs, including previously expensed pre-NDA approval inventory amounting to approximately $6,400,000. All R&D is expensed as incurred.

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 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 future product candidates.

Development timelines, probability of success and development costs vary widely. We are currently focused on the commercialization of DefenCath in the U.S.

Selling General and Administrative Marketing Expense

Selling and marketing expense includes the cost of salaries and related costs for personnel in sales and marketing, brand building, advocacy, market research and consulting. Selling and marketing expenses are expensed as incurred.

General and Administrative Expense

General and administrative expenses consist principally of salaries and related costs for personnel in executive, finance and administrative functions including payroll taxes and health insurance, stock-based compensation and travel expenses. Other 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 expenses include facility-related costs, not included in R&D expense, promotional expenses, costs associated with industry and trade shows, insurance and professional fees for legal, services patent review, consulting, and accounting services. General and administrative expenses are expensed as incurred.

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). The intercompany loans outstanding between our New Jersey-based subsidiary company and our Germany-based subsidiary subsidiaries will not be repaid and the nature of the funding advanced was of a long-term investment nature. As such, 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 and short-term investments.

Interest Expense

Interest expense consists of interest incurred on financing of expenditures.

Results of Operations

Comparison of the Three and Six Months Ended March 31, 2024 June 30, 2024 and 2023

The following is a tabular presentation of our consolidated operating results for the three months ended March 31, 2024 June 30, 2024 and 2023 *(in thousands)*:

	For the Three Months Ended March 31,		% of Change Increase	For the Three Months Ended June 30,		% Increase	For the Six Months Ended June 30,		% Increase
	2024	2023	(Decrease)	2024	2023	(Decrease)	2024	2023	(Decrease)
Revenues, net	$ -	$ -	-						
Cost of revenues	(819)	-	100%						
Gross loss	(819)	-	-						
Revenue				$ 806	$ -	-	$ 806	$ -	-
Cost of sales				(510)	-	-	(1,328)	-	-
Gross profit				296	-	-	(522)	-	-
Operating Expenses:									
Research and development	(838)	(3,407)	(75)%	(651)	(4,795)	(86)%	(1,489)	(8,202)	(82)%
Selling, general and administrative	(15,048)	(7,610)	98%						
Selling and marketing				(7,387)	(3,256)	127%	(13,724)	(5,897)	133%
General and administrative				(7,559)	(3,754)	101%	(16,270)	(8,723)	87%
Total operating expenses	(15,886)	(11,017)	44%	(15,597)	(11,805)	32%	(31,483)	(22,822)	38%
Loss from operations	(16,705)	(11,017)	52%	(15,301)	(11,805)	30%	(32,005)	(22,822)	40%
Interest income	857	446	92%	657	550	19%	1,514	997	52%
Foreign exchange transaction (loss) gain	(4)	12	(132)%						
Foreign exchange transaction loss				(1)	(13)	(89)%	(6)	(1)	436%
Other Income				500	-	-	500	-	-
Interest expense	(10)	(9)	12%	(6)	(6)	12%	(16)	(15)	12%
Net loss before income taxes	(15,862)	(10,568)	50%						
Total other income				1,150	531	116%	1,992	981	103%
Loss before income taxes				(14,151)	(11,274)	26%	(30,013)	(21,841)	37%
Tax benefit	1,395	-	-	-	-	-	1,395	-	-
Net loss	(14,467)	(10,568)	37%	(14,151)	(11,274)	26%	(28,618)	(21,841)	31%
Other comprehensive (loss) income	(10)	19	(158)%	2	(10)	(122)%	(8)	8	(205)%
Comprehensive loss	$ (14,477)	$ (10,549)	37%	$ (14,149)	$ (11,284)	25%	$ (28,626)	$ (21,833)	31%

Revenues. Revenue increased by $0.8 million for both the three and six months ended June 30, 2024. Revenue consists of sales of DefenCath, which was approved by the FDA in November 2023 and launched in the US in April 2024 in inpatient settings and reflects the shipment of DefenCath to specialty distributors, net of estimates for applicable variable consideration, which consists primarily of distribution service fees, prompt pay and other discounts, product returns, chargebacks, rebates and volume incentive rebates.

Cost of Revenues. Cost of revenues include direct and indirect costs related to the manufacturing and distribution of DefenCath, including product cost, packaging services, freight, amortization of the license intangible asset and an allocation of overhead costs that are primarily fixed such as salaries, benefits and insurance. We expect these relatively fixed costs to become less significant as a percentage of net sales with anticipated sales volume increases. There were no direct Direct costs of product sales during the three and six months ended March 31, 2024 June 30, 2024 are minimal as commercial launch of DefenCath occurred in the second quarter of 2024. sold to date, represents validation lot units previously expensed as R&D. Indirect costs of $819,000 approximately $0.5 million for the three months and $1.3 million for the six-months ended March 31, 2024 June 30, 2024, respectively, represent the proportion of salaries, benefits and insurance expenses representing excess capacity pertaining to pre-launch related activities. Certain pre-approval validation batch product previously expensed as R&D will improve margins throughout 2024 or until such inventory is depleted.

Research and Development Expense. R&D expense was $838,000 $0.7 million for the three months ended March 31, 2024 June 30, 2024, a decrease of $2,569,000, $4.1, or 75% 86%, from $3,407,000 $4.8 for the same period in 2023. For the six months ended June 30, 2024, R&D expense was $1.5 million, compared to $8.2 million for the six months ended June 30, 2023, a decrease of 82%. The decrease for both comparison periods was driven by the approval of DefenCath. As a result of the post FDA approval commercial operations, costs related to medical affairs and certain personnel expenses that supported R&D efforts prior to the FDA approval of DefenCath have been recognized in selling or general and administrative expense during the three months ended March 31, 2024 June 30, 2024, as compared to the same period last year that were recognized in R&D. In addition, a portion of the costs related to the manufacturing of DefenCath, previously recognized in R&D, are now capitalized as a result of the FDA approval. There was also a decrease in non-cash charges for stock-based compensation of $339,000. $0.1 million and $0.5 million for the three months and the six months ended June 30, 2024, respectively.

Selling and Marketing Expense. S&M expense was $7.4 million for the three months ended June 30, 2024, an increase of $4.1 million, or 127%. For the six months ended June 30, 2024, S&M expense increased $7.8 million to $13.7 million, an increase of 133%. The increase in both periods was due primarily to increased marketing efforts and new personnel, inclusive of our sales force and support for the commercial launch of DefenCath in the second quarter of 2024 as well as certain expenses previously expensed as a component of R&D prior to FDA approval.

General and Administrative Expense. SG G&A expense was $15,048,000 $7.6 million for the three months ended March 31, 2024 June 30, 2024, an increase of $7,438,000 $3.8 million, or 97% 103%, from $7,610,000 $3.8 million for the same period in 2023. For the six months ended June 30, 2024, G&A expense was $16.3 million, compared to $8.7 million for the six months ended June 30, 2023, an increase of $7.6 million, or 87%. The increase was primarily attributable to increases in personnel expenses of $3,756,000, due to $2.0 million and $4.2 million for the hiring of sales force, medical affairs three and marketing personnel. The increase in costs related to medical affairs, market research studies and launch activities six months ended June 30, 2024, respectively, in preparation for the support activities pertaining to commercial marketing launch, as well as certain expenses previously expensed as a component of DefenCath of $2,679,000 was a result of the post FDA approval operations that supported R&D efforts prior to the FDA approval, which are now recognized in selling, general and administrative expense during the three months ended March 31, 2024. approval. There were also increases in legal and compliance of $0.8 million and $1.2 million, consulting fees of $0.3 million and $0.5 million and non-cash charges for stock-based compensation of $449,000, consulting fees of $281,000 $0.2 million and business development activities of $218,000, $0.5 million, for the three and six month periods ended June 30, 2024, respectively.

Interest Income. Interest income was $857,000 $0.7 million and $1.5 million for the three three- and six months ended March 31, 2024 June 30, 2024, compared to $446,000 $0.6 million and $1.0 million for the same period last year, respectively, an increase of $411,000, $0.1 million, or 92%. 19% and $0.5 million, or 52%, respectively. The increase was attributable to higher interest rates and higher average balance in short-term investments during this period as compared to the same period last year.

Foreign Exchange Transaction Gain (Loss) Loss. Foreign exchange transaction gain (loss) losses were due to the re-measuring of transactions denominated in a currency other than our functional currency. For Balances and changes were immaterial for all periods presented.

Other Income. Other income relates to a settlement with a previously utilized vendor, occurring during the quarter three month period ended March 31, 2024, there was a loss of $4,000 and a gain of $12,000 for the same period in 2023. June 30, 2024.

Interest Expense. Interest expense was $10,000 pertains to certain liabilities we chose to finance. Balances and changes were immaterial for the three months ended March 31, 2024 as compared to $9,000 for the same period in 2023, an increase of $1,000, primarily due to higher interest rates on expenses that were financed this year as compared to the same period last year. all periods presented.

Other Comprehensive (Loss) Income. Unrealized foreign exchange movements related to long-term intercompany loans, 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 (loss) income which resulted in the loss of $10,000 income. Income and (loss) is considered immaterial for the three months ended March 31, 2024 and a gain of $19,000 for the three months ended March 31, 2023. all periods presented.

Liquidity and Capital Resources

Sources of Liquidity

As a result of our R&D, S&M and SG G&A expenditures and the lack of substantial product sales revenue, our ongoing operations have not been profitable since our inception. During the three six months ended March 31, 2024 June 30, 2024, we did not have any sales received net proceeds of $1.0 million from the issuance of 231,097 shares of common stock under our at-the-market-issuance sales agreement, or ATM program, as compared to $7,200,000 $12.5 million net proceeds for the same period in 2023 from the issuance of 1,684,592 2,866,421 shares of common stock. We will continue to be reliant on external sources of cash for the foreseeable future until we are able to generate profits.

In March 2024, we received $1,395,000, $1.4 million, net of expenses, from the sale of our unused New Jersey net operating losses ("NOL"), that was eligible for sale under the State of New Jersey's Economic Development Authority's New Jersey Technology Business Tax Certificate Transfer program ("NJEDA Program"). The NJEDA Program allowed us to sell our available NOL tax benefits for the state fiscal year 2023 in the amount of approximately $1,529,000. $1.5 million.

Net Cash Used in Operating Activities

Net cash used in operating activities for the three six months ended March 31, 2024 June 30, 2024, was $17,310,000 as $31.4 million compared to $10,394,000 $19.0 million for the same period in 2023, an increase of $6,916,000, $12.4 million. The increase is primarily driven by an increase in net loss of $3,899,000, $6.8 million, attributable to a net increase in operating expenses of $4,869,000. $8.7 million. As a result of the approval of DefenCath, cost of revenues of $819,000, $1.3 million, which are include indirect fixed costs related to the manufacturing and distribution of DefenCath were recognized, as compared to the same period last year, these costs were recognized as R&D. There was also an increase in prepaid expenses and other current assets of $1,226,000 $2.1 million and decreases in accrued expenses of $2,416,000 $1.4 million and accounts payable of $1,453,000, $0.9 million, among others of lesser significance.

Net Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities for the year six months ended March 31, 2024 June 30, 2024, was $8,945,000 $15.2 million as compared to $14,687,000 $17.1 million of net cash used in investing activities for the same period in 2023. The net cash provided during the three six months ended March 31, 2024 June 30, 2024, was mainly driven by an increase in maturity of the amount invested in short-term investments, partially offset by lower purchase of short-term investments in 2024 as compared to the same period in 2023.

Net Cash (Used in) Provided by Financing Activities

Net cash used in financing activities for the three months ended March 31, 2024 was $97,000 due to the payment of employee withholding taxes as a result of the issuance of shares for vested restricted stock units. Net cash provided by financing activities for the three six months ended March 31, 2023 June 30, 2024, was $7,200,000, $1.0 million as compared to $12.6 million for the same period in 2023, a decrease of $11.6 million. The decrease was mainly attributable to the decrease of $11.5 million in net proceeds generated from the sale of our common stock in our at-the-market program, or ATM program.

Funding Requirements and Liquidity

Our total cash, cash equivalents and short-term investments as of March 31, 2024 June 30, 2024, was $58,552,000, $45.6 million, excluding restricted cash of $179,000, $0.1 million, compared with $76,031,000 $76.0 million for the year ended December 31, 2023, excluding restricted cash of $181,000. $0.2 million. As of March 31, 2024 June 30, 2024, $48.8 million of the Company's common stock remains available for sale under the ATM program. Additionally, we have $104,400,000 $100 million of remaining capacity available under our 2021 2024 Shelf Registration Statement for the issuance of equity, debt or equity-linked Company securities.

Because our business has not generated positive operating cash flow, we may 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 on the commercial launch of DefenCath and we can provide no assurances that financing or strategic relationships will be available on acceptable terms, or at all, if additional funds are needed.

We expect to continue to fund operations from cash, cash equivalents and short-term investments and through capital raising sources as previously described, which may be dilutive to existing stockholders, through revenues from the sale of our products or through strategic alliances. We expect to implement In May 2024, we implemented an ATM program, which may be utilized to support our ongoing funding requirements. Additionally, we may enter into a credit facility in case necessary to support ongoing working capital needs. 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 timing of the commercial launch of DefenCath or the focus and direction of our research and development programs, any acquisition or pursuit of development of new product candidates, competitive and technical advances, the costs of commercializing any of our product candidates, and costs of filing, prosecuting, defending and enforcing any patent claims and any other intellectual property rights.

We expect to generate product sales for DefenCath in the U.S. In the absence of significant revenue, we are likely to continue generating operating cash flow deficits. We will continue to use cash as we increase other activities leading relating to the commercialization of DefenCath and pursue business development activities.

We currently estimate that as of March 31, 2024 June 30, 2024, we have sufficient cash, cash equivalents and short-term investments to fund operations for at least twelve months from the issuance of this Quarterly Report on Form 10-Q. These estimates are based upon the commercial launch in the second quarter of 2024, and other Company's base case assumptions for market penetration, average selling price, gross-to-net discounts, research and development expense and commercial infrastructure cost. Additional financing may be needed to build out our commercial infrastructure and to continue our operations. If we are unable to raise additional funds when needed, we may be forced to slow or discontinue the commercial launch of DefenCath. 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.

Contractual Obligations

We entered into a seven-year operating lease agreement in March 2020 for an our office space at 300 Connell Drive, Berkeley Heights, New Jersey 07922. The lease agreement, with a monthly average cost of approximately $17,000, commenced on September 16, 2020.

Critical Accounting Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these condensed consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses. On an ongoing basis, we evaluate these estimates and judgments, including those described below. judgments. 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 revenue and the carrying values of assets and liabilities, and revenues and expenses that are not readily apparent from other sources. Actual results and experiences may differ materially from these estimates. While our significant accounting policies are described in more detail in "Note 2 – Summary of Significant Accounting Policies and Liquidity and Uncertainties," to our consolidated financial statements included in Item 1, "Unaudited Condensed Consolidated Financial Statements," of this Quarterly Report on Form 10-Q, we believe that the following accounting policies require the application of significant judgments and estimates.

For the three-month six months period ended March 31, 2024 June 30, 2024, there were no significant changes to our critical accounting estimates as identified in our Annual Report on Form 10-K for the year ended December 31, 2023, except for the intangible asset probability assessment (see Note 2, "Summary of Significant Accounting Policies, as noted below:

- The contingent liability probability assessment (see Note 5, "Commitments and Contingencies," of the Notes to our Unaudited Condensed Consolidated Interim Financial statement contained in Item 1 of Part 1 of this Quarterly Report on Form 10-Q) and the assessment of going concern uncertainty. The intangible asset probability assessment is based on conditions that are known and reasonably knowable to us, we consider various scenarios, forecasts, projections, and estimates, and we make certain key assumptions, including the timing of DefenCath launch in the outpatient setting, uptake of our product in the inpatient and outpatient settings and commercial contract terms that align with our internal assumptions. Based on this assessment, as necessary or applicable, we make certain assumptions around revenue. Litigation contingencies are assessed to determine if an unfavorable outcome is reasonably possible, and if so, the contingency is disclosed along with an estimate of the possible loss or range of loss. If a liability is possible or probable, but no reasonable estimation of loss can be made, we will disclose the nature of the contingency and state that such an estimate cannot be made.
- The assessment of going concern uncertainty in our consolidated financial statements to determine if we have sufficient cash and cash equivalents on hand and working capital, including available loans or lines of credit, if any, to operate for a period of at least one year from the date our condensed consolidated financial statements are issued (the "look-forward period"). As part of this assessment, based on conditions that are known and reasonably knowable to us, we consider various scenarios, forecasts, projections, and estimates, and we make certain key assumptions, including the timing of DefenCath launch in the outpatient setting, uptake of our product in the inpatient and outpatient settings and commercial contract terms that align with our internal assumptions. Based on this assessment, as necessary or applicable, we make certain assumptions around revenue, gross profit, operating expenses, inventory build and working capital needs to the extent we deem probable those implementations can be achieved within the look-forward period. For additional information, refer to Note 2 to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.
- We account for product revenue from the sale of our product, DefenCath, in accordance with ASC 606, Revenue from Contracts with Customers (ASC 606). The provisions of ASC 606 require the following steps to determine revenue recognition: (1) identify the contract(s) with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when (or as) the entity satisfies a performance obligation. We only recognize revenue when we believe that it is probable that we will collect the consideration to which we are entitled in exchange for the goods or services that will be transferred to the customer. In accordance with ASC 606, revenue is recognized at a point in time when the performance obligation is satisfied by transferring control of the promised goods or services to a customer. In accordance with our contracts with customers, control of the product is transferred upon the conveyance of title, which occurs when the product is received by a customer. Our customers are located in the United States and consist primarily of wholesale distributors and outpatient service providers.

  We include an estimate of variable consideration in our transaction price at the time of sale when control of the product transfers to the customer. Variable consideration includes:

  - Distribution service fees;
  - Prompt pay and other discounts;
  - Product returns;
  - Chargebacks;
  - Rebates;
  - Volume incentive rebates.

  We assess whether or not an estimate of our variable consideration is constrained based on the probability that a significant reversal in the amount of cumulative revenue may occur in the future when the uncertainty associated with the variable consideration is subsequently resolved. Actual amounts of consideration ultimately received may vary from our estimates. If actual results in the future vary from our estimates, we will adjust these estimates, which would affect product sales and earnings in the period such variances become known.

The specific considerations that we use in estimating certain amounts related to variable considerations are as follows:

Distribution services fees – We pay distribution service fees primarily to our wholesale distributors. We reserve these fees based on actual net sales and the contractual fee rates negotiated with the customers in the distribution channel.

Prompt pay and other discounts – We provide customers with prompt pay discounts. The specific prompt pay terms vary by customer and are contractually fixed. Prompt pay discounts are expected to be taken by our customers, so an estimate of the discount is recorded at the time of sale based on the invoice price.

Product returns – Customers have the right to return the product that is within six months or less of the labeled expiration date or that is past the expiration date by no more than six months. An estimate for product returns is made based on: (i) data provided to us from our distributors and (ii) the estimated remaining shelf life of DefenCath previously shipped and currently being shipped to distributors.

Chargebacks – Certain covered entities, group purchasing organizations (GPO) and government entities will be able to purchase the product at a discounted price. The difference between the GPO, government or covered entity purchase price and the wholesale distributor purchase price will be charged back to us. We estimate the amount in chargebacks based on the expected number of claims and related cost that is associated with the revenue being recognized for product that remains in the distribution channel at the end of each reporting period.

Rebates – We are subject to negotiated discount obligations to different prescription benefit managers, other commercial organizations or government programs. The rebate amounts for these programs are determined by statutory requirements or contractual arrangements. Our liability for these rebates consists of invoices received for claims that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter are based on expected product utilization, and estimated future claims that will be made for product that has been recognized as revenue, but remains in the distribution channel at the end of each reporting period.

Volume Incentive Rebates – Volume incentive rebates are provided to certain customers. Rebates are owed based on predetermined volume levels and payable per the terms in the customer contracts. We estimate and record volume incentive rebates based on anticipated purchase volume with specific customers based on communications with the customer.

Item 3. Quantitative and Qualitative Disclosure about Market Risk.

The Company is not required to provide the information called for in this item due to its status as a Smaller Reporting Company.

Item 4. Controls and Procedures.

Disclosure controls and procedures are designed only to provide reasonable assurance that information to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Under the supervision and with the participation of our management, including our Chief Executive Officer and our 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 March 31, 2024 June 30, 2024. Based on the foregoing evaluation, our Chief Executive Officer and our 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 our 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 that occurred during the period covered by this report, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II
OTHER INFORMATION

Item 1. Legal Proceedings.

For information regarding our legal proceedings, see Note 4, 5, Commitments and Contingencies, included in Part I, Item 1, Financial Statements, in this Quarterly Report on Form 10-Q, which is incorporated into this item by reference.

Item 1A. Risk Factors.

There were no material changes from the risk factors previously disclosed in Part I, Item 1A "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2023.

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

None.

Item 3. Default Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

The exhibit index set forth below is incorporated by reference in response to this Item 6.

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 Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* Filed herewith.

\+ Indicates management contract or compensation plan.

SIGNATURES

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

CORMEDIX INC.

Date: May 9, 2024 August 14, 2024

By: /s/ /s/ Joseph Todisco
Name: Joseph Todisco
Title: Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.1

CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Joseph Todisco, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of CorMedix Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, subsidiary, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

   c) Any incidents of cybersecurity that have a significant impact on internal controls over financial reporting and financial statements.

Date: May 9, 2024 August 14, 2024

By: /s/ Joseph Todisco
Name: Joseph Todisco
Title: Chief Executive Officer

(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Matthew David, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of CorMedix Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   e) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, subsidiary, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   f) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   g) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   h) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   d) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   e) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

   f) Any incidents of cybersecurity that have a significant impact on internal controls over financial reporting and financial statements.

Date: May 9, 2024 August 14, 2024

By: /s/ Matthew David
Name: Matthew David
Title: Chief Financial Officer

(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of CorMedix Inc., a Delaware corporation (the "Company"), on Form 10-Q for the quarter ended March 31, 2024 June 30, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Joseph Todisco, Chief Executive Officer of the Company, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 9, 2024 August 14, 2024

By: /s/ Joseph Todisco
Name: Joseph Todisco
Title: Chief Executive Officer

(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of CorMedix Inc., a Delaware corporation (the "Company"), on Form 10-Q for the quarter ended March 31, 2024 June 30, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Matthew David, Chief Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 9, 2024 August 14, 2024

By: /s/ Matthew David
Name: Matthew David
Title: Chief Financial Officer

(Principal Financial Officer)

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