REFINITIV

DELTA REPORT

10-Q

CRMD - CORMEDIX INC.

10-Q - MARCH 31, 2024 COMPARED TO 10-Q - SEPTEMBER 30, 2023

The following comparison report has been automatically generated

TOTAL DELTAS	1416
CHANGES	119
DELETIONS	665
ADDITIONS	632

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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 September 30, 2023March 31, 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 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," filer", "smaller reporting company," 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 November 10, 2023March 31, 2024 was 54,812,042. 54,959,270.

CORMEDIX INC.™ AND SUBSIDIARIES

INDEX

PART I
FINANCIAL INFORMATION

Item 1. Unaudited Condensed Consolidated Financial Statements.

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

	September 30, 2023	December 31, 2022	March 31, 2024	December 31, 2023
ASSETS				
Current assets				
Cash and cash equivalents	$ 53,313,811	$ 43,148,323	$ 35,180,529	$ 43,642,684
Restricted cash	84,546	124,102	75,540	77,453
Short-term investments	33,273,259	15,644,062	23,370,989	32,388,130
Inventories			2,320,396	2,106,345
Prepaid research and development expenses	1,255,105	11,016	295,845	353,574
Other prepaid expenses and current assets	1,135,656	623,672	2,166,267	882,214
Total current assets	89,062,377	59,551,175	63,409,566	79,450,400
Property and equipment, net	1,588,963	1,609,679	1,905,704	1,866,224
License intangible asset			2,000,000	-
Restricted cash, long-term	102,664	102,320	103,838	103,055
Operating lease right-of-use assets	675,116	775,085		
Operating lease right-of-use asset			604,634	640,278
TOTAL ASSETS	$ 91,429,120	$ 62,038,259	$ 68,023,742	$ 82,059,957
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities				
Accounts payable	$ 2,386,108	$ 2,202,149	$ 2,826,322	$ 4,279,679
Accrued expenses	5,138,243	3,973,941	6,553,311	6,970,217
Current portion of operating lease liabilities	146,531	134,801		
Operating lease liability, short-term			154,801	150,619
Total current liabilities	7,670,882	6,310,891	9,534,434	11,400,515
Operating lease liabilities, net of current portion	556,416	667,632		
Operating lease liability, net of current portion			476,588	517,013
TOTAL LIABILITIES	8,227,298	6,978,523	10,011,022	11,917,528
COMMITMENTS AND CONTINGENCIES (Note 4)				
STOCKHOLDERS' EQUITY				
Preferred stock - $0.001 par value: 2,000,000 shares authorized; 181,622 shares issued and outstanding at September 30, 2023 and December 31, 2022	182	182		

Common stock - $0.001 par value: 160,000,000 shares authorized; 54,812,042 and 42,815,196 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	54,813	42,815		
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
Accumulated other comprehensive gain	84,399	82,743	83,461	94,108
Additional paid-in capital	390,008,412	330,294,782	394,040,254	391,693,214
Accumulated deficit	(306,945,984)	(275,360,786)	(336,166,136)	(321,700,013)
TOTAL STOCKHOLDERS' EQUITY	83,201,822	55,059,736	58,012,720	70,142,429
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 91,429,120	$ 62,038,259	$ 68,023,742	$ 82,059,957

See Accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

CORMEDIX INC.**CORMEDIX INC. AND SUBSIDIARIES**
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
AND COMPREHENSIVE LOSS

(Unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Revenue:				
Net sales	$ -	$ 6,817	$ -	$ 35,706
Cost of sales	-	(1,469)	-	(3,328)
Gross profit	-	5,348	-	32,378
Operating Expenses:				
Research and development	(2,663,976)	(2,339,268)	(10,866,236)	(7,836,327)
Selling, general and administrative	(7,803,307)	(4,628,014)	(22,422,808)	(14,430,791)
Total Operating Expenses	(10,467,283)	(6,967,282)	(33,289,044)	(22,267,118)
Loss From Operations	(10,467,283)	(6,961,934)	(33,289,044)	(22,234,740)
Other Income (Expense):				
Interest income	765,241	93,417	1,761,808	142,511
Foreign exchange transaction (loss) gain	(29,199)	23,572	(30,222)	31,598
Interest expense	(13,113)	(8,776)	(27,740)	(17,740)
Total Other Income	722,929	108,213	1,703,846	156,369
Loss before income taxes	(9,744,354)	(6,853,721)	(31,585,198)	(22,078,371)
Tax benefit	-	-	-	585,617
Net Loss	(9,744,354)	(6,853,721)	(31,585,198)	(21,492,754)
Other Comprehensive Income (Loss):				
Unrealized (loss) income from investments	(4,571)	15,811	1,090	(19,677)
Foreign currency translation (loss) gain	(1,727)	(9,558)	566	(21,681)
Total Other Comprehensive (Loss) Income	(6,298)	6,253	1,656	(41,358)
Comprehensive Loss	$ (9,750,652)	$ (6,847,468)	$ (31,583,542)	$ (21,534,112)
Net Loss Per Common Share – Basic and Diluted	$ (0.17)	$ (0.17)	$ (0.65)	$ (0.54)
Weighted Average Common Shares Outstanding – Basic and Diluted	56,553,174	41,183,585	48,715,585	39,741,555

	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

See Accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

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

For the three months ended September 30, 2023 March 31, 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 (Loss)	Capital	Deficit	Equity
Balance at June 30, 2023	45,805,283	$ 45,806	181,622	$ 182	$ 90,697	$ 346,116,054	$ (297,201,630)	$ 49,051,109
Stock and pre-funded warrants issued in connection with public offering, net	9,000,093	9,000	-	-	-	42,869,399	-	42,878,399
Stock issued in connection with options exercised	6,666	7	-	-	-	20,125	-	20,132
Stock-based compensation	-	-	-	-	-	1,002,834	-	1,002,834
Other comprehensive loss	-	-	-	-	(6,298)	-	-	(6,298)
Net loss	-	-	-	-	-	-	(9,744,354)	(9,744,354)
Balance at September 30, 2023	**54,812,042**	**$ 54,813**	**181,622**	**$ 182**	**$ 84,399**	**$ 390,008,412**	**$ (306,945,984)**	**$ 83,201,822**

For the nine months ended September 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 December 31, 2022	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 and pre-funded warrants issued in connection with public offering, net	9,000,093	9,000	-	-	-	42,869,399	-	42,878,399
Stock issued in connection with options exercised	64,041	64	-	-	-	253,924	-	253,988
Issuance of vested restricted stock, net of shares withheld for employee withholding taxes	66,291	67	-	-	-	(198,509)	-	(198,442)
Stock-based compensation	-	-	-	-	-	4,276,474	-	4,276,474
Other comprehensive gain	-	-	-	-	1,656	-	-	1,656
Net loss	-	-	-	-	-	-	(31,585,198)	(31,585,198)
Balance at September 30, 2023	**54,812,042**	**$ 54,813**	**181,622**	**$ 182**	**$ 84,399**	**$ 390,008,412**	**$ (306,945,984)**	**$ 83,201,822**

CORMEDIX INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

(Unaudited)

	Common Stock		Preferred Stock-Series C-3, Series E and Series G		Accumulated Other Comprehensive Income	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
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**

For the three months ended September 30, 2022 March 31, 2023

	Common Stock		Preferred Stock-Series C-3, Series E and Series G		Accumulated Other Comprehensive Income	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' 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
Stock issued in connection with ATM sale of common stock, net	1,684,592	1,685	-	-	-	7,198,721	-	7,200,406
Stock-based compensation	-	-	-	-	-	2,216,349	-	2,216,349
Other comprehensive gain	-	-	-	-	18,489	-	-	18,489
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**

See Accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

	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 June 30, 2022	41,106,777	$ 41,107	181,622	$ 182	$ 39,519	$ 321,956,046	$ (260,298,114)	$ 61,738,740
Stock issued in connection with ATM sale of common stock, net	76,933	77	-	-	-	308,588	-	308,665
Stock issued in connection with warrants exercised, cash	24,500	24	-	-	-	128,601	-	128,625
Stock-based compensation	-	-	-	-	-	983,524	-	983,524
Other comprehensive loss	-	-	-	-	6,253	-	-	6,253
Net loss	-	-	-	-	-	-	(6,853,721)	(6,853,721)
Balance at September 30, 2022	**41,208,210**	**$ 41,208**	**181,622**	**$ 182**	**$ 45,772**	**$ 323,376,759**	**$ (267,151,835)**	**$ 56,312,086**

For the nine months ended September 30, 2022 CORMEDIX INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	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 December 31, 2021	38,086,437	$ 38,086	181,622	$ 182	$ 87,130	$ 308,331,750	$ (245,659,081)	$ 62,798,067
Stock issued in connection with ATM sale of common stock, net	3,097,273	3,098	-	-	-	11,720,939	-	11,724,037
Stock issued in connection with warrants exercised, cash	24,500	24	-	-	-	128,601	-	128,625
Stock-based compensation	-	-	-	-	-	3,195,469	-	3,195,469
Other comprehensive loss	-	-	-	-	(41,358)	-	-	(41,358)
Net loss	-	-	-	-	-	-	(21,492,754)	(21,492,754)
Balance at September 30, 2022	**41,208,210**	**$ 41,208**	**181,622**	**$ 182**	**$ 45,772**	**$ 323,376,759**	**$ (267,151,835)**	**$ 56,312,086**

	For the Three Months Ended March 31,	
	2024	2023
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (14,466,123)	$ (10,567,226)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	2,444,179	2,216,349
Change in right-of-use assets	35,644	32,582
Depreciation	21,826	16,863
Changes in operating assets and liabilities:		
Increase in inventory	(214,051)	-
Increase in prepaid expenses and other current assets	(1,226,454)	(419,578)
Decrease in accounts payable	(1,453,352)	(755,582)
Decrease in accrued expenses	(2,415,719)	(884,872)
Decrease in operating lease liabilities	(36,244)	(32,422)
Net cash used in operating activities	(17,310,294)	(10,393,886)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of short-term investments	(7,693,762)	(25,422,039)
Maturity of short-term investments	16,700,000	10,750,000
Purchase of equipment	(61,306)	(14,766)

Net cash provided by (used in) investing activities	8,944,932	(14,686,805)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payment of employee withholding taxes on vested restricted stock units	(97,118)	-
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
Foreign exchange effect on cash	(805)	2,284
NET DECREASE IN CASH AND CASH EQUIVALENTS	(8,463,285)	(17,878,001)
CASH, CASH EQUIVALENTS AND RESTRICTED CASH - BEGINNING OF PERIOD	43,823,192	43,374,745
CASH, CASH EQUIVALENTS AND RESTRICTED CASH - END OF PERIOD	$ 35,359,907	$ 25,496,744
Cash paid for interest	$ 9,835	$ 8,776
Supplemental Disclosure of Non-Cash Investing Activities:		
Liability related to license agreement	$ 2,000,000	-
Unrealized gain (loss) from investments	$ 10,903	$ (16,393)

See Accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

CORMEDIX INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	For the Nine Months Ended September 30,	
	2023	**2022**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (31,585,198)	$ (21,492,754)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	4,276,474	3,195,469
Change in right-of-use assets	99,970	92,559
Depreciation	52,085	62,102
Changes in operating assets and liabilities:		
Decrease in trade receivables	-	42,583
Decrease in inventory	-	2,739
(Increase) Decrease in prepaid expenses and other current assets	(1,756,105)	271,932
Increase (Decrease) in accounts payable	183,903	(441,319)
Increase in accrued expenses	1,164,571	154,588
Decrease in operating lease liabilities	(99,486)	(89,792)
Net cash used in operating activities	(27,663,786)	(18,201,893)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of short-term investments	(60,978,108)	(22,366,898)
Maturity of short-term investments	43,350,000	18,750,000
Purchase of equipment	(31,369)	(90,605)
Net cash used in investing activities	(17,659,477)	(3,707,503)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from sale of common stock from at-the-market program, net	12,515,209	11,724,037
Payment of employee withholding taxes on vested restricted stock units	(198,442)	-
Proceeds from public offering of common stock and pre-funded warrants, net	42,878,399	-
Proceeds from exercise of warrants	-	128,625
Proceeds from exercise of stock options	253,988	-
Net cash provided by financing activities	55,449,154	11,852,662
Foreign exchange effect on cash	385	(24,464)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	10,126,276	(10,081,198)
CASH, CASH EQUIVALENTS AND RESTRICTED CASH – BEGINNING OF PERIOD	43,374,745	53,551,277
CASH, CASH EQUIVALENTS AND RESTRICTED CASH – END OF PERIOD	$ 53,501,021	$ 43,470,079
Cash paid for interest	$ 27,739	$ 17,740
Supplemental Disclosure of Non-Cash Investing Activities:		
Unrealized loss from investments	$ (1,090)	$ (19,677)

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 the prevention and treatment of life-threatening diseases and conditions. The Company was incorporated in the State of Delaware on July 28, 2006 and its principal executive office is located in Berkeley Heights, New Jersey. In 2013, the Company formed a wholly-owned subsidiary, CorMedix Europe GmbH and in 2020, the Company formed a wholly-owned Spanish subsidiary, CorMedix Spain, S.L.U.

The Company's primary focus is on the development commercialization of its lead product, candidate, DefenCath®, for potential commercialization in the United States, or U.S., and other key markets. The Company has in-licensed the worldwide rights to develop and commercialize DefenCath and Neutrolin®. DefenCath. The name DefenCath is the U.S. proprietary name conditionally approved by the U.S. Food and Drug Administration, or FDA, while the name Neutrolin was used in the European Union, or EU, and other territories where the Company received CE-Mark approval for the commercial distribution of Neutrolin as a catheter lock solution, or CLS, regulated as a medical device. 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, 2023 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 30, 2023 March 12, 2024. The accompanying consolidated balance sheet as of December 31, 2022 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: 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 development commercial plans and potential commercial launch development plans for DefenCath in the U.S. and its other operating requirements, the Company's existing cash, and cash equivalents and short-term investments and available resources at September 30, 2023, March 31, 2024 are expected to fund its operations for at least twelve months from the filing date 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's continued operations Company may depend on its ability to raise additional capital through various potential sources, such as equity and/or debt financings, strategic relationships, potential strategic transactions and/or out-licensing of its products in order to commercially launch DefenCath upon New Drug Application, or NDA, approval and until profitability is achieved, if ever. out-licensing. Management can provide no assurances that such financing or strategic relationships will be available on acceptable terms, or at all. As of September 30, 2023 March 31, 2024, the Company has $18,700,000 available under its At-the-Market Issuance Sales Agreement (the "ATM program") and has $104,000,000 $104,400,000 available under its current shelf registration for the issuance of equity, debt or equity-linked securities. securities (see Note 5).

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 condition. statements. Such factors include, but are not limited to: the results of clinical testing and trial activities of the Company's product candidates; the ability to obtain regulatory approval to market DefenCath and generate necessary revenue in the Company's products; the time periods required; ability to manufacture its products successfully; competition from products manufactured and sold or being developed by other companies; the price of, and demand for, Company products; the ability to obtain favorable, or any reimbursement for the Company's products from third party payors; the Company's ability to negotiate favorable licensing or other manufacturing and marketing agreements for its products; and the Company's ability to raise enough capital to support its operations.

Use of Estimates

The preparation of condensed consolidated 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 at in the date of Company's consolidated balance sheets and the financial statements and reported amounts of revenue and expenses during reported for each of the reporting period. Actual 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 CorMedix Europe GmbH and CorMedix Spain, S.L.U., its wholly owned subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation.

Financial Instruments

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

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

	September 30,			
	2023	2022	March 31, 2024	March 31, 2023
Cash and cash equivalents	$ 53,313,811	$ 43,254,116	$ 35,180,529	$ 25,268,225
Restricted cash	187,210	215,963	179,378	228,519
Total cash, cash equivalents and restricted cash	$ 53,501,021	$ 43,470,079	$ 35,359,907	$ 25,496,744

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 the condensed consolidated statement of operations. other comprehensive income. Realized gains and losses, amortization of premiums and discounts and interest and dividends earned are included in other income (expense). For declines in the fair value of equity securities that are considered other-than-temporary, impairment losses are charged to other income (expense), net. The Company considers available evidence in evaluating potential impairments of its investments, including the duration and extent to which fair value is less than cost. There were no deemed permanent impairments at September 30, 2023 March 31, 2024 or December 31, 2022 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 September 30, 2023 March 31, 2024 and December 31, 2022 December 31, 2023, all of the Company's investments had contractual maturities of less than one year. As of September 30, 2023, no allowance for credit loss was recorded. The following table summarizes the amortized cost, unrealized gains and losses and the fair value at September 30, 2023 March 31, 2024 and December 31, 2022 December 31, 2023:

	Amortized Cost	Gross Unrealized Losses	Gross Unrealized Gains	Fair Value	**Amortized Cost**	**Gross Unrealized Losses**	**Gross Unrealized Gains**	**Fair Value**
September 30, 2023:								
March 31, 2024:								
Money Market Funds included in Cash Equivalents	$ 6,057,189	$ -	$ -	$ 6,057,189	$ 28,343,324	$ -	$ -	$ 28,343,324
U.S. Government Agency Securities	29,920,029	(430)	1,700	29,921,299	20,690,147	(480)	315	20,689,982
Commercial Paper	3,352,743	(783)	-	3,351,960	2,682,664	(1,657)	-	2,681,007
Subtotal	33,272,772	(1,213)	1,700	33,273,259	23,372,811	(2,137)	315	23,370,989
Total September 30, 2023	$ 39,329,961	$ (1,213)	$ 1,700	$ 39,330,448				
December 31, 2022:								
Total March 31, 2024					$ 51,716,135	$ (2,137)	$ 315	$ 51,714,313
December 31, 2023:								
Money Market Funds included in Cash Equivalents	$ 7,311,327	$ -	$ 572	$ 7,311,899	$ 32,541,230	$ -	$ -	$ 32,541,230
U.S. Government Agency Securities	12,072,127	(3,184)	2,056	12,070,999	29,701,677	-	10,506	29,712,183
Corporate Securities	2,684,235	(183)	909	2,684,961				
Commercial Paper	888,875	(773)	-	888,102	2,677,372	(1,425)	-	2,675,947
Subtotal	15,645,237	(4,140)	2,965	15,644,062	32,379,049	(1,425)	10,506	32,388,130
Total December 31, 2022	$ 22,956,564	$ (4,140)	$ 3,537	$ 22,955,961				
Total December 31, 2023					$ 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 condensed consolidated balance sheets include cash and cash equivalents,

accounts receivable, investment securities, accounts payable and accrued expenses. The carrying value of certain financial instruments, primarily cash and cash equivalents, accounts receivable, accounts payable, and accrued expenses approximate their estimated fair values based upon the short-term nature of their maturity dates.

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

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

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

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

The following table provides the carrying value and fair value of the Company's financial assets measured at fair value on a recurring reoccurring basis as of September 30, 2023 March 31, 2024 and December 31, 2022 December 31, 2023:

	Carrying Value	Level 1	Level 2	Level 3	**Carrying Value**	**Level 1**	**Level 2**	**Level 3**
September 30, 2023:								
March 31, 2024:								
Money Market Funds and Cash Equivalents	$ 6,057,189	$ 6,057,189	$ -	$ -	$ 28,343,324	$ 28,343,324	$ -	$ -
U.S. Government Agency Securities	29,921,299	29,921,299	-		20,689,982	20,689,982	-	-
Commercial Paper	3,351,960	-	3,351,960	-	2,681,007	-	2,681,007	-
Subtotal	33,273,259	29,921,299	3,351,960	$ -	23,370,989	20,689,982	2,681,007	$ -
Total September 30, 2023	$ 39,330,448	$ 35,978,488	$ 3,351,960	$ -				
December 31, 2022:								
Total March 31, 2024					$ 51,714,313	$ 49,033,306	$ 2,681,007	$ -
December 31, 2023:								
Money Market Funds and Cash Equivalents	$ 7,311,899	$ 7,311,899	$ -	$ -	$ 32,541,230	$ 32,541,230	$ -	$ -
U.S. Government Agency Securities	12,070,999	12,070,999	-		29,712,183	29,712,183	-	-
Corporate Securities	2,684,961	-	2,684,961	-				
Commercial Paper	888,102	-	888,102	-	2,675,947	-	2,675,947	-
Subtotal	15,644,062	12,070,999	3,573,063	-	32,388,130	29,712,183	2,675,947	-
Total December 31, 2022	$ 22,955,961	$ 19,382,898	$ 3,573,063	$ -				
Total December 31, 2023					$ 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.

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 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**
Raw materials	$ 1,424,409	$ 1,525,420
Work in progress	471,415	580,925
Finished goods	424,572	-
Total	$ 2,320,396	$ 2,106,345

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 4 – 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 or ROU, ("ROU") assets, current portion of operating lease liabilities (included in accrued expenses), and operating lease liabilities, net of current portion, on the condensed consolidated balance sheet. sheet (see Note 6).

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 any potential 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. However,

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 their effect is anti-dilutive, they do not have contractual obligations that require participation in the Company's losses.

Since the Company has excluded only incurred losses, potentially dilutive shares. The following potentially dilutive shares have been securities are excluded from the calculation of diluted net loss per share as because their effect would be anti-dilutive. 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:

	Nine Months Ended September 30,		Three Months Ended March 31,	
	2023	2022	2024	2023
	(Number of Shares of Common Stock Issuable)		(Number of Shares of Common Stock Issuable)	
Series C non-voting preferred stock	4,000	4,000		
Series C-3 non-voting preferred stock			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	5,876,007	4,562,322	7,996,361	6,126,080
Shares underlying restricted stock units	103,735	207,469	366,235	207,469
Total potentially dilutive shares	11,428,673	10,218,722	13,811,527	11,782,480

Stock-Based Compensation

Stock-based Share-based compensation cost is measured at grant date, based on the estimated fair value of the award using the Black-Scholes option pricing model for options with service or performance-based conditions. Stock-based compensation is recognized as expense over the requisite service period on a straight-line basis or when the achievement of the performance condition is probable. For options with market-based vesting, stock-based compensation cost is measured at grant date using the Monte Carlo option pricing model and the expense is recognized over the derived service period.

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 and costs related to the manufacturing of the product that could potentially be available to support the commercial launch prior to marketing approval. expenses. The Company accrues for costs incurred as the services are being provided by monitoring the status of the activities 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.

Recently Issued Authoritative Recent Accounting Pronouncements

In October 2023, 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") 2023-06, "*Codification Amendments (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 Response 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 SEC's Disclosure Update chief operating decision maker (CODM), a description of other segment items by reportable segment, and Simplification Initiative," which modifies any additional measures of a segment's profit or loss used by the disclosure or presentation requirements of various FASB topics CODM when deciding how to allocate resources. The ASU also requires all annual disclosures currently required by Topic 280 to be included in the Codification. interim periods. The date on which this guidance standard is effective for the Company will be the date on which the SEC's removal of that related disclosure from Regulation S-X or Regulation S-K becomes effective, CorMedix beginning in annual reporting period ending December 31, 2024 and interim periods beginning in fiscal year 2025, with early adoption prohibited. The Company does not expect permitted and requires retrospective application to all prior periods presented in the adoption financial statements. CorMedix is currently assessing the impact of adopting this guidance to have an impact on its consolidated financial statements.

Note 3 — - Accrued Expenses:

Accrued Expenses

Accrued expenses consist of the following:

	September 30, 2023	December 31, 2022	March 31, 2024	December 31, 2023
Professional and consulting fees	$ 1,256,820	$ 514,354	$ 1,340,502	$ 2,270,022
Accrued payroll and payroll taxes	2,914,962	2,180,581	2,636,726	2,718,770
Manufacturing development related	911,698	1,214,550		
License agreement payable (see Note 4 – Commitments and Contingencies)			2,000,000	-
Manufacturing related			349,421	1,835,101
Other	54,763	64,456	226,662	146,324
Total	$ 5,138,243	$ 3,973,941	$ 6,553,311	$ 6,970,217

Note 4 —- 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 Securities Exchange Act of 1934, as amended, or the Exchange Act, along with Rule 10b-5 promulgated thereunder, and Sections 11 and 15 of the Securities Act of 1933, as amended, or the Securities Act. 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 second third amended complaint, the lead plaintiff seeks to represent two classes a class of shareholders: (i) shareholders who purchased or otherwise acquired CorMedix securities between October 16, 2019 and August 8, 2022, inclusive; and (ii) shareholders who purchased CorMedix securities pursuant or traceable to the Company's November 27, 2020 offering pursuant to CorMedix's Form S-3 Registration Statement, its Prospectus Supplement, dated November 27, 2020, and its Prospectus Supplement, dated August 12, 2021. inclusive. The second third amended complaint names as defendants the Company and twelve (12) six (6) current and former directors and 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") as well as Janet Dillione, Myron Kaplan, Alan W. Dunton, Steven Lefkowitz, Paulo F. Costa, Greg Duncan (the "Director Defendants"). The second 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), the Director Defendants, CorMedix, Baluch, and David violated Section 11 of the Securities Act, and that the Director Defendants, Baluch, and David violated Section 15. . 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. The Company and the other Defendants filed their Defendants' motion to dismiss the second third amended complaint is due on November 23, 2022; the lead plaintiff filed his or before June 6, 2024. Lead plaintiff's opposition to the is due on or before July 22, 2024. Defendants' motions to dismiss reply is due on January 7, 2023; and Defendants filed their reply brief on February 6, 2023 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, and 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. The On April 20, 2023, the consolidated derivative action was then administratively terminated and removed from the Court's docket until the motion to dismiss the class action is resolved. The individual defendants intend to vigorously contest resolved and the claims set forth Private Securities Litigation Reform Act, or PSLRA, stay is lifted. As noted above, on April 22, 2024, the lead plaintiff in the consolidated derivative class action when filed a third amended complaint. The class action remains stayed under the case moves forward. 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.

Patent Infringement

On September 9, 2014, the Company filed in the District Court of Mannheim, Germany, (the "Court") a patent infringement action against TauroPharm GmbH***License and Tauro-Implant GmbH as well as their respective CEOs (the "Defendants") claiming infringement of the Company's European Patent EP 1 814 562 B1, which was granted by the European Patent Office (the "EPO") on January 8, 2014 (the "Prosl European Patent"). The Company sought injunctive relief and raised claims for information, rendering of accounts, calling back, destruction and damages. Separately, TauroPharm filed an opposition with the EPO against the Prosl European Patent alleging that it lacks novelty and inventive step.***

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

The Court issued its decisions on May 8, 2015, staying both proceedings as it determined that it will defer any consideration of the request by the Company for injunctive and other relief until such time as the EPO or the German PTO made a final decision on the underlying validity of the Prosl European Patent and the Utility Model.

The German PTO declared that the Utility Model was invalid. The Company filed an appeal against the ruling on September 7, 2016. The German Federal Patent Court affirmed the first instance decision that the Utility Model was invalid. The decision has only a declaratory effect, as the Utility Model had expired in November 2015. On April 28, 2020, the Company filed a withdrawal of the complaint on the German utility model, thereby waiving its claims on these proceedings. The proceedings were closed and during the year ended December 31, 2020, final reimbursement of approximately $30,000 for the costs in connection with the utility model infringement were paid to TauroPharm.

On November 22, 2017, the EPO in Munich, Germany held that the Prosl European Patent would be invalidated. The Company disagrees with this decision and has appealed the decision. In a hearing on October 27, 2022 before the EPO Board of Appeals, the Board expressed the view that the patent claims of the Prosl European Patent on file were not inventive over prior art presented by TauroPharm. The Company thus withdrew its appeal against the first instance decision. This means that the invalidation of the patent has become final and that, as a consequence, the infringement proceedings, which are formally still ongoing, will also be closed because there is no underlying patent anymore. In order to avoid a dismissal, on January 12, 2023, the Company withdrew the infringement action with prejudice. Due to the withdrawal, there will be no decision on the merits, however, on March 9, 2023, the Court issued a decision that the Company has to bear the cost of the proceedings. Given that the court fees have already been paid by the Company, the cost of the proceedings are the costs that will have to be reimbursed to the Defendants, i.e., mainly statutory attorney's fees and expenses.

On January 16, 2015, the Company filed a complaint against TauroPharm GmbH and its managing directors in the District Court of Cologne, Germany. In the complaint, the Company alleged violation of the German Unfair Competition Act by TauroPharm and that TauroPharm is improperly and unfairly using its proprietary information relating to the composition and manufacture of Neutrolin, in the manufacture and sale of TauroPharm's products TauroLock™, TauroLock-HEP100 and TauroLock-HEP500. The Company sought a cease and desist order against TauroPharm from continuing to manufacture and sell any product containing taurolidine (the active pharmaceutical ingredient ("API") of Neutrolin) and citric acid in addition to possible other components, damages for any sales in the past and the removal of all such products from the market. A decision was rendered by the District Court of Cologne on December 11, 2018, dismissing the complaint in its entirety. The Company therefore appealed in January 2019. At the end of an oral hearing held on June 18, 2021, the District Court of Cologne indicated that it would dismiss the complaint of the Company, if the Company did not withdraw the appeal. As there were no advantages to further pursuing the matter in view of the District Court of Cologne's statements, the Company withdrew the appeal and the proceedings are therefore now closed. The Company reimbursed costs in the amount of approximately $41,000 plus interest to TauroPharm.

In connection with the aforementioned patent and utility model infringement and unfair competition proceedings against TauroPharm, the Company was required by the District Courts of Mannheim and Cologne to provide security deposits to cover legal fees in the event TauroPharm is entitled to reimbursement of these costs. The aggregate amount of security deposits made by the Company for such proceedings was 116,000 EUR (approximately $123,000). On February 8, 2023, the Regional Court of Cologne informed the Company that the security deposit in two proceedings, 81 HL 448/15 and 81 HL 903/19, in the amount of 36,000 EUR and 10,000 EUR, (approximately in aggregate of $49,000), was refunded to the Company. As of September 30, 2023, the aggregate remaining security deposit, including the 10,000 EUR that was received on October 16, 2023, was approximately 80,000 EUR (approximately $85,000), which the Company recorded as restricted cash on the consolidated balance sheets.

To summarize, one of the infringement proceedings initiated on September 9, 2014 before the District Court of Mannheim, has been terminated after the Company's withdrawal of the action; the parallel validity proceedings before the German Federal Patent Court are also terminated. The other infringement proceeding initiated on September 9, 2014 before the District Court of Mannheim is in its final stages; the parallel validity proceeding before the European Patent Office is also terminated. After the Company withdrew the infringement action and TauroPharm consented to the withdrawal, there is no decision on the merits, but the Court issued a decision that the Company has to bear the costs of the proceedings. The Defendants requested the Court to determine the amount of the cost to be paid by the Company at 46,000 EUR (approximately $49,000), of which 38,000 EUR (approximately $40,000) has been accrued. The Company's outside counsel filed a submission arguing that the amount of the cost to be paid by the Company amounts to 38,000 EUR, and not 46,000 EUR, and on September 26, 2023, the Court decided the amount of such cost to be reimbursed to the Defendants by the Company is approximately 38,000 EUR plus interest. A complaint filed on January 16, 2015 against TauroPharm in the District Court of Cologne has also been withdrawn by the Company and the proceedings were closed. In connection with the aforementioned proceedings, the Company was required to provide security deposits to the District Courts of Mannheim and Cologne in the aggregate amount of 116,000 EUR (approximately $123,000) of which 36,000 EUR (approximately $38,000) was received in April 2023 and 10,000 EUR (approximately $11,000) was received on October 16, 2023.

Commitments** **Assignment Agreement

In-Licensing

In 2008, the Company entered into a License and Assignment Agreement (the "NDP "ND License Agreement") with ND Partners, LLP ("NDP"). Pursuant to the NDP 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"). The Company acquired such licenses and patents through its assignment and assumption of NDP's rights under certain separate license agreements by and between NDP and Dr. Hans-Dietrich Polaschegg, Dr. Klaus Sodemann and Dr. Johannes Reinmueller. As consideration in part for the rights to the NDP Technology, 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.

The Under the ND License Agreement, the Company is required to make cash payments to NDP upon the achievement of certain regulatory and sales-based milestones. Certain of the milestone payments are to be made in the form of shares of common stock currently held in escrow for NDP, and other milestone payments are to be paid in cash. The maximum aggregate number of shares issuable upon achievement of milestones is 29,109 shares. In 2014, a certain milestone was achieved resulting in the release of 7,277 shares held in escrow. The number As of December 31, 2022, the shares held remaining in escrow as were cancelled in accordance with the terms of September 30, 2023 is 21,832 shares of common stock. The the escrow agreement. Under the ND License Agreement, the maximum aggregate amount of cash payments due upon achievement of milestones is was $3,000,000, with the balance being $2,500,000 $2,000,000 as of September 30, 2023 March 31, 2024 and December 31, 2022 December 31, 2023. Events that trigger The initial licensing fee of $325,000, the fair value of the 5% equity interest and an additional $500,000, as a result of the achievement of one milestone, payments include but are not limited 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 reaching of various stages of regulatory approval and upon achieving certain worldwide FDA approval. During the three months ended March 31, 2024, the Company determined it was probable that the net sales amounts. There were no milestones will be achieved during in future periods and, as a result, the nine months ended September 30, 2023 Company recorded a license intangible asset of $2,000,000 and 2022. 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.

The NDP license intangible asset will be amortized as cost of goods sold over its estimated economic life, beginning in the second quarter of 2024, correlating with the product launch of DefenCath and the first period in which revenue will be recognized.

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. notice in the event the Company's Board determines not to proceed with the development of the NDP Technology. If the NDP ND License Agreement is terminated by either party, the Company's rights to the NDP Technology will revert back to NDP.

Note 5 — - Stockholders' Equity:
Common Stock

In November 2020, On August 12, 2021, the Company filed a shelf registration statement (the "2020 Shelf Registration"), under which the Company could issue and sell up to an aggregate of $100,000,000 of shares of its common stock, $0.001 par value per share. In November 2020, the Company allocated to its at-the-market program ("ATM program"), an aggregate of $50,000,000 out of the $100,000,000 total under the 2020 "2021 Shelf Registration which has been fully sold.

In August 2021, the Company entered into an at-the-market issuance sales agreement with Truist Securities, Inc. and JMP Securities LLC, as sales agents, pursuant to which the Company may sell, from time to time, an aggregate of up to $50,000,000, which was the remaining balance under the 2020 Shelf Registration, of its common stock through the sales agents under its ATM program, subject to limitations imposed by the Company and subject to the sales agents' acceptance, such as the number or dollar amount of shares registered under the 2020 Shelf Registration to which the offering relates. The sales agents are entitled to a commission of up to 3% of the gross proceeds from the sale of common stock sold under the ATM program. As of September 30, 2023, the Company has $18,700,000 available under its ATM program relating to its 2020 Shelf Registration.

Also, in August 2021, the Company filed a new shelf registration statement (the "2021 Shelf Registration" Statement") for the issuance of up to $150,000,000 $150,000,000. As of shares of its common stock of which $104,400,000 is currently March 31, 2024, the Company has $104,000,000 available for under the issuance of equity, debt or equity-linked securities. 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.

During the nine months quarter ended September 30, 2023 March 31, 2023, the Company sold an aggregate of 2,866,421 shares 1,684,592 of its common stock under the previous ATM program and realized net proceeds of $12,500,000. $7,200,000.

The Company did not sell any shares of its common stock under its ATM program during the three months quarter ended September 30, 2023 March 31, 2024. For the three and nine months ended September 30, 2022, the Company sold an aggregate of 76,933 and 3,097,273 shares of its common stock, respectively, and realized net proceeds of $300,000 and $11,700,000, respectively.

Restricted Stock Units

In May 2023, 103,734 January 2024, the Company granted 283,333 restricted stock units ("RSUs") vested pursuant to its executive officers under its Amended and Restated 2019 Omnibus Stock Incentive Plan with a weighted average grant made 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 chief executive officer, of which 66,291 shares of common stock were 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 Company issued by 42,844 shares upon the Company vesting of 25% of these RSUs and 37,443 27,989 shares were withheld in lieu of withholding taxes.

As of September 30, 2023, March 31, 2024 and 2023, the Company had 103,735 has 366,235 and 207,469 outstanding RSUs. The RSUs, respectively, for which the Company recorded $53,000 $362,000 and $207,000 $86,000 compensation expense for the three quarter ended March 31, 2024 and nine months ended September 30, 2023 2023, respectively. As of March 31, 2024, respectively, and $88,000 and $138,000 for the three and nine months ended September 30, 2022, respectively. Unrecognized unrecognized compensation expense for these related to unvested RSUs amounted to $268,000 and the expected is $999,000, will be recognized over a weighted average remaining period for the expense to be recognized is 1.13 years of 1.8 at September 30, 2023 March 31, 2024.

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, and designated by the Company's board of directors all has designated (all with par value of $0.001 per share, share) the following were outstanding: following:

	As of September 30, 2023 and December 31, 2022			As of March 31, 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 nine three months ended September 30, 2023 March 31, 2024 and 2022, 2023, the Company granted ten-year qualified and non-qualified stock options covering an aggregate of 2,021,200 1,911,167 and 1,552,850 1,747,000 shares, respectively, of the Company's common stock under the Amended and Restated 2019 Omnibus Stock Incentive Plan, respectively. Plan. The weighted average exercise price of these options is $4.40 $3.52 and $3.84 $4.36 per share, respectively.

During the three and nine months ended September 30, 2023, the Company issued 6,666 March 31, 2024 and 64,041 shares of common stock, respectively, as a result of the exercise of stock options. The Company realized net proceeds of $20,000 and $254,000 from the exercise of stock options for the three and nine months ended September 30, 2023, respectively.

During the three and nine months ended September 30, 2023, total 2023, stock-based compensation expense for stock options issued to employees, directors, officers and consultants was $950,000 $2,082,000 and $4,069,000, respectively, and $895,000 and $3,057,000 for the three and nine months ended September 30, 2022, $2,130,000, respectively.

As of September 30, 2023 March 31, 2024, there was approximately $6,500,000 $9,132,000 in total unrecognized compensation expense related to stock options granted, which expense will be recognized over an expected remaining weighted average period of 1.5 1.6 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 nine three months ended September 30, 2023 March 31, 2024:

Expected term	5 years	
Expected term (in years)		5.96
Volatility weighted average	104.98 %	98.98 %
Dividend yield weighted average	0.0 %	0 %
Risk-free interest rate weighted average	3.69 %	4.13 %
Weighted average grant date fair value of options granted during the period	$ 3.43	$ 2.82

The

During the three months ended March 31, 2024, the Company estimated uses the simplified method to calculate the expected term which takes into account the vesting term and the expiration date of the stock options granted based on anticipated exercises in future periods. 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 common stock. stock price for the expected term. The expected dividend yield of 0.0% 0% reflects the Company's current and expected future policy for dividends on the Company's common stock. To determine the risk-free interest rate, the Company utilized the U.S. Treasury yield curve in effect at the time of grant with a term consistent with the expected term of the Company's awards which is 5 years for employees and 10 years for non-employees.

Pre-Funded Warrants

On July 3, 2023, pursuant to the Underwriting Agreement, the Company's issued pre-funded warrants to purchase 2,500,625 shares of its common stock to certain investors. The pre-funded warrants to purchase up to an aggregate of 2,500,625 shares of the Company's commons stock had a price of $3.999 per pre-funded warrant, which represents the per share public offering price for the common stock less the $0.001 per share exercise price for each such pre-funded warrant pursuant to the Underwriting Agreement. The Company realized net proceeds of approximately $9,400,000 from the sale of the pre-funded warrants.

awards.

Note 6 — - 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 in September 2020. on September 16, 2020.

The Company entered into an operating lease for office space in Germany that began in July 2017. 2017 that is set to expire in June 2024. The rental agreement has a three-month term which automatically renews and includes 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 nine months ended September 30, 2023 March 31, 2024 and 2023 was approximately $52,000, and $155,000, respectively, and $52,000 and $157,000 for the three and nine months ended September 30, 2022, respectively, which includes costs associated with leases for which ROU assets have been recognized as well as short-term leases.

At September 30, 2023 March 31, 2024, the Company has a total operating lease liability of $703,000, $632,000, of which $147,000 approximately $155,000 and $477,000 were classified as operating lease liabilities, short-term and operating lease liabilities, net of current portion, respectively, on the 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 $556,000 was classified as operating lease liabilities, net of current portion, on the condensed consolidated balance sheet. At December 31, 2022, the Company's total operating lease liability was $803,000, of which $135,000 was classified as operating lease liabilities, short-term and $668,000 $517,000 was classified as operating lease liabilities, net of current portion, on the condensed consolidated balance sheet. Operating ROU assets as of September 30, 2023 March 31, 2024 and December 31, 2022 are $675,000 December 31, 2023 were $605,000 and $775,000, $640,000, respectively.

For each of the three and nine months ended September 30, 2023 March 31, 2024 and 2022, 2023, cash paid for amounts included in the measurement of lease liabilities in operating cash flows from operating leases was $50,000 $51,000 and $150,000, $50,000, respectively.

The weighted average remaining lease term as of September 30, 2023 March 31, 2024 and 2022 was 4.1 2023 were 3.6 and 6.0 4.6 years, respectively, and the weighted average discount rate for operating leases was 9% at September 30, 2023 March 31, 2024 and 2022. 2023.

As of September 30, 2023 March 31, 2024, maturities of lease liabilities were as follows:

Remainder of 2023	$ 51,000
2024	205,000
2025	208,000
2026	211,000
2027	169,000
Total future minimum lease payments	844,000
Less imputed interest	(141,000)
Total	$ 703,000

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

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 2022 audited 2023 Annual Report on Form 10-K, filed with the Securities and Exchange Commission, or the SEC, on March 30, 2023 March 12, 2024.

Forward Looking Statements

This Quarterly Report on Form 10-Q contains "forward-looking statements" that involve risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. The statements contained in this Quarterly Report on Form 10-Q that are not purely historical are forward-looking statements within the meaning of 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, referred that are subject to herein as the Exchange Act. 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" "would," and similar expressions or variations intended to identify forward-looking statements. All statements, are based on the other than statements of historical facts, regarding management's expectations, beliefs, and assumptions of our management based on information currently available to management, including, but not limited to, statements regarding the timing goals, plans or ultimate outcome of the FDA's review of our New Drug Application, or NDA, the Prescription Drug User Fee Act target action date, our commercial launch efforts, the results of FDA pre-approval inspections as part of its NDA review process, the timing and qualification of our contract manufacturing organization alternative manufacturing site, and our future financial position, financing plans, future revenues, projected costs and sufficiency of our cash and short term investments to fund our operations CorMedix's prospects should be considered forward-looking. Such forward-looking statements statements. Readers are subject to risks, uncertainties and other important factors cautioned that could cause actual results and the timing of certain events to may differ materially from future results expressed projections or implied by such forward-looking statements. estimates due to a variety of important factors, and readers are directed to the Risk Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those discussed in CorMedix's filings with the section titled "Risk Factors" included in our SEC, including its most recent Annual Report on Form 10-K, as well as any amendments thereto, as filed with the SEC and copies of which are incorporated herein by reference. Furthermore, available free of charge at the SEC's website at www.sec.gov or upon request from CorMedix. 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 report. Except 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, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements. Set forth below is a summary of the principal risks we face: 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 not achieve profitability when expected or we may never be profitable. profitable
- Our expectation regarding the sufficiency of our existing cash, cash equivalents, short-term investments and available resources to fund the anticipated launch of DefenCath through anticipated profitability.
- Our ability to generate revenue from anticipated future product sales, and our ability to achieve and maintain profitability.
- Our cost of operations could increase significantly more than what we expect depending on the costs to complete our development and commercialization programs for DefenCath.
- We may need to finance additional our future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. Any additional funds that we obtain arrangements, which may not be on terms favorable to us or our stockholders and may require us to relinquish valuable rights. 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 Product Candidates our Other Products

- DefenCath,Successful development and commercialization of our lead product candidate, has received Fast Track designation and Qualified Infectious Disease Product designation from the FDA, but we cannot provide assurances that these designations will not be rescinded. candidates is uncertain
- We may seek a sales partner in the U.S. if DefenCath receives FDA approval or we may undertake marketing and sales of DefenCath in the U.S. on our own. If we are unable to sell DefenCath or any other product after approval or are unable to establish sufficient marketing and sales capabilities, we may not be able to generate significant or any product revenues.
- If the FDA requires a second clinical trial for DefenCath or imposes additional manufacturing requirements to approve the NDA, the development of DefenCath will take longer and cost more to complete, and we will likely need significant additional funds to undertake a second trial, if required.
- 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. revenues

Risks Related to Healthcare Regulatory and Legal Compliance Matters

- Successful developmentDefenCath, and commercialization of our other products is uncertain. product candidates (if approved), will be subject to extensive post-approval regulation
- If we fail to comply with environmental, health and safetyCurrent healthcare laws and regulations we could become subject in the U.S. and future legislative or regulatory reforms to fines or penalties or incur costs that could harm the U.S. healthcare system may affect our business. ability to commercialize DefenCath and future marketed products profitably
- The successful commercializationWe are subject to laws and regulations relating to privacy, data protection and the collection and processing of DefenCath will depend on obtaining coverage and reimbursement from third-party payors. personal data. Failure to maintain compliance with these regulations could create additional liabilities for us
- Health systems, physicians and other key stakeholders may not accept and use our products.
- Changes in funding for the FDA, Centers for Medicare & Medicaid Services or other government agencies or future government shutdowns or disruptions could cause delays in the submission and regulatory review of marketing applications, which could negatively impact our business or prospects
- Clinical trials required for our new product candidates may or for expanded uses of DefenCath will be expensive and time-consuming, and their outcome is uncertain. uncertain

Risks Related to Our Business and Industry

- If we fail to comply with international regulatory requirements, we could be subject to regulatory delays, finesHealthcare institutions, physicians and patients may not accept or other penalties. use our products
- Even if approved, our products will be subject to extensive post-approval regulation.

Risks Related to our Business Industry

- Competition and technological change may make our product candidates products and technologies less attractive or obsolete. 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. 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. 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. harmed
- We may not successfully manage our growth. 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. incur
- We may be exposed to liability claims associated with the use of hazardous materials and chemicals. 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 including interest rate fluctuations, may pose challenges to our business strategy, which relies on funding from the financial markets or collaborators. collaborators

Risks Related to Our Intellectual Property

- If we materially breach or default under any of our license agreements, the licensor party to such agreement will ND License Agreement with NDP, NDP would have the right to terminate the license agreement, ND License Agreement, which termination may would materially harm our business. business
- If we and our licensors 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. products
- Ongoing and future intellectualIntellectual property disputes could require us to spend time and money to address such disputes and could limit our intellectual property rights. rights
- The decisions by the European and German patent offices may affect patent rights in other jurisdictions.
- If we infringe the rights of third parties we could be prevented from selling products and forced to pay damages and defend against litigation. litigation

Risks Related to Dependence on Third Parties

- If we or our collaborators are unable to manufacture our products in sufficient quantities or are unable to obtain regulatory approvals for a experience quality or manufacturing facility, problems, we may be unable to meet demand for our products and we may lose potential revenues. 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 our products. 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. 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. all

Risks Related to Our Common Stock

- We will depend on third party suppliers and contract manufacturers for the manufacturing of our product candidates and have no direct control over the cost of manufacturing our product candidates. Increases in the cost of manufacturing our product candidates would increase our costs of conducting clinical trials and could adversely affect our future profitability.

Risks Related to our Common Stock

- We may need additional financing to fund our activities in the future, which may dilute our stockholders.
- Our executive officers and directors may sell shares of their stock, and these sales could adversely affect our stock price. price
- Our common stock price has fluctuated considerably and is likely to remain volatile, in part due to the limited market for our common stock and you could lose all or a part of your investment. 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. 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. 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. exchange
- Laws, rules and regulations relating to public companies may be costly and impact our ability to attract and retain directors and executive officers. officers
- Our internal control over financial reporting and our disclosure controls and procedures may not prevent all possible errors that could occur. occur
- Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer. suffer
- We do not intend to currently pay dividends on our common stock so any returns on our common stock will may be limited to the value of our common stock. 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. and (collectively, with our wholly owned subsidiaries, CorMedix Europe GmbH and CorMedix Spain, S.L.U., (collectively referred to herein as "we," "us," "our" and or the "Company"), is a biopharmaceutical company focused on developing and commercializing therapeutic products for the prevention and treatment of life-threatening diseases and conditions.

Our primary focus is on the development commercialization of our lead product, candidate, DefenCath,®, for potential commercialization in the United States, or U.S., and other key markets as a catheter lock solution, or CLS. We have in-licensed the worldwide rights to develop and commercialize DefenCath and Neutrolin®. The name DefenCath is the U.S. proprietary name conditionally that was approved by the U.S. Food and Drug Administration, or FDA, while the name Neutrolin was used in the European Union, or EU, and other territories where we received CE-Mark approval for the commercial distribution of Neutrolin as a CLS regulated as a medical device. DefenCath/Neutrolin FDA.

DefenCath is a novel an antimicrobial catheter lock solution ("CLS") (a formulation of taurolidine 13.5 mg/mL, and heparin 1000 USP Units/mL) intended for indicated to reduce the reduction and prevention incidence of catheter-related bloodstream infections and thrombosis ("CRBSI") in adult patients requiring with kidney failure receiving chronic hemodialysis through a central venous catheters catheter ("CVC"). It is indicated for use in clinical settings such as hemodialysis, total parenteral nutrition, a limited and oncology. Infection and thrombosis represent key complications among hemodialysis, total parenteral nutrition and oncology patients with central venous catheters. These complications 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 intravenous, or IV antibiotic treatment, long-term anticoagulation therapy, removal/replacement of the central venous catheter, CVC, related treatment costs, and as well as increased mortality. We believe DefenCath addresses can address a significant unmet medical need and a potential large market opportunity. need.

In January 2015, On November 15, 2023, we announced that the FDA designated approved the NDA for DefenCath as a Qualified Infectious Disease Product, or QIDP, for prevention of catheter-related blood stream infections in patients with end stage renal disease receiving hemodialysis through a central venous catheter. Catheter-related blood stream infections and clotting can be life-threatening. The QIDP designation provides five years of market exclusivity in addition to the five years granted for a new chemical entity upon approval of a New Drug Application, or NDA. In addition, in January 2015, the FDA granted Fast Track designation to DefenCath Catheter Lock Solution, a designation intended to facilitate development and expedite review of drugs that treat serious and life-threatening conditions so that the approved drug can reach the market expeditiously. The Fast Track designation of DefenCath provides us with the opportunity to meet with the FDA on a more frequent basis during the development process, and also ensures eligibility to request priority review of the marketing application.

In December 2015, we launched our Phase 3 Prospective, Multicenter, Double-blind, Randomized, Active Control Study to Demonstrate Safety & Effectiveness of DefenCath/Neutrolin in Preventing Catheter-related Bloodstream Infection in Subjects on Hemodialysis for End Stage Renal Disease, or LOCK-IT-100, in patients with hemodialysis catheters in the U.S. The clinical trial was designed to demonstrate the safety and effectiveness of DefenCath compared to the standard of care CLS, Heparin, in preventing CRBSI. The primary endpoint for the trial assessed reduce the incidence of CRBSI and time to CRBSI for each study subject. Secondary endpoints were catheter patency, which was defined as required use of tPA, or removal of catheter due to dysfunction, and removal of catheter for any reason.

As previously agreed with the FDA, an interim efficacy analysis was performed when the first 28 potential CRBSI cases were identified in our LOCK-IT-100 study that occurred through early December 2017. Based on these first 28 cases, there was a highly statistically significant 72% reduction in CRBSI by DefenCath relative to the active control of heparin (p=0.0034). Because the pre-specified level of statistical significance was reached for the primary endpoint and efficacy had been demonstrated with no safety concerns, the LOCK-IT-100 study was terminated early. The study continued enrolling and treating subjects until study termination, and the final analysis was based on a total of 795 subjects with a total of 41 cases. There was a 71% reduction in CRBSI by DefenCath relative to heparin, which was highly statistically significant (p=0.0006), with a good safety profile.

The FDA granted our request for a rolling submission and review of the NDA, which is designed to expedite the approval process for products being developed to address an unmet medical need. Although the FDA usually requires two pivotal clinical trials to provide substantial evidence of safety and effectiveness for approval of an NDA, the FDA will in some cases accept one adequate and well-controlled trial, where it is a large multicenter trial with a broad range of subjects and study sites that has demonstrated a clinically meaningful and statistically very persuasive effect on a disease with potentially serious outcome.

In March 2020, we began the modular submission process for the NDA for DefenCath for the prevention of CRBSI in hemodialysis patients, and in August 2020, the FDA accepted for filing the DefenCath NDA. The FDA also granted our request for priority review, which provides for a six-month review period instead of the standard ten-month review period. As we announced in March 2021, the FDA informed us in its Complete Response Letter, or CRL, that it could not approve the NDA for DefenCath in its present form. The FDA noted concerns at the third-party manufacturing facility after a review of records requested by the FDA and provided by the contract manufacturing organization, or CMO. Additionally, the FDA required a manual extraction study to demonstrate that the labeled volume can be consistently withdrawn from the vials despite an existing in-process control to demonstrate fill volume within specifications.

In April 2021, we and the CMO met with the FDA to discuss proposed resolutions for the deficiencies identified in the CRL to us and the Post-Application Action Letter, or PAAL, received by the CMO from the FDA for the NDA for DefenCath. There was an agreed upon protocol for the manual extraction study identified in the CRL, which has been successfully completed. Addressing the FDA's concerns regarding the qualification of the filling operation necessitated adjustments in the process and generation of additional data on operating parameters for manufacture of DefenCath. We and the CMO determined that additional process qualification was needed with subsequent validation to address these issues. The FDA did not request additional clinical data and did not identify any deficiencies related to the data submitted on the efficacy or safety of DefenCath from LOCK-IT-100. In draft labeling discussed with the FDA, the FDA added that the initial approval will be for the limited population of adult patients with kidney failure receiving chronic hemodialysis through a central venous catheter. This CVC. DefenCath is consistent with our request indicated for approval pursuant 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 Limited Population Pathway for Antibacterial and Antifungal Drugs, or LPAD. LPAD, passed as part risk of CRBSI by up to 71% in a Phase 3 clinical study. As a result of the 21st Century Cures Act, November 2023 FDA approval, CorMedix is a new program intended to expedite the development and approval of certain antibacterial and antifungal drugs to treat serious or life-threatening infections in limited populations of patients with unmet needs. LPAD provides for a streamlined clinical development program involving smaller, shorter, or fewer clinical trials and is intended to encourage the development of safe and effective products that address unmet medical needs of patients with serious bacterial and fungal infections. We believe that LPAD will provide additional flexibility for the FDA to approve DefenCath to reduce CRBSI in the limited population process of patients with kidney failure receiving hemodialysis through a central venous catheter. launching the product commercially.

On February 28, 2022, we resubmitted the NDA for DefenCath to address the CRL issued by the FDA. In parallel, our third-party manufacturer submitted responses to the deficiencies identified at the manufacturing facility is listed in the PAAL issued by Orange Book as having NCE exclusivity (5 years) expiring on November 15, 2028, and the FDA concurrently with the CRL. On March 28, 2022, we announced that the resubmission Generating Antibiotic Incentives Now or GAIN exclusivity extension of the NDA for 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 had been accepted for filing by the FDA. The FDA considered the resubmission as a complete, Class 2 response with a six-month review cycle. The CMO notified us that an onsite inspection by the FDA was conducted that resulted in FORM FDA 483 observations that are being addressed. The CMO submitted responses to the inspectional observations along with a corrective action plan and requested a meeting with the FDA to discuss. We were also notified by our supplier of heparin, an active pharmaceutical ingredient, or API, for DefenCath, that an inspection by the FDA for an unrelated API resulted in a Warning Letter due to deviations from good manufacturing practices for the unrelated API.

On August 8, 2022, we announced receipt of a second CRL from the FDA regarding our DefenCath NDA. The FDA stated that the DefenCath NDA cannot be approved until deficiencies conveyed to the CMO and the heparin API supplier are resolved to the satisfaction of the FDA. There were no other requirements identified by the FDA for us prior to resubmission of the NDA. The FDA has acknowledged the progress reports submitted by the CMO on implementation of the ongoing corrective actions. Validation of manufacturing with heparin from an alternative supplier is underway to prepare for resubmission of the NDA in the event that the Warning Letter at our current API supplier remains unresolved. Corrective actions have been implemented to address the inspectional observations at the CMO and are under review by the FDA.

On May 15, 2023, we resubmitted the NDA for DefenCath after meeting with the FDA to discuss timing and content of the resubmission. At the meeting, the FDA informed us that it is in receipt of the close out report for inspectional observations received from our existing CMO, and the NDA resubmission with the CMO can be done at our discretion. The NDA was resubmitted, accepted for filing by the FDA and received a target review date of November 15, 2023 Qualified Infectious Disease Product ("QIDP"). As the resubmission contained new manufacturing information, it was classified as a Class 2 resubmission with a six-month review period. The FDA scheduled a pre-approval inspection at the CMO's facility as part of the NDA review process, and such inspection was completed by the end of September 2023, and the Company is not aware of any outstanding review items.

As part of the NDA review process, the FDA again reviewed the proposed tradename DefenCath, which was conditionally approved, to ensure that there is no potential confusion with another approved or pending product name that is also under review. FDA has again granted conditional approval of the proposed tradename DefenCath, pending NDA approval.

We previously announced agreements with additional CMOs, including Alcami Corporation and Siegfried Hameln, with proven capabilities for manufacturing commercial sterile parenteral drug products. They may function as alternate manufacturing sites for DefenCath for the U.S. market. As part of the technology transfer and validation of the manufacturing process, we also qualified an alternate source of heparin API sourced from a major U.S. supplier.

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 the 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 is 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.

We announced on May 1, 2023 that the United States Patent and Trademark Office (“USPTO”) allowed our patent claims directed to a locking solution composition for treating and reducing infection and flow reduction in central venous catheters. Our newly allowed U.S. Patent Application (No. 17/721,699) reflects the unique and proprietary formulation of our product, DefenCath, for which we resubmitted our NDA on May 15, 2023. The newly allowed application provides patent coverage that supplements 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.

We intend to 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 CRBSI CRBSIs in total parenteral nutrition patients using a central venous catheter and in certain oncology patients using a central venous catheter.

In addition to DefenCath, we are sponsoring a pre-clinical research collaboration for 2024, the use of taurolidine as a possible treatment for rare orphan pediatric tumors. In February 2018, Company anticipates discussing with the FDA granted orphan drug designation to taurolidine potential pathways for the treatment of neuroblastoma in children. We may seek one or more strategic partners or other sources of capital to help us develop and commercialize taurolidine for the treatment of neuroblastoma in children. We are also evaluating opportunities for the possible expansion of taurolidine as a platform compound for use in certain medical devices. Patent applications have been filed in several indications, including wound closure, surgical meshes, and wound management. We would seek to establish development/commercial partnerships to advance these programs. expanded indications.

We were 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 a deferral by 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 that 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 have made a commitment 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 after approval of during our Type C meeting with the NDA for use in adult hemodialysis patients. FDA during 2024. 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, would provide provides an additional six months of exclusivity that attaches to the end of existing marketing exclusivity. exclusivity and patent periods for DefenCath. Depending on the timing of final report submission, DefenCath would then have the potential to 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 including of exclusivity pursuant to New Chemical Entity (5 years) and QIDP designation (5 years). associated with this pediatric study.

Since our inception, our operations have been primarily limited to conducting clinical trials The Company previously marketed and establishing manufacturing for our sold Neutrolin, a CLS product candidates, licensing product candidates, business and financial planning, research and development, seeking regulatory where we received CE-Mark approval for our products, initial commercialization activities for DefenCath in the U.S. and Neutrolin commercial distribution in the EU and other foreign markets, and maintaining and improving our patent portfolio. We have funded territories. The Company previously elected to discontinue sales of Neutrolin for lack of commercial viability. The winding down of our operations primarily through debt in the EU is nearly complete and equity financings. We Neutrolin sales in both the EU and the Middle East have generated significant losses been discontinued since 2022.

In addition, the following events have occurred subsequent to date, and we expect to use substantial amounts of cash for our operations as we prepare our pre-launch commercial activities for DefenCath for the U.S. market, pursue business development activities, and incur additional legal costs to defend our intellectual property. As of September 30, 2023, we had an accumulated deficit of approximately $306,946,000. We are unable to predict the extent of any future losses or when we will become profitable, if ever. 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

Revenue 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 September 30, 2023 March 31, 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, 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, or CRO, contract manufacturers, investigative sites, and consultants; (iii) technology and intellectual property license costs; (iv) manufacturing development costs; (v) personnel related expenses, including salaries, stock–based compensation expense, benefits, travel and related costs for the personnel involved in drug development; (vi) activities relating to regulatory filings and the advancement of our product candidates through preclinical 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, related including previously expensed pre-NDA approval inventory amounting to the manufacturing of the product that could potentially be available to support the commercial launch prior to marketing approval. approximately $6,400,000. All R&D is expensed as incurred.

Conducting a significant amount of development is central to our business model. Product candidates in later-stage clinical development generally have higher development costs than those in earlier stages of development, primarily due to the significantly increased size and duration of the clinical trials.

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

Development timelines, probability of success and development costs vary widely. We are currently focused on securing the marketing approval for commercialization of DefenCath in the U.S. as well as on continuing sales in foreign markets where Neutrolin is approved. In December 2015, we signed an agreement with a clinical research organization, or CRO, to help us conduct our LOCK-IT-100 Phase 3 clinical trial in hemodialysis patients with central venous catheters to demonstrate the efficacy and safety of DefenCath in preventing catheter-related bloodstream infections and blood clotting in subjects receiving hemodialysis therapy as treatment for end stage renal disease. Our LOCK-IT-100 study was completed and all costs related to the agreement with the CRO has been paid.

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

Selling, General and Administrative Expense

Selling, general and administrative, or SG&A, expense includes costs related to commercial personnel, medical education professionals, marketing and advertising, salaries and other related costs, including stock-based compensation expense, for persons serving in our executive, sales, finance and accounting functions. Other SG&A expense includes facility-related costs not included in R&D expense, promotional expenses, costs associated with industry and trade shows, and professional fees for legal services and accounting services.

Foreign Currency Exchange Transaction Gain (Loss)

Foreign currency exchange transaction gain (loss) is the result of re-measuring transactions denominated in a currency other than our functional currency and is reported in the condensed consolidated statement of operations as a separate line item within other income (expense). The intercompany loans outstanding between our company based in New Jersey Jersey-based subsidiary and our Germany-based subsidiary based in Germany are will not expected to be repaid in the foreseeable future and the nature of the funding advanced is 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 our convertible debt, amortization of debt discount and on financing of expenditures.

Results of Operations

Comparison of the Three Months Ended March 31, 2024 and nine months ended September 30, 2023 compared to three and nine months ended September 30, 2022. 2023

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

	For the Three Months Ended September 30,		% Increase (Decrease)	For the Nine Months Ended September 30,		% Increase (Decrease)
	2023	2022		2023	2022	
Revenue	$ -	$ 6,817	(100)%	$ -	$ 35,706	(100)%
Cost of sales	-	(1,469)	(100)%	-	(3,328)	(100)%
Gross profit	-	5,348	(100)%	-	32,378	(100)%
Operating Expenses:						
Research and development	(2,663,976)	(2,339,268)	14%	(10,866,236)	(7,836,327)	39%
Selling, general and administrative	(7,803,307)	(4,628,014)	69%	(22,422,808)	(14,430,791)	55%
Total operating expenses	(10,467,283)	(6,967,282)	50%	(33,289,044)	(22,267,118)	50%
Loss from operations	(10,467,283)	(6,961,934)	50%	(33,289,044)	(22,234,740)	50%
Interest income	765,241	93,417	719%	1,761,808	142,511	1,136%
Foreign exchange transaction (loss) gain	(29,199)	23,572	(224)%	(30,222)	31,598	(196)%
Interest expense	(13,113)	(8,776)	49%	(27,740)	(17,740)	56%
Total other income	722,929	108,213	568%	1,703,846	156,369	990%
Loss before income taxes	(9,744,354)	(6,853,721)	42%	(31,585,198)	(22,078,371)	43%
Tax benefit	-	-	(100)%	-	585,617	(100)%
Net loss	(9,744,354)	(6,853,721)	42%	(31,585,198)	(21,492,754)	47%
Other comprehensive (loss) income	(6,298)	6,253	(201)%	1,656	(41,358)	(104)%
Comprehensive loss	$ (9,750,652)	$ (6,847,468)	42%	$ (31,583,542)	$ (21,534,112)	47%

Revenue. Revenue for each of the three and nine months ended September 30, 2023 was $0 as compared to $7,000 and $36,000 in the same periods last year, respectively, a decrease of $7,000 and $36,000, respectively. The decrease for each period was the result of winding down of our operations in the EU and the discontinuance of Neutrolin sales in both the EU and the Middle East.

	For the Three Months Ended March 31,		% of Change Increase (Decrease)
	2024	2023	
Revenues, net	$ -	$ -	-
Cost of revenues	(819)	-	100%
Gross loss	(819)	-	-
Operating Expenses:			
Research and development	(838)	(3,407)	(75)%
Selling, general and administrative	(15,048)	(7,610)	98%
Total operating expenses	(15,886)	(11,017)	44%
Loss from operations	(16,705)	(11,017)	52%
Interest income	857	446	92%
Foreign exchange transaction (loss) gain	(4)	12	(132)%
Interest expense	(10)	(9)	12%
Net loss before income taxes	(15,862)	(10,568)	50%
Tax benefit	1,395	-	-

Net loss	(14,467)	(10,568)	37%
Other comprehensive (loss) income	(10)	19	(158)%
Comprehensive loss	$ (14,477)	$ (10,549)	37%

Cost of Sales. *Revenues.* Cost of revenues include direct and indirect costs related to the manufacturing and distribution of DefenCath, including product cost, packaging services, freight, 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 was $0 for each with anticipated sales volume increases. There were no direct costs of product sales during the three and nine months ended September 30, 2023 compared to $1,000 and $3,000 March 31, 2024 as commercial launch of DefenCath occurred in the same periods last year, respectively, a decrease second quarter of $1,000 2024. Indirect costs of $819,000 for the three months ended March 31, 2024 represent the proportion of salaries, benefits and $3,000, respectively. The decrease for each period was the result of winding down of our operations in the EU and the discontinuance of Neutrolin sales in both the EU and the Middle East. 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 $2,664,000 $838,000 for the three months ended September 30, 2023 March 31, 2024, an increase a decrease of $325,000, $2,569,000, or 14% 75%, from $2,339,000 $3,407,000 for the same period in 2022. 2023. The increase decrease was driven by an increase in the approval of DefenCath. As a result of the post FDA approval commercial operations, costs related to medical affairs activities of $283,000, and an increase in certain personnel expenses that supported R&D efforts prior to the FDA approval of $226,000 due to additional hires DefenCath have been recognized in 2023 selling, general and administrative expense during the three months ended March 31, 2024, as compared to 2022, partially offset by the same period last year that were recognized in R&D. In addition, a decrease in portion of the costs related to the technical and quality operations for the manufacturing of DefenCath, prior to its potential marketing approval previously recognized in R&D, are now capitalized as a result of $145,000 and the FDA approval. There was also a decrease in consulting fees non-cash charges for stock-based compensation of $61,000. $339,000.

R&D expense was $10,866,000 for the nine months ended September 30, 2023, an increase of $3,030,000, or 39%, from $7,836,000 for the same period in 2022. The increase was driven by an increase in personnel expenses of $1,285,000 due to additional hires in 2023 as compared to 2022, an increase in costs related to medical affairs activities of $854,000, and an increase in costs related to the technical and quality operations for the manufacturing of DefenCath prior to its potential marketing approval of $845,000, partially offset by a decrease in consulting fees of $190,000.

Selling, General and Administrative Expense. SG&A expense was $7,803,000 $15,048,000 for the three months ended September 30, 2023 March 31, 2024, an increase of $3,175,000, $7,438,000 or 69% 97%, from $4,628,000 $7,610,000 for the same period in 2022. 2023. The increase was primarily attributable to an increases in personnel expenses of $3,756,000, due to the hiring of sales force, medical affairs and marketing personnel. The increase in costs related to medical affairs, market research studies and pre-launch launch activities in preparation for the potential commercial marketing approval of DefenCath of $2,279,000, and an increase in personnel expenses of $880,000 as $2,679,000 was a result of additional SG&A hires the post FDA approval operations that supported R&D efforts prior to the FDA approval, which are now recognized in 2023 as compared to 2022. These increases were partially offset, among others of lesser significance, by a decrease in legal fees of $98,000.

SG&A selling, general and administrative expense was $22,423,000 for during the nine three months ended September 30, 2023, an increase of $7,992,000, or 55%, from $14,431,000 for the same period in 2022. The increase was primarily attributable to an increase in costs related to market research studies and pre-launch activities in preparation for the potential marketing approval of DefenCath of $6,001,000, an increase in personnel expenses of $1,817,000 and an increase March 31, 2024. There were also increases in non-cash charges for stock-based compensation of $870,000. These increases were partially offset, among others of lesser significance, by a decrease in legal $449,000, consulting fees of $829,000. $281,000 and business development activities of $218,000.

Interest Income. Interest income was $765,000 $857,000 for the three months ended September 30, 2023 March 31, 2024 compared to $93,000 $446,000 for the same period last year, an increase of $672,000. $411,000, or 92%. 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.

Interest income was $1,762,000 for the nine months ended September 30, 2023 compared to $143,000 for the same period last year, an increase of $1,619,000. 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). Foreign exchange transaction gains (losses) are gain (loss) were due to the re-measuring of transactions denominated in a currency other than our functional currency. For the quarter ended September 30, 2023 March 31, 2024, there was a loss of $29,000 compared to $4,000 and a gain of $24,000 $12,000 for the same period in 2022. 2023.

A foreign exchange transaction loss of $30,000 was recorded for the nine months ended September 30, 2023 compared to a gain of $32,000 for the same period in 2022.

Interest Expense. Interest expense was $13,000 $10,000 for the three months ended September 30, 2023 March 31, 2024 as compared to $9,000 for the same period in 2022, 2023, an increase of $4,000, $1,000, primarily due to higher interest rates on expenses that were financed this year as compared to the same period last year.

Interest expense was $28,000 for the nine months ended September 30, 2023 as compared to $18,000 for the same period in 2022, an increase of $10,000 due to higher interest rates on expenses that were financed this year as compared to the same period last year.

Tax Benefit. Tax benefits for the nine months ended September 30, 2022 of $586,000 was an income tax benefit due to the sale of our unused net operating losses for the state fiscal years 2021 through the New Jersey Economic Development Authority Program. There was no tax benefit from the unused net operating losses that were utilized for 2023.

Other Comprehensive (Loss) Income (Loss). 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 (loss) which resulted in a the loss of $6,000 $10,000 for the three months ended September 30, 2023, March 31, 2024 and a gain of $6,000 $19,000 for the three months ended September 30, 2022 March 31, 2023.

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 resulted in a gain of $2,000 and a loss of $41,000 for the nine months ended September 30, 2023 and 2022, respectively.

Liquidity and Capital Resources

Sources of Liquidity

As a result of our cost of sales, R&D and SG&A expenditures and the lack of substantial product sales revenue, our ongoing operations have not been profitable since our inception. During the nine three months ended September 30, 2023 March 31, 2024, we received net proceeds of $42,878,000 from the issuance of 9,000,093 shares did not have any sales of common stock and pre-funded warrants to purchase 2,500,625 shares of common stock in connection with the public offering, $12,515,000 from the issuance of 2,866,421 shares of common stock under our at-the-market-issuance sales agreement, or ATM program, as compared to $11,724,000 $7,200,000 net proceeds for the same period in 2022 2023 from the issuance of 3,097,273 1,684,592 shares of common stock. We may need will continue to raise additional capital through various potential be reliant on external sources such as equity and/or debt financings, strategic relationships, potential strategic transactions or out-licensing of cash for the foreseeable future until we are able to generate profits.

In March 2024, we received $1,395,000, net of expenses, from the sale of our products until profitability is achieved, if ever. 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.

Net Cash Used in Operating Activities

Net cash used in operating activities for the nine three months ended September 30, 2023 March 31, 2024 was $27,664,000 $17,310,000 as compared to $18,202,000 $10,394,000 for the same period in 2022, 2023, an increase of $9,462,000. $6,916,000. The increase is primarily driven by an increase in net loss of $10,092,000, $3,899,000, attributable to a net increase in operating expenses of $11,022,000, primarily due $4,869,000. As a result of the approval of DefenCath, cost of revenues of $819,000, which are indirect fixed costs related to increased pre-launch commercial activities for DefenCath.

Net Cash Used in Investing Activities

Cash used in investing activities for the nine months ended September 30, 2023 was $17,659,000 as compared to $3,708,000 provided by in the same period in 2022, an increase manufacturing and distribution of $13,951,000, mainly driven by increased amounts invested in short-term investments DefenCath were recognized, as compared to the same period last year, these costs were recognized as R&D. There was also an increase in 2022. prepaid expenses and other current assets of $1,226,000 and decreases in accrued expenses of $2,416,000 and accounts payable of $1,453,000, among others of lesser significance.

Net Cash Provided by Financing (Used in) Investing Activities

Net cash provided by financing investing activities for the nine months year ended September 30, 2023 March 31, 2024 was $55,449,000 $8,945,000 as compared to $11,853,000 $14,687,000 of net cash used in investing activities for the same period in 2022, 2023. The net cash provided during the three months ended March 31, 2024, was mainly driven by an increase in maturity of $43,596,000, primarily 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 months ended March 31, 2023 was $7,200,000, attributable to the net proceeds we received generated from the sale of our common stock and pre-funded warrants in the public offering that closed during the nine months ended September 30, 2023. our at-the-market program, or ATM program.

Funding Requirements and Liquidity

Our total cash, on hand cash equivalents and short-term investments as of September 30, 2023 March 31, 2024 was $86,587,000, $58,552,000, excluding restricted cash of $187,000, $179,000, compared with $58,792,000 at December 31, 2022 $76,031,000 for the year ended December 31, 2023, excluding $226,000 restricted cash. During the nine months ended September 30, 2023, we received an aggregate cash of $42,878,000 of net proceeds from the public offering and exercise of the underwriters' option and an aggregate of $12,515,000 of net proceeds from the issuance of 2,866,421 shares of common stock under our ATM program. $181,000. As of August 8, 2023 March 31, 2024, we have approximately $18,700,000 $104,400,000 available under our ATM program and $104,400,000 under the shelf registration statement filed in August 2021 Shelf Registration Statement for the issuance of equity, debt or equity-linked securities.

Because our business has not generated positive operating cash flow, and if we do not raise significant revenue, 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 primarily on activities leading to the pre-launch and commercialization 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, on hand 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 licensing sale of our products or through strategic alliances. We expect to continue to utilize our implement an ATM program, if conditions allow, which may be utilized to support our ongoing funding requirements. Additionally, we may seek to sell additional equity or debt securities through one or more discrete transactions, or enter into a strategic alliance arrangement, but can provide no assurances that any such financing or strategic alliance arrangement will be available on acceptable terms, or at all. Moreover, the incurrence of indebtedness would result in increased fixed obligations and could contain covenants that would restrict our operations. Raising additional funds through strategic alliance arrangements with third parties may require significant time to complete and could force us to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or to grant licenses on terms that may not be favorable to us or our stockholders. Our actual cash requirements may vary materially from those now planned due to a number of factors, including any change in the 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 grow generate product sales for DefenCath in the U.S., should we receive FDA approval. 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 to the commercialization of DefenCath upon approval, and pursue business development activities, and incur additional legal costs to defend our intellectual property. activities.

We currently estimate that our as of March 31, 2024, we have sufficient cash, and cash equivalents and short-term investments and available resources as of September 30, 2023, will be sufficient to fund our operations for at least twelve months from the filing date issuance of this Quarterly Report on Form 10-Q, and will enable us to fund the launch of DefenCath through to anticipated profitability. 10-Q. These estimates are based upon the assumption of an approval of the DefenCath NDA in November 2023, commercial launch in the first second quarter of 2024, and other base case assumptions for market penetration, average selling price, R&D research and development expense and commercial infrastructure cost. Additional financing may be needed to build out our commercial infrastructure should we receive FDA approval and to continue our operations. If we are unable to raise additional funds when needed, we may be forced to slow or discontinue our preparations for 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 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 Policies and 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 accounting principles generally accepted in the United States, or 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 and expenses. On an ongoing basis, we evaluate these estimates and judgments, including those described below. We base our estimates on our historical experience and on various other assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about revenue and the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results and experiences may differ materially from these estimates.

For the nine-month three-month period ended September 30, 2023 March 31, 2024, there were no significant changes to our critical accounting policies and estimates as identified in our Annual Report on Form 10-K for the year ended December 31, 2022 December 31, 2023, except for the intangible asset probability assessment (see Note 2, "Summary of Significant Accounting Policies," 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. 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.

Item 3. Quantitative and Qualitative Disclosure about Market Risk.

Interest Rate Risk

We are exposed The Company is not required to market risks provide the information called for in the ordinary course of our business. Market risk is the risk of change in fair value of a financial instrument this item due to changes in interest rates, equity prices, financing, exchange rates or other factors. These market risks are principally limited to interest rate fluctuations.

We had cash, cash equivalents and short-term investments (excluding restricted cash) of $86,587,000 and $58,792,000 at September 30, 2023 and December 31, 2022, respectively, consisting primarily of funds in cash, money market accounts, U.S. government agency securities, high-grade corporate obligations and commercial paper with original maturities of more than 90 days. The primary objective of our investment activities is to preserve principal and liquidity while maximizing income without significantly increasing risk. We do not enter into investments for trading or speculative purposes. Due to the short-term nature of our investment portfolio, we do not believe an immediate 10.0% increase in interest rates would have its status as a material effect on the fair market value of our portfolio, and accordingly we do not expect our operating results or cash flows to be materially affected by a sudden change in market interest rates.

Our results of operations and cash flows are subject to fluctuations due to changes in interest rates. We do not believe that we are materially exposed to changes in interest rates. We do not currently use interest rate derivative instruments to manage exposure to interest rate changes. We estimate that a 1% unfavorable change in interest rates would not have a material effect on interest expense for the nine months ended September 30, 2023.

Inflation Risk

Inflation generally affects us by increasing our cost of labor and pricing of contracts and agreements. We do not believe that inflation had a material effect on our business, financial condition, or results of operations during the nine months ended September 30, 2023. Smaller Reporting Company.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures are designed only to provide reasonable assurance that information to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Under the supervision and with the participation of our management, including our Chief Executive Officer and 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 September 30, 2023 March 31, 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 quarter ended September 30, 2023, or in other factors period covered by this report, that could significantly affect these controls, 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, 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.

See 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, 2022 December 31, 2023. The information set forth in this Quarterly Report on Form 10-Q, including the risk factors presented below, updates and should be read in conjunction with the risk factors and information disclosed in such Annual Report.

Our internal control over financial reporting and our disclosure controls and procedures may not prevent all possible errors that could occur.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with GAAP. Failure on our part to have effective internal financial and accounting controls would cause our financial reporting to be unreliable, could have a material adverse effect on our business, operating results, and financial condition, and could cause the trading price of our common stock to fall dramatically. In June 2023, our registered public accounting firm agreed to a settlement with the SEC with respect to certain matters relating to systemic quality control failures and violations of audit standards in connection with audit work for hundreds of special purpose acquisition company (SPAC) clients beginning at the latest in 2020 and continuing through 2022. We are actively monitoring the situation but do not currently believe this settlement will affect CorMedix or our financial statements. In future periods, if the process required by Section 404 of the Sarbanes-Oxley Act reveals any material weaknesses or significant deficiencies, the correction of any such material weaknesses or significant deficiencies could require remedial measures which could be costly and time-consuming. In addition, in such a case, we may be unable to produce accurate financial statements on a timely basis. Any associated accounting restatement could create a significant strain on our internal resources and cause delays in our release of quarterly or annual financial results and the filing of related reports, increase our costs and cause management distraction. Any of the foregoing could cause investors to lose confidence in the reliability of our financial statements, which could cause the market price of our common stock to decline and make it more difficult for us to finance our operations and growth.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds, and Issuer Purchases of Equity Securities. Proceeds.

None.

Item 3. Default Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

During the three months ended September 30, 2023, no director or officer of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K. None.

Item 6. Exhibits.

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

Exhibit Number	Description
	Description
31.1*	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	
31.2*	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	
32.1**	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	
32.2**	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	
101.INS	Inline XBRL Instance Document.
101.SCH	
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	
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.

** Furnished, not 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
Date: November 14, 2023By:

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, 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: November 14, 2023
May 9, 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, 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: November 14, 2023
May 9, 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 September 30, 2023 March 31, 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: November 14, 2023 May 9, 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 September 30, 2023 March 31, 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: November 14, 2023 May 9, 2024

By: /s/ Matthew David
Name: Matthew David
Title: Chief Financial Officer
(Principal Financial Officer)

DISCLAIMER

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