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

FORM 10-Q

(Mark One)

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

For the Quarterly Period Ended March 31, 2024

or

[_] 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: **0-12305**

KORU MEDICAL SYSTEMS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**13-3044880**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
100 Corporate Drive, Mahwah, New Jersey	**07430**
(Address of principal executive offices)	(Zip Code)

(845) 469-2042
(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, $0.01 par value	**KRMD**	**The Nasdaq Stock Market**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. **[X]** 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). **[X]** 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 emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer [_]	Accelerated filer [_]
Non-accelerated filer **[X]**	Smaller reporting company **[X]**
	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 **[X]** No

As of May 1, 2024, 45,764,225 shares of common stock, $0.01 par value per share, were outstanding, which excludes 3,420,502 shares of treasury stock.

KORU MEDICAL SYSTEMS, INC.
FORM 10-Q
FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2024
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PART I — FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

KORU MEDICAL SYSTEMS, INC.
BALANCE SHEETS
(UNAUDITED)

	March 31, 2024	December 31, 2023
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 10,820,317	$ 11,482,240
Accounts receivable less allowance for doubtful accounts of $24,777 as of March 31, 2024 and $24,777 as of December 31, 2023	4,392,511	4,045,211
Inventory	3,147,312	3,481,301
Other receivables	288,714	28,889
Prepaid expenses	830,408	1,218,288
TOTAL CURRENT ASSETS	19,479,262	20,255,929
Property and equipment, net	3,755,530	3,837,657
Intangible assets, net of accumulated amortization of $406,801 and $390,341 as of March 31, 2024 and December 31, 2023, respectively	737,901	754,361
Operating lease right-of-use assets	3,428,885	3,514,055
Deferred income tax assets, net of allowance for non-realization of deferred tax assets of $6,391,452 and $6,002,777 for March 31, 2024 and December 31, 2023, respectively	—	—
Other assets	98,970	98,970
TOTAL ASSETS	$ 27,500,548	$ 28,460,972
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 1,774,185	$ 975,193
Accrued expenses	1,459,405	1,711,427
Note payable	159,031	314,344
Other liabilities	457,653	512,520
Accrued payroll and related taxes	519,441	462,941
Financing lease liability – current	111,103	109,540
Operating lease liability – current	372,109	368,313
TOTAL CURRENT LIABILITIES	4,852,927	4,454,278
Financing lease liability, net of current portion	288,253	316,623
Operating lease liability, net of current portion	3,241,837	3,336,300
TOTAL LIABILITIES	8,383,017	8,107,201
STOCKHOLDERS' EQUITY		
Common stock, $0.01 par value, 75,000,000 shares authorized, 49,143,589 and 49,089,864 shares issued 45,723,087 and 45,669,362 shares outstanding as of March 31, 2024, and December 31, 2023, respectively	491,436	490,899
Additional paid-in capital	47,717,888	47,018,707
Treasury stock, 3,420,502 shares as of March 31, 2024 and December 31, 2023, at cost	(3,843,562)	(3,843,562)
Accumulated deficit	(25,248,231)	(23,312,273)
TOTAL STOCKHOLDERS' EQUITY	19,117,531	20,353,771
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 27,500,548	$ 28,460,972

The accompanying notes are an integral part of these financial statements.

KORU MEDICAL SYSTEMS, INC.
STATEMENTS OF OPERATIONS
(UNAUDITED)

	Three Months Ended March 31,	
	2024	**2023**
NET REVENUES	$ 8,197,798	$ 7,392,605
Cost of goods sold	3,094,500	3,245,570
Gross Profit	5,103,298	4,147,035
OPERATING EXPENSES		
Selling, general and administrative	5,357,620	5,425,877
Research and development	1,475,674	1,564,869
Depreciation and amortization	231,370	213,117
Total Operating Expenses	7,064,664	7,203,863
Net Operating Loss	(1,961,366)	(3,056,828)
Non-Operating Income/(Expense)		
Loss on currency exchange	(11,479)	(680)
Loss on disposal of fixed assets, net	(300)	(56,279)
Interest income, net	37,187	125,502
TOTAL OTHER INCOME	25,408	68,543
LOSS BEFORE INCOME TAXES	(1,935,958)	(2,988,285)
Income Tax Benefit	—	577,400
NET LOSS	$ (1,935,958)	$ (2,410,885)
NET LOSS PER SHARE		
Basic	$ (0.04)	$ (0.05)
Diluted	$ (0.04)	$ (0.05)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING		
Basic	45,712,224	45,487,593
Diluted	45,712,224	45,487,593

The accompanying notes are an integral part of these financial statements.

KORU MEDICAL SYSTEMS, INC.
STATEMENTS OF CASH FLOWS
(UNAUDITED)

	For the Three Months Ended March 31,	
	2024	**2023**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	$ (1,935,958)	$ (2,410,885)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense and warrant expense	699,718	881,222
Depreciation and amortization	231,370	213,117
Deferred income taxes	—	(577,400)
Loss on disposal of fixed assets	300	56,279
ROU landlord credit	(5,497)	(5,497)
Changes in operating assets and liabilities:		
Increase in Accounts receivable	(607,125)	(647,994)
Decrease / (Increase) in Inventory	333,989	(233,551)
Decrease in Prepaid expenses and other assets	387,880	288,786
(Decrease) / Increase in Other liabilities	(54,867)	4,207
Increase / (Decrease) in Accounts payable	798,992	(888,679)
Increase / (Decrease) in Accrued payroll and related taxes	56,500	(41,984)
Decrease in Accrued expenses	(252,022)	(1,298,204)
NET CASH USED IN OPERATING ACTIVITIES	(346,720)	(4,660,583)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property and equipment	(133,083)	(272,605)
Purchases of intangible assets	(0)	(11,232)
NET CASH USED IN INVESTING ACTIVITIES	(133,083)	(283,837)
CASH FLOWS FROM FINANCING ACTIVITIES		
Payments on indebtedness	(155,313)	(214,892)
Payments on finance lease liability	(26,807)	(24,080)
NET CASH USED IN FINANCING ACTIVITIES	(182,120)	(238,972)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(661,923)	(5,183,392)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	11,482,240	17,408,257
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 10,820,317	$ 12,224,865
Supplemental Information		
Cash paid during the periods for:		
Interest	$ 12,296	$ 12,326
Income taxes	$ —	$ —
Schedule of Non-Cash Operating, Investing and Financing Activities:		
Issuance of common stock as compensation	$ 123,804	$ 175,776

The accompanying notes are an integral part of these financial statements.

KORU MEDICAL SYSTEMS, INC.
STATEMENTS OF STOCKHOLDERS' EQUITY
(UNAUDITED)

Three Months Ended March 31, 2024

	Common Stock		Additional Paid-in	Retained	Treasury	Total Stockholders'
	Shares	Amount	Capital	Deficit	Stock	Equity
BALANCE, DECEMBER 31, 2023	49,089,864	$ 490,899	$ 47,018,707	$ (23,312,273)	$ (3,843,562)	$ 20,353,771
Issuance of stock-based compensation	53,725	537	123,267	—	—	123,804
Compensation expense related to stock options	—	—	393,113	—	—	393,113
Compensation related to Restricted Stock	—	—	130,676	—	—	130,676
Issuance of warrants	—	—	52,125	—	—	52,125
Net loss	—	—	—	(1,935,958)	—	(1,935,958)
BALANCE, MARCH 31, 2024	49,143,589	$ 491,436	$ 47,717,888	$ (25,248,231)	$ (3,843,562)	$ 19,117,531

Three Months Ended March 31, 2023

	Common Stock		Additional Paid-in	Retained	Treasury	Total Stockholders'
	Shares	Amount	Capital	Deficit	Stock	Equity
BALANCE, DECEMBER 31, 2022	48,861,891	$ 488,619	$ 44,252,117	$ (9,571,211)	$ (3,843,562)	$ 31,325,963
Issuance of stock-based compensation	48,875	489	175,287	—	—	175,776
Compensation expense related to stock options	—	—	535,059	—	—	535,059
Compensation related to Restricted Stock	50,000	500	169,887			170,387
Net loss	—	—	—	(2,410,885)	—	(2,410,885)
BALANCE, MARCH 31, 2023	48,960,766	$ 489,608	$ 45,132,350	$ (11,982,096)	$ (3,843,562)	$ 29,796,300

KORU MEDICAL SYSTEMS, INC.
NOTES TO THE UNAUDITED FINANCIAL STATEMENTS

NOTE 1 — NATURE OF OPERATIONS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

NATURE OF OPERATIONS

KORU MEDICAL SYSTEMS, INC. (the "Company," "KORU Medical," "we," "us" or "our") designs, manufactures and markets proprietary portable and innovative medical devices primarily for the subcutaneous drug delivery market as governed by the United States Food and Drug Administration (the "FDA") quality and regulatory system and international regulations and standards for quality system management. The Company operates as one segment.

BASIS OF PRESENTATION

The accompanying financial statements should be read in conjunction with the Company's annual report on Form 10-K for the year ended December 31, 2023 ("Annual Report"). In accordance with the rules and regulations of the U.S. Securities and Exchange Commission ("SEC"), the Company has omitted footnote disclosures that would substantially duplicate the disclosures contained in the audited financial statements of the Company. The accompanying interim financial statements are unaudited and reflect all adjustments which are in the opinion of management necessary for a fair statement of the Company's financial position, results of operations, and cash flows for the periods presented. All such adjustments are of a normal, recurring nature. The Company's results of operations and cash flows for the interim periods are not necessarily indicative of the results of operations and cash flows that it may achieve in future periods.

CASH AND CASH EQUIVALENTS

For purposes of the statements of cash flows, the Company considers all short-term investments with an original maturity of three months or less to be cash equivalents. The Company has historically held cash balances in excess of $250,000 at its primary commercial bank, which exceeds FDIC insurance limits. To reduce the risk of uninsured deposits, the Company entered an insured cash sweep program with KeyBank during the second quarter of 2023 to automatically invest its uninsured bank cash balances over $250,000 into FDIC insured banks so there is no more than $250,000 maintained at any one bank. As of March 31, 2024 the Company has an investment balance of $10.2 million in a US Treasury bill that matures every 90 days.

PATENTS

Costs incurred in obtaining patents have been capitalized and are being amortized over the legal life of the patents.

STOCK-BASED COMPENSATION

The Company maintains a stock option plan and an omnibus equity incentive plan under which it grants stock options to certain executives, key employees and consultants. The fair value of each option grant is estimated on the date of the grant using the Black-Scholes option-pricing model. All options are charged against income at their fair value. The entire compensation expense of the award is recognized over the vesting period.

The Company also maintains a non-employee director compensation plan. Shares of stock granted for director fees are recorded at the fair value of the shares at the grant date.

The Company issues restricted stock awards. Restricted stock awards are equity classified and measured at the fair market value of the underlying stock at the grant date. The fair value of restricted stock awards vesting at certain market capitalization thresholds were estimated on the date of grant using the Brownian Motion Monte Carlo lattice model. The fair value of restricted stock awards with time-based vesting were estimated on the date of grant at the current stock price. The fair value of restricted stock awards vesting at certain annual sales growth thresholds were estimated as of the date of Board acknowledgement of the achievement, at the current stock price. We recognize restricted stock expense using the straight-line attribution method over the requisite service period and account for forfeitures as they occur.

NET LOSS PER COMMON SHARE

Basic net loss per common share is calculated by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted net loss per common share is computed by dividing net loss by the weighted average number of common and common equivalent shares outstanding during the period. The Company's potentially dilutive common shares are those that result from diluted common stock options and unvested restricted stock awards. The calculation of diluted net loss per share excluded stock options of zero and 14,626, respectively, in weighted-average shares for each of the three months ended March 31, 2024 and 2023, as their effect was anti-dilutive as a result of the net loss incurred for those periods.

The calculation of diluted net loss per share excluded stock options, performance-based restricted stock and performance-based restricted stock units (PSUs) of 904,496 and 914,626 respectively, in weighted-average shares for each of the three months ended March 31, 2024 and 2023, as their effect was anti-dilutive as a result of the net loss incurred for those periods.

The following securities were not included in the computation of diluted shares outstanding for the three months ended March 31, 2024, and 2023 because the effect would be anti-dilutive:

	Three Months Ended March 31,	
	2024	**2023**
Common stock options	$ —	$ 14,626
PSUs	54,496	—
Restricted stock	850,000	900,000
Total	$ 904,496	$ 914,626

Therefore, diluted weighted average number of shares outstanding and diluted net loss per share were the same as basic weighted average number of shares outstanding and net loss per share for the three months ended March 31, 2024 and 2023.

	Three Months Ended March 31,	
	2024	**2023**
Net loss	$ (1,935,958)	$ (2,410,885)
Weighted Average Outstanding Shares:		
Basic weighted average shares outstanding	45,712,224	45,487,593
Dilutive effect of outstanding stock options and unvested restricted stock	—	—
Diluted weighted average shares outstanding	45,712,224	45,487,593
Net loss per share		
Basic	$ (0.04)	$ (0.05)
Diluted	$ (0.04)	$ (0.05)

USE OF ESTIMATES IN THE FINANCIAL STATEMENTS

The preparation of financial statements in conformity with United States generally accepted accounting principles ("GAAP") requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates. Important estimates include but are not limited to asset lives, deferred tax valuation allowances, inventory valuation, and customer rebate and incentive accruals. The results of operations for the three months ended March 31, 2024 are not necessarily indicative of the results that may be expected for the entire 2024 fiscal year.

REVENUE RECOGNITION

Our revenues are derived from three business sources: (i) domestic core (which consists of US and Canada), (ii) international core, and (iii) novel therapies. Our core domestic and international revenues consist of sales of our syringe drivers, tubing and needles ("Product Revenue") for the delivery of subcutaneous drugs that are FDA cleared for use with the KORU Medical infusion system, with the primary delivery for immunoglobulin to treat Primary Immunodeficiency Diseases ("PIDD") and Chronic Inflammatory Demyelinating Polyneuropathy ("CIDP"). Novel therapies consist of Product Revenue for feasibility/clinical trials (pre-clinical studies, Phase I, Phase II, Phase III) of biopharmaceutical companies in the drug development process as well as non-recurring engineering services ("NRE") revenues (including testing and registration services) received from biopharmaceutical companies to ready or customize the FREEDOM System for clinical and commercial use across multiple drug categories.

For Product Revenue, we recognize revenues when shipment occurs, and at which point the customer obtains control and ownership of the goods. Shipping costs generally are billed to customers and are included in Product Revenue.

The Company generally does not accept return of goods shipped unless it is a Company error. The only credits provided to customers are for defective merchandise. The Company warrants the syringe driver from defects in materials and workmanship under normal use and the warranty does not include a performance obligation. The costs under the warranty are expensed as incurred.

Rebates are provided to distributors for the difference in selling price to distributor and pricing specified to select customers. In addition, rebates are provided to customers for meeting growth targets. Provisions for both distributor pricing and customer growth rebates are variable consideration and are recorded as a reduction of revenue in the same period the related sales are recorded or when it is probable the growth target will be achieved.

We recognize NRE revenue under an input method, which recognizes revenue on the basis of our efforts or inputs (for example, resources consumed, labor hours expended, costs incurred, or time elapsed) to the satisfaction of a performance obligation relative to the total expected inputs to the satisfaction of that performance obligation (i.e. completion milestone). The input method that we use is based on costs incurred.

Contracts are often modified to account for changes in contract specifications and requirements. Contract modifications exist when the modification either creates new, or changes existing, enforceable rights and obligations. Generally, when contract modifications create new performance obligations, the modification is considered to be a separate contract and revenue is recognized prospectively. When contract modifications change existing performance obligations, the impact on the existing transaction price and measure of progress for the performance obligation to which it relates is generally recognized as an adjustment to revenue (either as an increase in or a reduction of revenue) on a cumulative catch-up basis. Contract assets primarily represent revenue earnings over time that are not yet billable based on the terms of the contracts. Contract liabilities (i.e., deferred revenue) consist of fees invoiced or paid by the Company's customers for which the associated performance obligations have not been satisfied and revenue has not been recognized based on the Company's revenue recognition criteria described above. As of March 31, 2024, the Company has recognized a contract asset of zero.

The following table summarizes net revenues by geography for the three months ended March 31, 2024, and 2023:

	Three Months Ended March 31,	
	2024	**2023**
Revenues		
Domestic	$ 6,384,083	$ 6,283,965
International	1,813,715	1,108,640
Total	$ 8,197,798	$ 7,392,605

ACCOUNTING PRONOUNCEMENTS RECENTLY ADOPTED

The Company considers the applicability and impact of all recently issued accounting pronouncements. Recent accounting pronouncements not specifically identified in our disclosures are either not applicable to the Company or are not expected to have a material effect on our financial condition or results of operations.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which amends guidance on reporting credit losses for assets held at amortized cost basis and available for sale debt securities. For assets held at amortized cost basis, Topic 326 eliminates the probable initial recognition threshold in current GAAP and, instead, requires an entity to reflect its current estimate of all expected credit losses. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis of the financial assets to present the net amount expected to be collected. For available for sale debt securities, credit losses should be measured in a manner similar to current GAAP, however Topic 326 will require that credit losses be presented as an allowance rather than as a write-down. This ASU affects entities holding financial assets and net investment in leases that are not accounted for at fair value through net income. The amendments affect loans, debt securities, trade receivables, net investments in leases, off balance sheet credit exposures, reinsurance receivables, and any other financial assets not excluded from the scope that have the contractual right to receive cash. The Company adopted the pronouncement on January 1, 2023, and there was no impact on its financial statements.

FAIR VALUE MEASUREMENTS

Fair value is the exit price that would be received to sell an asset or paid to transfer a liability. Fair value is a market-based measurement that should be determined using assumptions that market participants would use in pricing an asset or liability. Valuation techniques used to measure fair value should maximize the use of observable inputs and minimize the use of unobservable inputs. To measure fair value, the Company uses the following fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable:

- Level 1 – Quoted prices in active markets for identical assets or liabilities.

- Level 2 – Inputs other than Level 1 that are observable for the asset or liability, either directly or indirectly, such as quoted prices for similar assets and liabilities in active markets; quoted prices for identical or similar assets or liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data by correlation or other means.

- Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. Value is determined using pricing models, discounted cash flow methodologies, or similar techniques and includes instruments for which the determination of fair value requires significant judgment or estimation.

The carrying amounts of cash and cash equivalents, including investments in short-term U.S. Treasury bills, accounts receivable, prepaid expenses, accounts payable and accrued expenses are considered to be representative of their fair values because of the short-term nature of those instruments. There were no transfers between levels in the fair value hierarchy during the three months ended March 31, 2024 and 2023.

IMPAIRMENT OF LONG-LIVED ASSETS

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be fully recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than the carrying amount. The impairment loss, if recognized, would be based on the excess of the carrying value of the impaired asset over its respective fair value. The Company did not record any impairment losses through March 31, 2024.

NOTE 2 — PROPERTY AND EQUIPMENT

Property and equipment consists of the following at:

	March 31, 2024	December 31, 2023
Furniture and office equipment	$ 1,423,093	$ 1,412,164
Leasehold improvements	1,953,653	1,953,653
Manufacturing equipment and tooling	3,311,833	3,193,113
Total property and equipment	6,688,579	6,558,930
Less: accumulated depreciation and amortization	(2,933,049)	(2,721,273)
Property and equipment, net	$ 3,755,530	$ 3,837,657

Depreciation and amortization expense was $214,910 and $197,233 for the three months ended March 31, 2024 and 2023, respectively.

NOTE 3 — STOCK-BASED COMPENSATION

The Company maintains a stock option plan and omnibus equity incentive plan under which it grants stock options to certain executives, key employees and consultants. It also has granted stock options outside of the plans as inducement awards. The fair value of each option grant is estimated on the date of the grant using the Black-Scholes option-pricing model. All options are charged against income at their fair value. The entire compensation expense of the award is recognized over the vesting period.

The Company issues performance share units (PSUs) under its omnibus equity incentive plan. Performance share units are equity classified and measured at the fair market value of the underlying stock at the grant date.

Shares of stock granted for director fees under the non-employee director compensation plan and under its omnibus equity incentive plan are recorded at the fair value of the shares at the grant date.

The Company issues restricted stock awards under its omnibus equity incentive plan and outside the plan as incentive awards. Restricted stock awards are equity classified and measured at the fair market value of the underlying stock at the grant date. The fair value of restricted stock awards vesting at certain market capitalization thresholds were estimated on the date of grant using the Brownian Motion Monte Carlo lattice model. The fair value of other restricted stock awards were estimated on the date of grant at the current stock price. We recognize restricted stock expense using the straight-line attribution method over the requisite service period and account for forfeitures as they occur.

The Company has three equity incentive plans: the 2015 Stock Option Plan, as amended (the “2015 Plan”), the 2021 Omnibus Equity Incentive Plan (the “2021 Plan”), and the Non-Employee Director Compensation Plan. The Company has also issued restricted stock and stock options as employment inducement awards to its Chief Executive Officer and Chief Commercial Officer, respectively.

The 2015 plan provides for the grant of incentive stock options and nonqualified stock options. As of March 31, 2024, there were 2,120,000 shares reserved for outstanding awards and 604,250 shares available for issuance under the 2015 Plan. Additional options may be issued under the 2015 Plan as outstanding options are forfeited.

The 2021 Plan provides for the grant of incentive stock options, nonqualified stock options, stock awards, restricted stock awards, restricted stock units and/or stock appreciation rights to employees, consultants and directors. As of March 31, 2024, there were 656,744 shares reserved for outstanding awards and 152,811 shares available for issuance under the 2021 Plan. Additional awards may be issued under the 2021 Plan as outstanding awards are forfeited.

Each non-employee director of the Company (other than the Chairman of the Board) is eligible to receive $110,000 annually, to be paid quarterly $12,500 in cash and $15,000 in common stock. The Chairman of the Board is eligible to receive $140,000 annually, to be paid quarterly $12,500 in cash and $22,500 in common stock. Non-employee director compensation is paid pursuant to the Non-Employee Director Compensation Plan. All payments were and are pro-rated for partial service.

Time Based Stock Options

The following table summarizes the activities for our stock options with time based vesting for the three months ended March 31, 2024, and 2023.

	March 31,	
	2024	2023
Dividend yield	0.00%	0.00%
Expected Volatility	46.18 - 46.21%	61.3%
Weighted-average volatility	—	—
Expected dividends	—	—
Expected term (in years)	10	10
Risk-free rate	4.2% - 4.3%	3.53%

The following table summarizes the status of the stock options:

	Three Months Ended March 31,			
	2024		2023	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at January 1	3,256,250	$ 3.66	3,035,000	$ 3.93
Granted	65,000	$ 2.21	40,000	$ 3.91
Exercised	—	$ —	—	$ —
Forfeited	381,250	$ 7.0	—	$ —
Outstanding at March 31	2,940,000	$ 3.19	3,075,000	$ 3.92
Options exercisable at March 31	1,393,750	$ 3.59	1,010,000	$ 4.63
Weighted average fair value of options granted during the period	—	$ 1.39	—	$ 2.83
Stock-based compensation expense	—	$ 393,113	—	$ 535,059

Total stock-based compensation expense was $393,113 and $535,059 for the three months ended March 31, 2024, and 2023, respectively. No cash was received from option exercises for the three months ended March 31, 2024, and 2023, respectively.

The following table presents information pertaining to options outstanding at March 31, 2024:

Range of Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$2.18 - $4.37	2,940,000	6.9 years	$ 3.19	1,393,750	$ 3.59

As of March 31, 2024, there was $2,719,478 of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the Plans. That cost is expected to be recognized over a weighted-average period of 46 months. The total fair value of shares vested as of March 31, 2024, and March 31, 2023, was $3,884,426 and $3,511,874, respectively.

Performance Based Stock Options

The following table summarizes the activities for our unvested performance based stock option awards for the three months ended March 31, 2024, and 2023.

	Three Months Ended March 31,			
	2024		2023	
	Shares	Weighted Average Grant-Date Fair Value	Shares	Weighted Average Grant-Date Fair Value
Unvested at January 1	200,000	$ 1.48	—	$ —
Granted	—	$ —	—	$ —
Vested	—	$ —	—	$ —
Forfeited/canceled	—	$ —	—	$ —
Unvested at March 31	200,000	$ 1.48	—	$ —

Total stock-based compensation expense was $8,121 and zero for the three months ended March 31, 2024, and 2023, respectively.

As of March 31, 2024, there was $168,223 of unrecognized compensation cost related to unvested employee performance based options. This amount is expected to be recognized over a weighted-average period of 36 months.

Restricted Stock Awards and PSUs

The following table summarizes the activities for our restricted stock awards and PSUs for the three months ended March 31, 2024, and 2023.

	Three Months Ended March 31,			
	2024		2023	
	Shares	Weighted Average Grant-Date Fair Value	Shares	Weighted Average Grant-Date Fair Value
Unvested at January 1	904,496	$ 1.80	950,000	$ 3.04
Granted	—	$ —	—	$ —
Vested	—	$ —	50,000	$ 3.31
Forfeited/canceled	—	$ —	—	$ —
Unvested at March 31	904,496	$ 1.80	900,000	$ 2.93

Total stock-based compensation expense was $122,551 and $170,387 for the three months ended March 31, 2024, and 2023, respectively.

As of March 31, 2024, and 2023, there was $755,513 and $1,447,790 of unrecognized compensation cost related to unvested employee restricted stock awards and PSUs. This amount is expected to be recognized over a weighted-average period of 21 months.

Common Stock Warrants

The following table summarizes the activities for our common stock warrants issued in connection with our loan financing agreement with HSBC for the three months ended March 31, 2024, and 2023.

	Three Months Ended March 31,			
	2024		2023	
	Shares	Weighted Average Grant-Date Fair Value	Shares	Weighted Average Grant-Date Fair Value
Unvested at January 1	—	$ —	—	$ —
Granted	76,104	$ 1.37	—	$ —
Vested	38,052	$ 1.37	—	$ —
Forfeited/canceled	—	$ —	—	$ —
Unvested at March 31	38,052	$ 1.37	—	$ —

As of March 31, 2024, and 2023, there was $52,125 and zero of unrecognized cost related to unvested warrants.

NOTE 4 — DEBT OBLIGATIONS

On July 28, 2023, the Company entered into a commercial insurance premium finance and security agreement with AON Premium Finance, LLC in the aggregate principal amount of $0.57 million bearing an annual percentage rate of 9.5%, to finance its insurance premiums. Monthly payments are due on the first of each month beginning August 1, 2023 through June 1, 2024. The balance of the AON note was $314,344 as of December 31, 2023 and $159,031 as of March 31, 2024.

On March 8, 2024, the Company entered into a loan and security agreement with HSBC Ventures USA Inc., as lender, providing for a $5,000,000 revolving credit facility and a $5,000,000 term loan facility. Borrowings are secured by a first-priority lien on substantially all of the assets of the Company, subject to customary exceptions. The revolving credit facility matures on December 31, 2025 and the term loan matures on December 1, 2028. Our former revolving credit facility with Key Bank expired during the quarter ended September 30, 2023. As of March 31, 2024, there were no outstanding borrowings under the term loan nor the revolving credit facility.

NOTE 5 — LEASES

We have finance and operating leases for our corporate office and certain office and computer equipment. Our two operating leases have remaining lease terms of 8.4 years and 4.8 years, respectively. Our three finance leases have remaining lease terms of 3.2 years, 2.75 years, and 4.5 years, respectively, as of March 31, 2024.

The components of lease expense were as follows:

	Three Months Ended March 31,	
	2024	2023
Operating lease cost	$ 111,548	$ 112,522
Short-term lease cost	3,460	52,894
Total lease cost	$ 115,008	$ 165,416
Finance lease cost:		
Amortization of right-of-use assets	$ 28,896	$ 27,223
Interest on lease liabilities	6,053	6,720
Total finance lease cost	$ 34,949	$ 33,943

Supplemental cash flow information related to leases was as follows:

	Three Months Ended March 31,	
	2024	2023
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 120,365	$ 113,813
Financing cash flows from finance leases	32,859	30,800

Supplemental balance sheet information related to leases was as follows:

	March 31, 2024	December 31, 2023
Operating Leases		
Operating lease right-of-use assets	$ 3,428,885	$ 3,514,055
Operating lease current liabilities	372,109	368,313
Operating lease long term liabilities	3,241,837	3,336,300
Total operating lease liabilities	$ 3,613,946	$ 3,704,613
Finance Leases		
Property and equipment, at cost	$ 577,929	$ 577,929
Accumulated depreciation	(190,358)	(161,461)
Property and equipment, net	$ 387,571	$ 416,468
Finance lease current liabilities	111,103	109,540
Finance lease long term liabilities	288,253	316,623
Total finance lease liabilities	$ 399,356	$ 426,163

	March 31, 2024	December 31, 2023
Weighted Average Remaining Lease Term		
Operating leases	6.6 Years	6.9 Years
Finance leases	3.6 Years	3.7 Years
Weighted Average Discount Rate		
Operating leases	5.73%	5.76%
Finance leases	6.17%	6.19%

Maturities of lease liabilities are as follows:

Year Ending December 31,	Operating Leases	Finance Leases
Remainder of 2024	$ 384,041	98,578
2025	512,055	131,437
2026	512,055	131,437
2027	512,055	74,194
2028	511,009	6,179
Thereafter	1,833,604	—
Total undiscounted lease payments	4,264,819	441,825
Less: imputed interest	(650,873)	(42,469)
Total lease liabilities	$ 3,613,946	$ 399,356

NOTE 6 — INCOME TAXES

For interim income tax reporting, the Company estimates its annual effective tax rate and applies it to fiscal year-to-date pretax loss, excluding unusual or infrequently occurring discrete items. Tax jurisdictions with losses for which tax benefits cannot be realized are excluded. The Company reported an income tax expense of zero and income tax benefit of $0.6 million for the periods ended March 31, 2024 and 2023, respectively.

We evaluate our deferred tax assets to determine if they are more likely than not to be realized by assessing both positive and negative evidence in accordance with ASC Topic 740, Income Taxes. After considering our cumulative pretax loss (the three-year period ending with the current year), as well as analyzing all available evidence, we have recorded a valuation allowance of $6.0 million against our net deferred tax assets during the year ended December 31, 2023. As of March 31, 2024, the valuation allowance is $6.4 million As we continue to assess the realizability of our deferred tax assets, reported pretax income and new evidence may result in a partial or full reduction of the valuation allowance in future periods.

Recurring items cause our effective tax rate to differ from the U.S. federal statutory rate of 21%, including U.S. federal R&D credits, U.S. state tax rates, and stock-based compensation.

Beginning in 2022, certain research and development costs are required to be capitalized and amortized over a five-year period under the Tax Cuts and Jobs Act enacted in December 2017. This change will impact the expected U.S. federal and state income tax expense and cash taxes to be paid for our fiscal 2024.

The Company files income tax returns in the U.S. federal jurisdiction and in various state jurisdictions. Income tax returns for years prior to fiscal 2020 are no longer subject to examination by tax authorities.

NOTE 7 — COMMITMENTS AND CONTINGENCIES

LEGAL PROCEEDINGS

The Company has been and may again become involved in legal proceedings, claims and litigation arising in the ordinary course of business. KORU Medical Systems Inc. is not presently a party to any litigation or other legal proceeding that is believed to be material to its financial condition.

NOTE 8 — SUBSEQUENT EVENTS

On April 8, 2024, the Company’s appeal to BSI in connection with a prior audit matter was upheld resulting in no disruption of sales of the Company to the market and patients. Our products remain certified, marketed and sold in the EU. The Company intends to address the identified nonconformance through the routine BSI assessment process.

PART I — ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Quarterly Report on Form 10-Q contains, and our officers and representatives may from time to time make, certain "forward-looking" statements (as such term is defined in the Private Securities Litigation Reform Act of 1995) and information relating to us that are based on the beliefs of the management, as well as assumptions made and information currently available. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control.

Our actual results may vary materially from the forward-looking statements made in this report due to important factors such as uncertainties associated with global health crises, inflation, war and other geopolitical conflicts, customer ordering patterns, availability and costs of raw materials and labor and our ability to recover such costs, our ability to convert inventory to a source of cash, future operating results, growth of new patient starts and the SCIg market, our ability to partner with biopharmaceutical companies in our novel therapies business, Food and Drug Administration and foreign authority regulations and the outcome of regulatory audits, introduction of competitive products, acceptance of and demand for new and existing products, ability to penetrate new markets, success in enforcing and obtaining patents, reimbursement related risks, government regulation of the home health care industry, success of our research and development effort, expanding the market of FREEDOM system demand in the SCIg market, availability of sufficient capital if or when needed, dependence on key personnel, and the impact of recent accounting pronouncements, as well as those risks and uncertainties described in Part II.— Item IA. "Risk Factors" in this report and from time to time in our past and future reports filed with the Securities and Exchange Commission, including in our Annual Report on Form 10-K for the year ended December 31, 2023 in addition to others. When used in this report, the words "estimate," "project," "believe," "may," "will," "anticipate," "intend," "expect" and similar expressions are intended to identify forward-looking statements, which include, without limitation, statements regarding reduction of inventory, and need for additional financing. Such statements reflect current views with respect to future events based on currently available information and are subject to risks and uncertainties that could cause actual results to differ materially from those contemplated in such forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. The Company does not undertake any obligation to release publicly any revision to these forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.

Throughout this report, the "Company," "KORU Medical," "we," "us" or "our" refers to KORU Medical Systems, Inc.

OVERVIEW

The Company develops, manufactures and markets proprietary portable and innovative medical devices primarily for the subcutaneous drug delivery market as governed by the United States Food and Drug Administration (the "FDA") quality and regulatory system and international regulations and standards for quality system management.

Our revenues derive from three business sources: (i) domestic core (which consists of US and Canada), (ii) international core, and (iii) novel therapies. Our domestic core and international core revenues consist of sales of our products for the delivery of subcutaneous drugs that are FDA cleared for use with the FREEDOM Infusion System, with the primary delivery for immunoglobulin to treat Primary Immunodeficiency Diseases ("PIDD") and Chronic Inflammatory Demyelinating Polyneuropathy ("CIDP"). Novel therapies revenues consist of product revenues from our infusion system (syringe drivers, tubing and needles) for feasibility/clinical trials (pre-clinical studies, Phase I, Phase II, Phase III) of biopharmaceutical companies in the drug development process as well as non-recurring engineering services revenues ("NRE") received from biopharmaceutical companies to ready or customize the FREEDOM System for clinical and commercial use.

The Company ended the first quarter of 2024 with $8.2 million in net revenues, a 10.9% increase compared with $7.4 million in the same period last year. Revenues were driven by volume growth in our core domestic and international business of 4.1% and 63.1% respectively, slightly offset by a 21.3% decline in our novel therapies business.

Gross profit for the three months ended March 31, 2024, was $5.1 million, an increase of $1 million, or 23.1%, from $4.1 million for the same period last year, driven primarily by additional revenue from volume in our core businesses and manufacturing efficiencies from our outsourced manufacturing compared to the same period last year. Gross margin was 62.3%, an increase from 56.1% in the prior year period. We define gross margin as gross profit stated as a percentage of net revenues.

Operating expenses for the three months ended March 31, 2024, were $7.1 million, compared to $7.2 million for the same period last year, driven primarily by a decrease of $0.1 million in research and development expenses.

RESULTS OF OPERATIONS

Three months ended March 31, 2024, compared to March 31, 2023

Net Revenues

The following table summarizes our net revenues for the three months ended March 31, 2024, and 2023:

	Three Months Ended March 31,		Change from Prior Year		% of Net Revenues	
	2024	2023	$	%	2024	2023
Net Revenues						
Domestic Core	$ 5,953,865	$ 5,719,135	$ 234,730	4.1%	72.7%	77.4%
International Core	1,790,483	1,097,490	692,993	63.1%	21.8%	14.8%
Total Core	7,744,348	6,816,625	927,723	13.6%	94.5%	92.2%
Novel Therapies	453,450	575,980	(122,530)	(21.3%)	5.5%	7.8%
Total	$ 8,197,798	$ 7,392,605	$ 805,193	10.9%	100%	100%

Total net revenues increased $0.8 million, or 10.9%, to $8.2 million for the three months ended March 31, 2024, as compared with the same period in 2023. Domestic Core revenues increased by 4.1% from higher consumable volumes driven by new patients starts and share gains. International Core revenues increased by 63.1%, from higher consumable and pump volumes driven largely by increased Ig supply, increased penetration within approved indications, and geographic expansion. International orders were expedited for certain distribution partners of $0.26 million in March 2024 to ensure adequate inventory to fulfill patient needs in the event of a supply disruption related to the BSI regulatory review process. Novel therapies net revenues declined by 21.3% primarily driven by a milestone completion for a collaboration agreement in the prior year period.

Gross Profit

Our gross profit for the three months ended March 31, 2024 and 2023 is as follows:

	Three Months Ended March 31,		Change from Prior Year	
	2024	2023	$	%
Gross Profit	$ 5,103,298	$ 4,147,035	$ 956,263	23.1%
Gross Margin	62.3%	56.1%		

Gross profit increased $1.0 million to $5.1 million in the three months ended March 31, 2024, compared to $4.1 million in the same period in 2023. Gross margin increased to 62.3% compared to 56.1% in the first quarter of 2023. The increase in gross margin was primarily driven by production efficiencies from outsourced manufacturing and consolidation of US manufacturing sites when compared to the prior year period.

Operating Expenses

Our selling, general and administrative, research and development and depreciation and amortization expenses for the three months ended March 31, 2024 and 2023 are as follows:

	Three Months Ended March 31,		Change from Prior Year	
	2024	2023	$	%
Selling, general and administrative	$ 5,357,620	$ 5,425,877	$ (68,257)	(1.3%)
Research and development	1,475,674	1,564,869	(89,195)	(5.7%)
Depreciation and amortization	231,370	213,117	18,253	8.6%
	$ 7,064,664	$ 7,203,863	$ (139,199)	(1.9%)

Selling, general and administrative expenses decreased $0.1 million, or 1.3%, during the three months ended March 31, 2024 compared with the same period last year.

Research and development expenses decreased $0.1 million, or 5.7% during the three months ended March 31, 2024 compared with the same period last year, primarily due to timing of project spend in support of our innovation efforts for both core and novel therapies businesses.

Depreciation and amortization expense increased by 8.6% to $231,370 in the three months ended March 31, 2024 compared with $213,117 in the three months ended March 31, 2023. The increase was driven by research and development tooling and equipment commissioned during 2023.

Net Loss

	Three Months Ended March 31,		Change from Prior Year	
	2024	2023	$	%
Net Loss	$ (1,935,958)	$ (2,410,885)	$ 474,927	19.7%

Our net loss decreased $0.5 million in the three months ended March 31, 2024 compared with the same period last year, mostly driven by an increase in gross profit of $1.0 million and a decrease in operating expenses of $0.1 million partially offset by a decrease in tax benefit of $0.6 million.

LIQUIDITY AND CAPITAL RESOURCES.

Our principal source of liquidity is our cash on hand of $10.8 million as of March 31, 2024. Our principal source of operating cash inflows is from sales of our products and NRE. Our principal cash outflows relate to the purchase and production of inventory, funding of research and development, and selling, general and administrative expenses. To develop new products, support future growth, achieve operating efficiencies, and maintain product quality, we are continuing to invest in research and development, and equipment.

Our inventory position was $3.1 million at March 31, 2024, which reflects a decrease of $0.3 million from December 31, 2023.

We expect that our cash on hand and cash flows from operations will be sufficient to meet our requirements at least through the next twelve months. Continued execution on our longer-term strategic plan may require the Company to draw on our new credit facility, take on additional debt, raise capital through issuance of equity, or a combination of both. Our future capital requirements may vary from those currently planned and will depend on many factors, including our rate of sales growth, the timing and extent of spending on various strategic initiatives including research and development, our international expansion, the timing of new product introductions, market acceptance of our solutions, and overall economic conditions including inflation and the potential impact of global supply imbalances on the global financial markets. To the extent that current and anticipated future sources of liquidity are or are expected to be insufficient to fund our future business activities and requirements, we may be required to draw on our new credit facility or seek additional equity or debt financing sooner. There can be no assurance the Company will be able to obtain the financing or raise the capital required to fund its operations or planned expansion.

Cash Flows

The following table summarizes our cash flows:

	Three Months Ended March 31, 2024	Three Months Ended March 31, 2023
Net cash used in operating activities	$ (346,720)	$ (4,660,583)
Net cash used in investing activities	$ (133,083)	$ (283,837)
Net cash used in financing activities	$ (182,120)	$ (238,972)

Operating Activities

Net cash used in operating activities was $0.3 million for the three months ended March 31, 2024 vs $4.7 million in the prior year. This net cash usage of $0.3 million was primarily due to the net loss of $1.9 million, an increase in accounts receivable of $0.3 million, a reduction of accrued expenses of $0.2 million driven by payment of 2023 bonuses, offset by an increase in accounts payable of $0.8 million, a decrease in inventory of $0.3 million, and non-cash items including stock-based compensation expense of $0.7 million, and depreciation and amortization expense of $0.2 million.

Net cash used in operating activities of $4.7 million for the three months ended March 31, 2023 was primarily due to the net loss of $2.4 million, working capital changes which included an increase in accounts receivable of $0.6 million, an increase in inventory of $0.2 million, a decrease in accrued expenses of $1.3 million, a decrease in accounts payable of $0.9 million, and a decrease in prepaid expense of $0.3 million. Further contributing was an increase in deferred tax assets of $0.6 million. Offsetting these were primarily non-cash charges for stock-based compensation of $0.9 million, depreciation and amortization of $0.2 million, and a loss on disposal of fixed assets of $0.1 million.

Investing Activities

Net cash used in investing activities of $0.1 million for the three months ending March 31, 2024, was for capital expenditures for research and development and manufacturing equipment.

Net cash used in investing activities of $0.3 million for the three months ending March 31, 2023, was for capital expenditures for research and development and office equipment.

Financing Activities

Net cash used in financing activities for the three months ended March 31, 2024 was $0.2 million, due to payments on our note payable for insurance premium financing.

Net cash used in financing activities for the three months ended March 31, 2023, was $0.2 million, due to payments on our note payable for insurance premium financing.

ACCOUNTING PRONOUNCEMENTS NOT YET ADOPTED

Refer to "NOTE 1 — NATURE OF OPERATIONS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES" in the accompanying financial statements, which is incorporated herein by reference.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

The Company's management, including the Company's Principal Executive Officer and Principal Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures as such is defined in Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Based upon their evaluations, the Principal Executive Officer and Principal Financial Officer concluded that, as of the end of the period covered by this report, the Company's disclosure controls and procedures were effective for the purpose of ensuring that the information required to be disclosed in the reports that the Company files or submits under the Exchange Act with the Securities and Exchange Commission (the "SEC") (1) is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (2) is accumulated and communicated to the Company's management, including its Principal Executive Officer and Principal Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

There have been no changes in the Company's internal control over financial reporting during the three months ended March 31, 2024, that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II – OTHER INFORMATION

ITEM 1A. RISK FACTORS

Our operations and financial results are subject to various risks and uncertainties, including those described in "PART 1, ITEM 1A. RISK FACTORS" in our Annual Report on Form 10-K for the year ended December 31, 2023, which could adversely affect our business, financial condition, results of operations, cash flows, and the trading price of our common stock.

PART II – ITEM 6. EXHIBITS.

Exhibit No.	Description
31.1	Certification of Principal Executive Officer Pursuant to Section 302 of Sarbanes-Oxley Act 2002
31.2	Certification of Principal Financial Officer Pursuant to Section 302 of Sarbanes-Oxley Act 2002
32.1	Certification of Principal Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act 2002
32.2	Certification of Principal Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act 2002
101.INS	Inline XBRL Instance Document - the XBRL Instance Document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

SIGNATURES

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

KORU MEDICAL SYSTEMS, INC.

May 1, 2024

/s/ Linda Tharby
Linda Tharby, President and Chief Executive Officer

(Principal Executive Officer)

May 1, 2024

/s/ Thomas Adams
Thomas Adams, Chief Financial Officer and Treasurer

(Principal Financial Officer)

EXHIBIT 31.1

RULE 13A-14(A) / 15D-14(A) CERTIFICATION OF
PRINCIPAL EXECUTIVE OFFICER

I, Linda Tharby, Principal Executive Officer, certify that:

1) I have reviewed this Quarterly Report on Form 10-Q of KORU Medical Systems, Inc. (the "Report");

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 this equivalent function):

   (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 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.

Date: May 1, 2024

/s/ Linda Tharby
Linda Tharby, President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

RULE 13A-14(A) / 15D-14(A) CERTIFICATION OF
PRINCIPAL FINANCIAL OFFICER

I, Thomas Adams, Principal Financial Officer, certify that:

1) I have reviewed this Quarterly Report on Form 10-Q of KORU Medical Systems, Inc. (the "Report");

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 this equivalent function):

   (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 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.

Date: May 1, 2024

/s/ Thomas Adams
Thomas Adams, Chief Financial Officer and Treasurer
(Principal Financial Officer)

EXHIBIT 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350
AS ADDED BY SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of KORU Medical Systems, Inc. (the "Company") on Form 10-Q (the "Report") for the quarter ended March 31, 2024 as filed with the Securities and Exchange Commission, I, Linda Tharby, Principal Executive Officer, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: May 1, 2024

/s/ Linda Tharby
Linda Tharby, President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350
AS ADDED BY SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of KORU Medical Systems, Inc. (the "Company") on Form 10-Q (the "Report") for the quarter ended March 31, 2024 as filed with the Securities and Exchange Commission, I, Thomas Adams, Principal Financial Officer, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: May 1, 2024

/s/ Thomas Adams
Thomas Adams, Chief Financial Officer and Treasurer
(Principal Financial Officer)