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 June 30, 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 August 7, 2024, 45,855,328 shares of common stock, $0.01 par value per share, were outstanding, which excludes 3,438,526 shares of treasury stock.

KORU MEDICAL SYSTEMS, INC.
FORM 10-Q
FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2024
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PART I — FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

KORU MEDICAL SYSTEMS, INC.
BALANCE SHEETS
(UNAUDITED)

	June 30, 2024	December 31, 2023
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 10,458,001	$ 11,482,240
Accounts receivable less allowance for credit losses of $24,777 as of June 30, 2024 and December 31, 2023	5,846,082	4,045,211
Inventory	2,588,750	3,481,301
Other receivables	—	28,889
Prepaid expenses	472,864	1,218,288
TOTAL CURRENT ASSETS	19,365,697	20,255,929
Property and equipment, net	3,678,984	3,837,657
Intangible assets, net of accumulated amortization of $423,834 and $390,341 as of June 30, 2024 and December 31, 2023, respectively	745,084	754,361
Operating lease right-of-use assets	3,414,831	3,514,055
Deferred income tax assets, net of allowance for non-realization of deferred tax assets of $6,581,206 and $6,002,777 as of June 30, 2024 and December 31, 2023, respectively	—	—
Other assets	98,970	98,970
TOTAL ASSETS	$ 27,303,566	$ 28,460,972
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 1,595,691	$ 975,193
Accrued expenses	2,144,722	1,711,427
Note payable	—	314,344
Other liabilities	447,788	512,520
Accrued payroll and related taxes	444,251	462,941
Financing lease liability – current	112,689	109,540
Operating lease liability – current	391,699	368,313
TOTAL CURRENT LIABILITIES	5,136,840	4,454,278
Financing lease liability, net of current portion	259,479	316,623
Operating lease liability, net of current portion	3,202,697	3,336,300
TOTAL LIABILITIES	8,599,016	8,107,201
STOCKHOLDERS' EQUITY		
Common stock, $0.01 par value, 75,000,000 shares authorized, 49,257,812 and 49,089,864 shares issued 45,819,286 and 45,669,362 shares outstanding as of June 30, 2024, and December 31, 2023, respectively	492,398	490,899
Additional paid-in capital	48,331,591	47,018,707
Treasury stock, 3,438,526 shares as of June 30, 2024 and December 31, 2023, at cost	(3,882,493)	(3,843,562)
Accumulated deficit	(26,236,946)	(23,312,273)
TOTAL STOCKHOLDERS' EQUITY	18,704,550	20,353,771
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 27,303,566	$ 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 June 30,		Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
NET REVENUES	$ 8,430,089	$ 6,935,931	$ 16,627,887	$ 14,328,536
Cost of goods sold	2,950,339	3,047,807	6,044,839	6,293,377
Gross Profit	5,479,750	3,888,124	10,583,048	8,035,159
OPERATING EXPENSES				
Selling, general and administrative	5,319,688	5,303,167	10,677,308	10,729,044
Research and development	1,134,232	1,596,614	2,609,907	3,161,483
Depreciation and amortization	217,864	212,919	449,233	426,036
Total Operating Expenses	6,671,784	7,112,700	13,736,448	14,316,563
Net Operating Loss	(1,192,034)	(3,224,576)	(3,153,400)	(6,281,404)
Non-Operating Income/(Expense)				
Loss on currency exchange	(10,680)	(2,472)	(22,159)	(3,152)
Loss on disposal of fixed assets, net	—	—	(300)	(56,279)
Interest income, net	213,999	131,167	251,186	256,669
TOTAL OTHER INCOME	203,319	128,695	228,727	197,238
LOSS BEFORE INCOME TAXES	(988,715)	(3,095,881)	(2,924,673)	(6,084,166)
Income Tax Benefit	—	599,995	—	1,177,395
NET LOSS	$ (988,715)	$ (2,495,886)	$ (2,924,673)	$ (4,906,771)
NET LOSS PER SHARE				
Basic	$ (0.02)	$ (0.05)	$ (0.06)	$ (0.11)
Diluted	$ (0.02)	$ (0.05)	$ (0.06)	$ (0.11)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING				
Basic	45,811,373	45,606,603	45,761,799	45,547,427
Diluted	45,811,373	45,606,603	45,761,799	45,547,427

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

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

	For the Six Months Ended June 30,	
	2024	**2023**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	$ (2,924,673)	$ (4,906,771)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense and warrant expense	1,314,384	1,681,955
Depreciation and amortization	449,233	426,036
Deferred income taxes	—	(1,177,395)
Loss on disposal of fixed assets	300	56,279
Non-cash lease adjustments	(10,994)	(10,994)
Changes in operating assets and liabilities:		
Accounts receivable	(1,800,871)	(239,590)
Inventory	892,551	1,126,643
Prepaid expenses and other assets	774,313	687,994
Other liabilities	(64,731)	5,916
Accounts payable	620,498	(817,169)
Accrued payroll and related taxes	(18,691)	(119,776)
Accrued expenses	433,296	(1,527,648)
NET CASH USED IN OPERATING ACTIVITIES	(335,385)	(4,814,520)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property and equipment	(257,367)	(375,246)
Purchases of intangible assets	(24,216)	(17,298)
NET CASH USED IN INVESTING ACTIVITIES	(281,583)	(392,544)
CASH FLOWS FROM FINANCING ACTIVITIES		
Payments on insurance finance indebtedness	(314,344)	(433,295)
Payments on finance lease liability	(53,995)	(48,493)
Payments for taxes related to net share settlement of equity awards	(38,932)	—
NET CASH USED IN FINANCING ACTIVITIES	(407,271)	(481,788)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(1,024,239)	(5,688,852)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	11,482,240	17,408,257
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 10,458,001	$ 11,719,405
Supplemental Information		
Cash paid during the periods for:		
Interest	$ 20,491	$ 20,165
Income taxes	$ —	$ 3,160
Schedule of Non-Cash Operating, Investing and Financing Activities:		
Issuance of common stock as compensation	$ 221,182	$ 266,023

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

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

Three and Six Months Ended June 30, 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
Issuance of stock-based compensation	41,138	411	136,020	—	(38,932)	97,500
Compensation expense related to stock options	—	—	401,218	—	—	401,218
Compensation related to restricted stock	55,061	551	63,434	—	—	63,984
Issuance of warrants	—	—	13,032	—	—	13,032
Net loss	—	—	—	(988,715)	—	(988,715)
BALANCE, JUNE 30, 2024	49,239,788	$ 492,398	$ 48,331,591	$ (26,236,946)	$ (3,882,493)	$ 18,704,550

Three and Six Months Ended June 30, 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
Accrued compensation paid in shares	48,875	489	175,287	—	—	175,776
Compensation expense related to stock options	—	—	535,059	—	—	535,059
Compensation expense related to restricted stock awards	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
Accrued compensation paid in shares	22,886	229	90,018	—	—	90,247
Compensation expense related to stock options	—	—	540,099	—	—	540,099
Compensation expense related to restricted stock awards	50,000	500	169,887	—	—	170,387
Net loss	—	—	—	(2,495,886)	—	(2,495,886)
BALANCE, JUNE 30, 2023	49,033,652	$ 490,337	$ 45,932,354	$ (14,477,982)	$ (3,843,562)	$ 28,101,147

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. As of June 30, 2024 the Company held cash and cash-equivalents of $10.5 million, the majority of which was held in a secured US-treasury money market mutual fund.

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 an omnibus equity incentive plan under which it grants options and other equity incentive awards to certain executives, key employees and consultants, as well as shares of common stock to non-employee directors.

The fair value of each stock 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.

Shares of stock granted for director fees are recorded at the fair value of the shares at the grant date.

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.

Performance share units are equity classified and measured at the fair market value of the underlying stock at the grant date.

NET LOSS PER SHARE

The Company computes net loss per share using the weighted-average number of common shares outstanding during the period. Basic and diluted net loss per share are the same because the conversion, exercise or issuance of all potential common stock equivalents, which comprise the Company's outstanding common stock options, unvested restricted stock units, performance stock units and warrants, would be anti-dilutive, due to the reporting of a net loss for each of the periods in the accompanying statements of operations.

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, expected credit losses, and customer rebate and incentive accruals. The results of operations for the three and six months ended June 30, 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 domestic and international core 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 June 30, 2024, the Company does not have a contract asset or a contract liability in the accompanying balance sheet.

The following table summarizes net revenues by geography for the three and six months ended June 30, 2024, and 2023.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenues				
Domestic	$ 6,779,298	$ 5,686,427	$ 13,163,381	$ 11,970,392
International	1,650,791	1,249,504	3,464,506	2,358,144
Total	$ 8,430,089	$ 6,935,931	$ 16,627,887	$ 14,328,536

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.

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 June 30, 2024.

NOTE 2 — PROPERTY AND EQUIPMENT

Property and equipment consists of the following at:

	June 30, 2024	December 31, 2023
Furniture and office equipment	$ 1,435,083	$ 1,412,164
Leasehold improvements	1,953,653	1,953,653
Manufacturing equipment and tooling	3,424,129	3,193,113
Total property and equipment	6,812,865	6,558,930
Less: accumulated depreciation and amortization	(3,133,881)	(2,721,273)
Property and equipment, net	$ 3,678,984	$ 3,837,657

Depreciation and amortization expense was $217,864 and $212,919 for the three months ended June 30, 2024 and 2023, respectively, and $449,233 and $426,036 for the six months ended June 30, 2024 and 2023, respectively.

NOTE 3 — STOCK-BASED COMPENSATION

Prior to May 9, 2024, the Company maintained a stock option plan and an omnibus equity incentive plan under which it granted options and other equity incentive awards to certain executives, key employees and consultants, as well as a non-employee director compensation plan under which it granted shares of common stock to non-employee directors. As of May 9, 2024, a new omnibus equity incentive plan replaced these plans with respect to awards made after that date to employees, consultants and directors. The Company has also made inducement awards of equity-based compensation outside of the plans.

The fair value of each option and warrant grant is estimated on the date of the grant using the Black-Scholes option-pricing model. All options and warrants are charged against income at their fair value. The entire compensation expense of the grant is recognized over the vesting period.

Performance share units are equity classified and measured at the fair value of the underlying stock at the grant date.

Shares of stock granted for director fees are recorded at the fair value of the shares at the grant date.

Restricted stock awards are equity classified and measured at the fair 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 four equity incentive plans: the 2015 Stock Option Plan, as amended (the “2015 Plan”), the 2021 Omnibus Equity Incentive Plan (the “2021 Plan”), the 2024 Omnibus Equity Incentive Plan (the “2024 Plan”), and the Non-Employee Director Compensation Plan (the “Director Plan”). No new awards have been or will be issued pursuant to the 2015 Plan, the 2021 Plan or the Director Plan from and after May 9, 2024. The Company has also issued employment inducement awards to certain key executives.

The 2015 Plan provides for the grant of incentive stock options and nonqualified stock options. As of June 30, 2024, there were 2,270,000 shares reserved for outstanding awards under the 2015 Plan.

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 June 30, 2024, there were 656,744 shares reserved for outstanding awards under the 2021 Plan.

The 2024 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 June 30, 2024, there were no awards outstanding and 2,907,061 shares available for issuance under the 2024 Plan. In addition, awards previously made under the 2015 Plan and the 2021 Plan that are forfeited or cancelled after May 9, 2024 will be available for issuance under the 2024 Plan.

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. Prior to May 9, 2024 non-employee director compensation was paid pursuant to the Non-Employee Director Compensation Plan. From and after May 9, 2024 non-employee director compensation is paid pursuant to the 2024 Plan. All payments were and are pro-rated for partial service.

Time-Vesting Stock Options

The following table summarizes the inputs into the Black-Scholes model for all time-vesting stock options granted during the six months ended June 30, 2024 and 2023:

	June 30,	
	2024	2023
Dividend yield	0.00%	0.00%
Expected Volatility	46.18 - 47.83%	56.83 - 61.29%
Expected dividends	—	—
Expected term (in years)	6.25	10
Risk-free rate	4.24% - 4.63%	3.50 - 3.53%

The following table summarizes the status of the stock options:

	Six Months Ended June 30,			
	2024		2023	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at January 1	3,256,250	$ 3.66	3,035,000	$ 3.92
Granted	215,000	$ 2.12	85,000	$ 3.91
Exercised	—	$ —	—	$ —
Forfeited	433,750	$ 6.58	—	$ —
Outstanding at June 30	3,037,500	$ 3.36	3,120,000	$ 3.92
Options exercisable at June 30	1,392,500	$ 3.40	1,158,750	$ 4.37
Weighted average fair value of options granted during the period	—	$ 1.37	—	$ 2.78
Stock-based compensation expense	—	$ 791,792	—	$ 1,075,158

Total stock-based compensation expense for time-vested stock options was $791,792 and $1,075,158 for the six months ended June 30, 2024, and 2023, respectively. No cash was received from option exercises for the six months ended June 30, 2024, and 2023, respectively.

The following table presents information pertaining to options outstanding at June 30, 2024:

Range of Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$2.08 - $3.96	3,037,500	6.64 years	$ 3.36	1,392,500	$ 3.40

As of June 30, 2024, there was $2,383,087 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 48 months. The total fair value of shares vested as of June 30, 2024, and June 30, 2023, was $3,665,166 and $3,798,884, respectively.

Performance-Vesting Stock Options

The following table summarizes the activities for our unvested performance-vesting stock option awards for the six months ended June 30, 2024, and 2023.

	Six Months Ended June 30,			
	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/outstanding at June 30	200,000	$ 1.48	—	$ —

Total stock-based compensation expense for performance-vesting stock options was $16,244 and zero for the six months ended June 30, 2024, and 2023, respectively.

As of June 30, 2024, there was $160,223 of unrecognized compensation cost related to unvested employee performance-vesting options. This amount is expected to be recognized over a weighted-average period of 33 months.

Restricted Stock Awards and PSUs

The following table summarizes the activities for our restricted stock awards and PSUs for the six months ended June 30, 2024, and 2023.

	Six Months Ended June 30,			
	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	—	$ —	54,496	$ 3.68
Vested	81,789	$ 3.38	100,000	$ 3.31
Forfeited/canceled	—	$ —	—	$ —
Unvested at June 30	822,707	$ 1.98	904,496	$ 2.97

Total stock-based compensation expense for restricted stock awards and PSUs was $236,933 and $340,774 for the six months ended June 30, 2024, and 2023, respectively.

As of June 30, 2024, and 2023, there was $641,132 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 18 months.

Common Stock Warrants

The following table summarizes the activities for our common stock warrants issued in connection with our loan financing agreement with our lender for the six months ended June 30, 2024, and 2023.

	Six Months Ended June 30,			
	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 June 30	38,052	$ 1.37	—	$ —

As of June 30, 2024, and 2023, there was $39,096 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 an insurance provider in the aggregate principal amount of $565,172 bearing an annual percentage rate of 9.5%, to finance its insurance premiums. Monthly payments were due on the first of each month beginning August 1, 2023 through June 1, 2024. The balance of the note was $314,344 as of December 31, 2023 and zero as of June 30, 2024.

On March 8, 2024, the Company entered into a loan and security agreement with a large domestic banking institution, 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. As of June 30, 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, vehicles, and certain office and computer equipment. Our three operating leases have remaining lease terms of 8.17 years, 4.58 years, and 3.92 years, respectively. Our three finance leases have remaining lease terms of 2.92 years, 3.25 years, and 4.25 years, respectively, as of June 30, 2024.

The components of lease expense were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Operating lease cost	$ 112,806	$ 112,279	$ 224,354	$ 224,801
Short-term lease cost	556	25,143	4,016	78,037
Total lease cost	$ 113,362	$ 137,422	$ 228,370	$ 302,838
Finance lease cost:				
Amortization of right-of-use assets	$ 28,896	$ 27,224	$ 57,793	$ 54,447
Interest on lease liabilities	5,671	6,387	11,724	13,107
Total finance lease cost	$ 34,567	$ 33,611	$ 69,517	$ 67,554

Supplemental cash flow information related to leases was as follows:

	Six Months Ended June 30,	
	2024	2023
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 244,879	$ 229,879
Financing cash flows from finance leases	65,718	61,600

Supplemental balance sheet information related to leases was as follows:

	June 30, 2024	December 31, 2023
Operating Leases		
Operating lease right-of-use assets	$ 3,414,831	$ 3,514,055
Operating lease current liabilities	391,699	368,313
Operating lease long term liabilities	3,202,697	3,336,300
Total operating lease liabilities	$ 3,594,396	$ 3,704,613
Finance Leases		
Property and equipment, at cost	$ 577,929	$ 577,929
Accumulated depreciation	(219,254)	(161,461)
Property and equipment, net	$ 358,675	$ 416,468
Finance lease current liabilities	112,689	109,540
Finance lease long term liabilities	259,479	316,623
Total finance lease liabilities	$ 372,168	$ 426,163

	June 30, 2024	December 31, 2023
Weighted Average Remaining Lease Term		
Operating leases	5.56 Years	6.88 Years
Finance leases	3.22 Years	3.72 Years
Weighted Average Discount Rate		
Operating leases	6.60%	5.76%
Finance leases	6.25%	6.19%

Maturities of lease liabilities are as follows:

Year Ending December 31,	Operating Leases	Finance Leases
Remainder of 2024	$ 266,990	65,718
2025	533,979	131,437
2026	533,979	131,437
2027	533,979	74,194
2028	520,985	6,180
Thereafter	1,833,603	—
Total undiscounted lease payments	4,223,515	408,966
Less: imputed interest	(629,119)	(36,799)
Total lease liabilities	$ 3,594,396	$ 372,168

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 $599,995 for the three months ended June 30, 2024 and 2023, respectively. For the six months ended June 30, 2024 and 2023, the Company reported income tax expense of zero and income tax benefit of $1,177,395, 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 $6,002,777 against our net deferred tax assets during the year ended December 31, 2023. As of June 30, 2024, the valuation allowance is $6,581,206. 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. The Company 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

The Company renewed its commercial insurance premium finance and security agreement with its insurance provider on August 1, 2024, for the insurance period covering July 1, 2024 – June 30, 2025. The aggregate principal amount of the note is $487,516. The Company retains the right to terminate the agreement at any time and pay the remaining balance in full along with a minimal penalty.

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, future operating results, growth of new patient starts and the Ig market, our compliance with 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^{TM} 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 our Annual Report on Form 10-K for the year ended December 31, 2023. 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 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^{TM} 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^{TM} System for clinical and commercial use.

The Company ended the second quarter of 2024 with $8.4 million in net revenues, a 21.5% increase compared with $6.9 million in the same period last year. Revenues were driven by growth in our core domestic and international business of 14.3% and 45.8%, respectively, and 49.9% in our novel therapies business.

Gross profit for the three months ended June 30, 2024, was $5.5 million, an increase of $1.6 million, or 40.9%, from $3.9 million for the same period last year, driven primarily by additional revenue from volume growth in each of our core and novel therapies businesses, and manufacturing efficiencies compared to the same period last year. Gross margin was 65.0% for the three months ended June 30, 2024, 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 June 30, 2024, were $6.7 million, compared to $7.1 million for the same period last year, driven primarily by a decrease of $0.5 million in research and development expenses primarily due to timing of project spend.

RESULTS OF OPERATIONS

Three months ended June 30, 2024, compared to June 30, 2023

Net Revenues

The following table summarizes our net revenues for the three months ended June 30, 2024, and 2023:

	Three Months Ended June 30,		Change from Prior Year		% of Net Revenues	
	2024	2023	$	%	2024	2023
Net Revenues						
Domestic Core	$ 6,156,098	$ 5,388,172	$ 767,926	14.3%	73.0%	77.7%
International Core	1,628,191	1,117,004	511,187	45.8%	19.3%	16.1%
Total Core	7,784,289	6,505,176	1,279,113	19.7%	92.3%	93.8%
Novel Therapies	645,800	430,754	215,046	49.9%	7.7%	6.2%
Total	$ 8,430,089	$ 6,935,930	$ 1,494,159	21.5%	100%	100%

Total net revenues increased $1.5 million, or 21.5%, to $8.4 million for the three months ended June 30, 2024, as compared with the same period in 2023. Domestic core revenues increased by 14.3% to $6.2 million, primarily due to higher consumable and pump volumes driven by new patients starts and share gains. International core revenues increased by 45.8% to $1.6 million, primarily due to higher consumable and pump volumes driven largely by increased Ig supply, increased penetration within certain approved indications, and geographic expansion. International orders were expedited for certain distribution partners of $0.3 million in the second quarter of 2024 related to the BSI regulatory review process which has since been successfully appealed. Novel therapies net revenues increased by 49.9% to $0.6 million in the three months ended June 30, 2024 primarily driven by Phase III clinical trial orders and milestone completion from our collaboration agreements.

Gross Profit

Our gross profit for the three months ended June 30, 2024 and 2023 is as follows:

	Three Months Ended June 30,		Change from Prior Year	
	2024	2023	$	%
Gross Profit	$ 5,479,750	$ 3,888,124	$ 1,591,626	40.9%
Gross Margin	65.0%	56.1%		

Gross profit increased $1.6 million to $5.5 million in the three months ended June 30, 2024, compared to $3.9 million in the same period in 2023. Gross margin increased to 65.0% compared to 56.1% in the three months ended June 30, 2023. The increase in gross margin was primarily driven by increased production efficiencies, favorable sales mix driven by clinical trial orders, and increased average selling prices when compared to the prior year period. We also had a positive inventory valuation adjustment of $0.1 million during the three months ended June 30, 2024 which is not expected to recur in 2024.

Operating Expenses

Our selling, general and administrative, research and development and depreciation and amortization expenses for the three months ended June 30, 2024 and 2023 are as follows:

	Three Months Ended June 30,		Change from Prior Year	
	2024	2023	$	%
Selling, general and administrative	$ 5,319,688	$ 5,303,167	$ 16,521	0.3%
Research and development	1,134,232	1,596,614	(462,382)	(29.0%)
Depreciation and amortization	217,864	212,919	4,945	2.3%
Total Operating Expenses	$ 6,671,784	$ 7,112,700	$ (440,916)	(6.2%)

Selling, general and administrative expenses remained flat during the three months ended June 30, 2024 compared with the same period last year.

Research and development expenses decreased $0.5 million, or 29.0% during the three months ended June 30, 2024 compared with the same period last year, primarily due to increased efficiencies related to insourcing and timing of project spend.

Depreciation and amortization expense remained flat at $0.2 million in the three months ended June 30, 2024 compared with $0.2 million in the three months ended June 30, 2023 primarily driven by timing of projects and related capital spending.

Net Loss

	Three Months Ended June 30,		Change from Prior Year	
	2024	2023	$	%
Net Loss	$ (988,715)	$ (2,495,886)	$ 1,507,171	60.4%

Our net loss decreased $1.5 million in the three months ended June 30, 2024 compared with the same period last year, mostly driven by an increase in gross profit of $1.6 million and in interest income of $0.1 million, partially offset by a decrease in tax benefit of $0.6 million and in operating expenses of $0.4 million.

Six months ended June 30, 2024, compared to June 30, 2023

Net Revenues

The following table summarizes our net revenues for the six months ended June 30, 2024, and 2023:

	Six Months Ended June 30,		Change from Prior Year		% of Net Revenues	
	2024	2023	$	%	2024	2023
Net Revenues						
Domestic Core	$ 12,109,963	$ 11,107,308	$ 1,002,655	9.0%	72.8%	77.5%
International Core	3,418,674	2,214,494	1,204,180	54.4%	20.6%	15.5%
Total Core	15,528,637	13,321,801	2,206,836	16.6%	93.4%	93.0%
Novel Therapies	1,099,250	1,006,734	92,516	9.2%	6.6%	7.0%
Total	$ 16,627,887	$ 14,328,536	$ 2,299,351	16.0%	100%	100%

Total net revenues increased $2.3 million, or 16.0% to $16.6 million, for the six months ended June 30, 2024, as compared with the same period last year. Domestic core revenues increased by 9.0% to $12.1 million, primarily due to volume growth in pumps and consumables driven by new patients starts and share gains. International core revenues increased by 54.4% to $3.4 million, primarily due to higher consumable and pump volumes driven largely by increased Ig supply, increased penetration within certain approved indications, and geographic expansion. International orders were expedited for certain distribution partners of $0.3 million in the second quarter of 2024, related to the BSI regulatory review process, which has since been successfully appealed. Novel therapies net revenues increased by 9.2% to $1.1 million in the six months ended June 30, 2024 as compared to the prior year period, driven by Phase 3 clinical trial orders and milestone completion from our collaboration agreements.

Gross Profit

Our gross profit for the six months ended June 30, 2024 and 2023 is as follows:

	Six Months Ended June 30,		Change from Prior Year	
	2024	2023	$	%
Gross Profit	$ 10,583,048	$ 8,035,159	$ 2,547,889	31.7%
Gross Margin	63.6%	56.1%		

Gross profit increased $2.5 million or 31.7% in the six months ended June 30, 2024, compared to the same period in 2023. The increase in the first half of 2024 was driven by the increase in net revenues of $2.3 million as described above and improvements in manufacturing efficiency. Gross margin increased to 63.6% in the first half of 2024 compared to 56.1% from the first half of 2023. The increase in gross margin was primarily driven by increased manufacturing efficiencies versus the prior year. Additionally, we realized improved NRE margin compared with the prior year period driven by a more profitable mix of services performed.

Operating Expenses

Our selling, general and administrative, research and development and depreciation and amortization expenses for the six months ended June 30, 2024 and 2023 are as follows:

	Six Months Ended June 30,		Change from Prior Year	
	2024	2023	$	%
Selling, general and administrative	$ 10,677,308	$ 10,729,044	$ (51,736)	(0.5%)
Research and development	2,609,907	3,161,483	(551,576)	(17.4%)
Depreciation and amortization	449,233	426,036	23,197	5.4%
Total Operating Expenses	$ 13,736,448	$ 14,316,563	$ (580,115)	(4.1%)

Selling, general and administrative expenses decreased $0.1 million, or 0.5%, during the six months ended June 30, 2024 compared with the same period last year, primarily due to decreases in compensation and benefits expense.

Research and development expenses decreased $0.6 million, or 17.4% during the six months ended June 30, 2024 compared with the same period last year, primarily due to a $0.8 million decrease in consulting expense due to less outsourcing activities and timing of project spend, partially offset by a $0.3 million increase in compensation and benefits.

Depreciation and amortization expense remained flat at $0.4 million in the six months ended June 30, 2024 compared with $0.4 million in the six months ended June 30, 2023 resulting from minimal purchases of new PP&E during the period.

Net Loss

	Six Months Ended June 30,		Change from Prior Year	
	2024	2023	$	%
Net Loss	$ (2,924,673)	$ (4,906,771)	$ 1,982,098	40.4%
Stated as a Percentage of Net Revenues	(17.6%)	(34.2%)		

Our net loss decreased $2.0 million in the six months ended June 30, 2024 compared with the same period last year mostly driven by an increase in gross profit of $2.5 million and a decrease in operating expenses of $0.6 million, partially offset by a prior year tax benefit of $1.2 million.

LIQUIDITY AND CAPITAL RESOURCES

Our principal source of liquidity is our cash on hand of $10.5 million as of June 30, 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 manufacturing equipment.

Our inventory position was $2.6 million at June 30, 2024, which reflects a decrease of $0.9 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 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:

	Six Months Ended June 30, 2024	Six Months Ended June 30, 2023
Net cash used in operating activities	$ (335,385)	$ (4,814,520)
Net cash used in investing activities	$ (281,583)	$ (392,544)
Net cash used in financing activities	$ (407,271)	$ (481,788)

Operating Activities

Net cash used in operating activities was $0.3 million for the six months ended June 30, 2024 vs $4.8 million in the prior year. This net cash usage of $0.3 million was primarily due to the net loss of $2.9 million and an increase in accounts receivable of $1.8 million, which was mostly offset by decreases in inventory of $0.9 million, decreases in pre-paid expenses of $0.8 million, and increases in accounts payable and accruals of $1.0 million. Additional offsets to the net loss were non-cash items including stock-based compensation expense of $1.3 million, and depreciation and amortization expense of $0.4 million.

Net cash used in operating activities was $4.8 million for the six months ended June 30, 2023. This net cash usage was primarily due to the net loss of $4.9 million, plus cash flows used to fund a decrease in accrued expenses of $1.7 million, primarily from the payment of 2022 employee bonuses, and a decrease in accounts payable of $0.8 million, offset by cash flows generated from a decrease in inventory of $1.1 million, an increase in accounts receivable of $0.2 million and a decrease in prepaid expense of $0.7 million. Further contributing to this change were non-cash items including an increase in deferred tax assets of $1.2 million offset by stock-based compensation expense of $1.7 million, depreciation and amortization expense of $0.4 million and a loss on disposal of fixed assets of $0.1 million.

Investing Activities

Net cash used in investing activities of $0.3 million for the six months ending June 30, 2024, was for capital expenditures for research and development and manufacturing equipment.

Net cash used in investing activities of $0.4 million for the six months ending June 30, 2023, was for capital expenditures for research and development and office equipment.

Financing Activities

Net cash used in financing activities of $0.4 million for the six months ended June 30, 2024 was due to payments on our note payable for insurance premium financing.

Net cash used in financing activities of $0.5 million for the six months ended June 30, 2023, was due to payments on our note payable for insurance premium financing as well as for payments on our finance leases.

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 six months ended June 30, 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.

August 7, 2024 /s/ Linda Tharby
Linda Tharby, President and Chief Executive Officer

(Principal Executive Officer)

August 7, 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: August 7, 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: August 7, 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 June 30, 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: August 7, 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 June 30, 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: August 7, 2024

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