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 September 30, 2025

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 November 12, 2025, 46,322,655 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 SEPTEMBER 30, 2025
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PART I — FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

KORU MEDICAL SYSTEMS, INC.
BALANCE SHEETS

	September 30, 2025 (UNAUDITED)	December 31, 2024
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 8,464,019	$ 9,580,947
Accounts receivable less allowance for credit losses of $0 as of September 30, 2025 and December 31, 2024	5,412,004	5,720,750
Inventory	4,411,710	2,803,669
Other receivables	103,079	277,193
Prepaid expenses	1,028,484	749,851
TOTAL CURRENT ASSETS	19,419,296	19,132,410
Property and equipment, net	4,235,983	4,290,515
Intangible assets, net of accumulated amortization of $510,597 and $458,538 as of September 30, 2025 and December 31, 2024, respectively	681,621	730,279
Operating lease right-of-use assets	2,667,656	2,966,341
Other assets	98,970	98,970
TOTAL ASSETS	$ 27,103,526	$ 27,218,515
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 1,872,162	$ 1,649,969
Accrued expenses	4,634,183	3,924,184
Note payable	334,931	271,152
Other liabilities	2,893	29,269
Accrued payroll and related taxes	456,066	811,401
Financing lease liability	120,211	115,587
Operating lease liability	413,486	400,258
TOTAL CURRENT LIABILITIES	7,833,932	7,201,820
Financing lease liability, net of current portion	116,279	202,613
Operating lease liability, net of current portion	2,688,490	3,000,403
TOTAL LIABILITIES	10,638,701	10,404,836
STOCKHOLDERS' EQUITY		
Common stock, $0.01 par value, 75,000,000 shares authorized, 49,713,694 and 49,377,617 shares issued 46,293,192 and 45,957,115 shares outstanding as of September 30, 2025, and December 31, 2024, respectively	497,137	493,776
Additional paid-in capital	51,380,158	49,581,303
Treasury stock, 3,438,526 shares as of September 30, 2025 and December 31, 2024, at cost	(3,882,494)	(3,882,494)
Accumulated deficit	(31,529,976)	(29,378,906)
TOTAL STOCKHOLDERS' EQUITY	16,464,825	16,813,679
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 27,103,526	$ 27,218,515

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	**2024**	**2025**	**2024**
NET REVENUES	$ 10,402,163	$ 8,179,977	$ 30,232,038	$ 24,807,864
Cost of goods sold	4,137,592	2,993,986	11,445,362	9,038,825
Gross Profit	6,264,571	5,185,991	18,786,676	15,769,038
OPERATING EXPENSES				
Selling, general and administrative	5,994,661	5,127,658	17,338,183	15,804,966
Research and development	933,107	1,533,845	3,242,505	4,143,751
Depreciation and amortization	204,482	227,785	631,326	677,019
Total Operating Expenses	7,132,250	6,889,288	21,212,014	20,625,736
Net Operating Loss	(867,679)	(1,703,297)	(2,425,338)	(4,856,698)
Non-Operating Income (Expense)				
Gain (Loss) on currency exchange	11,790	9,485	61,571	(12,674)
Other income	3,206	—	3,205	(300)
Interest income, net	74,567	112,995	226,698	364,183
TOTAL OTHER INCOME	89,563	122,480	291,474	351,208
LOSS BEFORE INCOME TAXES	(778,116)	(1,580,817)	(2,133,864)	(4,505,490)
Income Tax Refund (Expense)	150	—	(17,206)	—
NET LOSS	$ (777,966)	$ (1,580,817)	$ (2,151,070)	$ (4,505,490)
NET LOSS PER SHARE				
Basic & Diluted	$ (0.02)	$ (0.03)	$ (0.05)	$ (0.10)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING				
Basic & Diluted	46,238,819	45,851,019	46,140,347	45,791,756

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

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

	For the Nine Months Ended September 30,	
	2025	**2024**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	$ (2,151,070)	$ (4,505,490)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense and warrant expense	1,740,727	1,924,131
Depreciation and amortization	631,326	677,019
Loss on disposal of fixed assets	—	300
Non-cash lease adjustments	—	243,762
Changes in operating assets and liabilities:		
Accounts receivable	308,749	(1,119,490)
Inventory	(1,608,041)	(447,017)
Prepaid expenses and other assets	(104,520)	217,652
Other liabilities	(26,379)	(330,773)
Accounts payable	222,193	695,107
Accrued payroll and related taxes	(355,335)	303,927
Accrued expenses	709,999	1,081,539
NET CASH USED IN OPERATING ACTIVITIES	(632,351)	(1,259,333)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property and equipment	(524,735)	(1,340,994)
Purchases of intangible assets	(3,400)	(42,786)
NET CASH USED IN INVESTING ACTIVITIES	(528,135)	(1,383,780)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from exercise of employee stock options	89,025	—
Borrowings from insurance finance indebtedness	406,751	487,516
Payments on insurance finance indebtedness	(342,972)	(399,867)
Payments on finance lease liability	(81,710)	(81,534)
Payments for taxes related to net share settlement of equity awards	(27,536)	(38,932)
NET CASH PROVIDED BY (USED IN) FINANCING ACTIVITIES	43,558	(32,817)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(1,116,928)	(2,675,930)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	9,580,947	11,482,240
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 8,464,019	$ 8,806,310
Supplemental Information		
Cash paid during the periods for:		
Interest	$ 36,690	$ 46,014

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

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

Three and Nine Months Ended September 30, 2025

	Common Stock		Additional Paid-in	Accumulated	Treasury	Total Stockholders'
	Shares	Amount	Capital	Deficit	Stock	Equity
BALANCE, DECEMBER 31, 2024	49,377,617	$ 493,776	$ 49,581,303	$ (29,378,906)	$ (3,882,494)	$ 16,813,679
Issuance of stock-based compensation	183,881	1,839	95,661	—	—	97,500
Compensation expense related to stock options	—	—	359,197	—	—	359,197
Compensation related to restricted stock	—	—	227,860	—	—	227,860
Issuance of warrants	—	—	13,032	—	—	13,032
Net loss	—	—	—	(1,166,237)	—	(1,166,237)
BALANCE, MARCH 31, 2025	49,561,498	$ 495,615	$ 50,277,053	$ (30,545,143)	$ (3,882,494)	$ 16,345,031
Issuance of stock-based compensation	93,961	940	96,560	—	—	97,500
Compensation expense related to stock options	—	—	147,944	—	—	147,944
Compensation related to restricted stock	—	—	142,766	—	—	142,766
Net loss	—	—	—	(206,867)	—	(206,867)
BALANCE, JUNE 30, 2025	49,655,459	$ 496,555	$ 50,664,323	$ (30,752,010)	$ (3,882,494)	$ 16,526,374
Issuance of stock-based compensation	25,454	254	97,246	—	—	97,500
Compensation expense related to stock options	—	—	254,697	—	—	254,697
Compensation related to restricted stock	—	—	275,195	—	—	275,195
Proceeds from exercise of employee stock options	32,781	328	88,697	—	—	89,025
Net loss	—	—	—	(777,966)	—	(777,966)
BALANCE, SEPTEMBER 30, 2025	49,713,694	$ 497,137	$ 51,380,158	$ (31,529,976)	$ (3,882,494)	$ 16,464,825

Three and Nine Months Ended September 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
Issuance of stock-based compensation	36,042	360	97,140	—	—	97,500
Compensation expense related to stock options	—	—	305,376	—	—	305,376
Compensation related to restricted stock	—	—	193,839	—	—	193,839
Issuance of warrants	—	—	13,032	—	—	13,032
Net loss	—	—	—	(1,580,817)	—	(1,580,817)
BALANCE, SEPTEMBER 30, 2024	49,275,830	$ 492,758	$ 48,940,978	$ (27,817,763)	$ (3,882,493)	$ 17,733,480

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," "KORU," "we," "us" or "our") develops, manufactures and commercializes innovative and patient-centric large volume subcutaneous infusion solutions 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 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, 2024 ("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

The Company considers all short-term investments with an original maturity of three months or less to be cash equivalents. As of September 30, 2025 the Company held cash and cash-equivalents of approximately $8.5 million, the majority of which was held in a secured US-treasury money market 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, 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.

Restricted stock units ("RSUs") and performance stock units ("PSUs") 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 nine months ended September 30, 2025 are not necessarily indicative of the results that may be expected for the entire 2025 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) pharma services and clinical trials. 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"). Pharma services and clinical trials 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 distributors 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. The Company has recognized a contract asset, which is included in other receivables in the accompanying balance sheet, of $103,079, $161,190, and $222,623 as of September 30, 2025, June 30, 2025 and December 31, 2024, respectively.

The following table summarizes net revenues from our distributors and direct customers by geography for the three and nine months ended September 30, 2025, and 2024.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Revenues				
Domestic	$ 6,706,639	$ 7,022,811	$ 21,924,544	$ 20,186,191
International	3,695,524	1,157,166	8,307,494	4,621,672
Total	$ 10,402,163	$ 8,179,977	$ 30,232,038	$ 24,807,864

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 for the three or nine months ended September 30, 2025 nor September 30, 2024.

NOTE 2 — PROPERTY AND EQUIPMENT

Property and equipment consists of the following at:

	September 30, 2025	December 31, 2024
Furniture and office equipment	$ 1,441,790	$ 1,433,622
Leasehold improvements	1,953,653	1,953,653
Manufacturing equipment and tooling	4,887,834	4,376,147
Total property and equipment	8,283,277	7,763,422
Less: accumulated depreciation and amortization	(4,047,294)	(3,472,907)
Property and equipment, net	$ 4,235,983	$ 4,290,515

NOTE 3 — STOCK-BASED COMPENSATION

The Company maintains 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 2024 Omnibus Equity Incentive Plan (the "2024 Plan"). All equity awards issued to employees, consultants, and non-employee directors on or after May 9, 2024 are issued from the 2024 Plan. The Company has also issued restricted stock and stock options as employment inducement awards outside of these plans to certain executive officers.

The 2015 Plan provides for the grant of incentive stock options and nonqualified stock options. As of September 30, 2025, there were 1,981,500 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, performance share units, stock appreciation rights, and/or other equity-based awards to employees, consultants and directors. As of September 30, 2025, there were 100,000 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, performance share units, stock appreciation rights and/or other equity-based awards to employees, consultants and directors. 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. As of September 30, 2025, there were 1,310,903 shares reserved for outstanding awards and 1,678,621 shares 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 in arrears of $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 in arrears of $12,500 in cash and $22,500 in common stock. Prior to May 9, 2024 in the periods presented in this report, non-employee director equity compensation was issued from the Non-Employee Director Compensation Plan. From and after May 9, 2024 non-employee director equity compensation is issued from the 2024 Plan. All payments were and are pro-rated for partial service.

Time-Vesting Stock Options

The following table summarizes the activity of time-based stock options for the nine months ending September 30, 2025:

	Shares	Weighted Average Exercise Price
Outstanding at January 1	2,687,024	$ 3.07
Granted	834,445	$ 3.37
Exercised	(95,783)	$ 2.39
Forfeited	(211,506)	$ 2.26
Outstanding at September 30	3,214,180	$ 3.23
Options exercisable at September 30	1,777,221	$ 3.40

Total stock-based compensation expense for time-vested stock options, included in operating expense in the accompanying statements of operations, was $254,697 and $775,966 for the three and nine months ended September 30, 2025, respectively. $89,025 was received from option exercises for the three and nine months ended September 30, 2025. As of September 30, 2025, the intrinsic value of all time-based stock options was $1,995,479.

The following table presents information pertaining to time-based stock options outstanding at September 30, 2025:

Range of Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$2.08-$3.98	3,214,180	7.33 years	$ 3.23	1,777,221	$ 3.40

As of September 30, 2025, there was $2,384,190 of total unrecognized compensation cost related to time-vested stock option awards granted under the Plans. That cost is expected to be recognized over a weighted-average period of 26 months.

Performance-Vesting Stock Options

The following table summarizes the activities for our unvested performance-vesting stock option awards for the nine months ended September 30, 2025.

	Shares	Weighted Average Grant-Date Fair Value
Outstanding at January 1	155,334	$ 1.48
Granted	—	$ —
Exercised	(22,000)	$ 1.48
Vested	—	$ —
Forfeited/canceled	(133,334)	$ 1.48
Outstanding at September 30	—	$ —

Total stock-based compensation expense for performance-vesting stock options was $0 for the nine months ended September 30, 2025. No cash was received from option exercises for the nine months ended September 30, 2025.

As of September 30, 2025, there was $0 of unrecognized compensation cost related to unvested employee performance-vesting stock options.

Restricted Stock Awards, Restricted Stock Units ("RSUs"), and Performance Stock Units ("PSUs")

The following table summarizes the activities for our unvested restricted stock awards, RSUs, and PSUs for the nine months ended September 30, 2025.

	Shares	Weighted Average Grant-Date Fair Value
Unvested at January 1	1,269,937	$ 2.54
Granted	745,399	$ 3.59
Vested	(199,750)	$ 3.06
Forfeited/canceled	(63,439)	$ 2.20
Unvested at September 30	1,752,147	$ 2.99

Total stock-based compensation expense for restricted stock awards, RSUs, and PSUs, included in operating expense in the accompanying statements of operations, was $275,195 and $673,357 for the three and nine months ended September 30, 2025, respectively.

As of September 30, 2025, there was $3,210,584 of unrecognized compensation cost related to unvested employee restricted stock awards, RSUs, and PSUs. This amount is expected to be recognized over a weighted-average period of 26 months.

NOTE 4 — DEBT OBLIGATIONS

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. On March 31, 2025 the loan and security agreement was amended to extend the maturity of the revolving credit facility to December 31, 2026 and the interest-only portion of the term loan facility to October 1, 2026. In addition, certain other covenants were also modified. As of September 30, 2025, 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.

The components of lease expense were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Operating lease cost	$ 130,785	$ 116,772	$ 388,372	$ 341,126
Short-term lease cost	—	556	6,086	4,572
Total lease cost	$ 130,785	$ 117,328	$ 394,458	$ 345,698
Finance lease cost:				
Amortization of right-of-use assets	$ 28,896	$ 28,896	$ 86,689	$ 86,689
Interest on lease liabilities	3,674	5,283	12,249	17,007
Total finance lease cost	$ 32,570	$ 34,179	$ 98,938	$ 103,696

Supplemental cash flow information related to leases was as follows:

	Nine Months Ended September 30,	
	2025	2024
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 392,871	$ 373,046
Financing cash flows from finance leases	98,578	98,578

	September 30, 2025	December 31, 2024
Weighted Average Remaining Lease Term		
Operating leases	4.3 Years	5.1 Years
Finance leases	2.0 Years	2.7 Years
Weighted Average Discount Rate		
Operating leases	6.36%	6.52%
Finance leases	6.56%	6.34%

Maturities of lease liabilities are as follows:

Year Ending December 31,	Operating Leases	Finance Leases
Remainder of 2025	$ 133,495	$ 32,859
2026	533,979	131,437
2027	533,979	74,194
2028	520,985	6,180
2029	501,595	—
Thereafter	1,332,009	—
Total undiscounted lease payments	3,556,042	244,670
Less: imputed interest	(454,066)	(8,180)
Total lease liabilities	$ 3,101,976	$ 236,490

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 $17,206 and $0 for the nine months ended September 30, 2025, and 2024, 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 maintained the full valuation allowance against our net deferred tax assets. 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.

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 2021 are no longer subject to examination by tax authorities. The Company was previously under audit for tax year 2022 but has since received notification from the Internal Revenue Services that the Company is no longer under audit.

NOTE 7 — COMMITMENTS AND CONTINGENCIES

LEGAL PROCEEDINGS

The Company has been and continues to be 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 proceedings that is believed to be material to its financial condition.

NOTE 8 — SUBSEQUENT EVENTS

Newly enacted tariffs and other trade restrictions have recently been imposed by the United States and other countries around the world. At this time, we expect tariff-related charges to have a gross margin impact of less than 100 basis points on an annualized basis, although the actual results of tariff-related charges may differ from estimates.

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 inflation, tariffs, 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™ 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, 2024 and Quarterly Report for the quarter ended March 31, 2025. 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 and impact of tariff-related charges. 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," "KORU," "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) pharma services and clinical trials. 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™ System, with the primary delivery for immunoglobulin to treat Primary Immunodeficiency Diseases ("PIDD") and Chronic Inflammatory Demyelinating Polyneuropathy ("CIDP"). Pharma services and clinical trials 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 third quarter of 2025 with $10.4 million in net revenues, a 27.2% increase compared to $8.2 million in the same period last year. Revenues in our core business were $9.8 million, a 29.7% increase over the prior year period. Growth in our international core business of 229.6% was offset by a decline in our domestic core business of 5.0%, as well as a decline in our pharma services and clinical trials business of 4.4%. Our geographic mix within core revenues was impacted by a US distributor's purchase of KORU products from an international distributor.

Gross profit for the third quarter of 2025 was $6.3 million, a 20.8% increase compared to $5.2 million in the same period last year, primarily driven by additional revenue from volume growth in the international core business. Gross margin was 60.2% for the three months ended September 30, 2025, a decrease from 63.4% in the prior year period due to higher manufacturing costs, geographic mix, and tariff charges. We define gross margin as gross profit stated as a percentage of net revenues.

Operating expenses for the third quarter of 2025 were $7.1 million, compared to $6.9 million for the same period last year, driven by an increase in selling, general, and administrative expenses, partially offset by decreases in research and development expenses.

During the third quarter of 2025, we incurred tariff-related charges of $0.1 million. At this time, we expect tariff-related charges to have a gross margin impact of less than 100 basis points on an annualized basis.

RESULTS OF OPERATIONS

Three months ended September 30, 2025, compared to September 30, 2024

Net Revenues

The following table summarizes our net revenues for the three months ended September 30, 2025, and 2024:

	Three Months Ended September 30,		Change from Prior Year		% of Net Revenues	
	2025	2024	$	%	2025	2024
Net Revenues						
Domestic Core	$ 6,122,365	$ 6,447,469	$ (325,104)	(5.0%)	58.9%	78.8%
International Core	3,695,524	1,121,196	2,574,328	229.6%	35.5%	13.7%
Total Core	9,817,889	7,568,665	2,249,224	29.7%	94.4%	92.5%
Pharma Services and Clinical Trials	584,274	611,312	(27,038)	(4.4%)	5.6%	7.5%
Total	$ 10,402,163	$ 8,179,977	$ 2,222,186	27.2%	100%	100%

Total net revenues increased $2.2 million, or 27.2%, to $10.4 million for the three months ended September 30, 2025, as compared to $8.2 million in the prior year period. Domestic core revenues were $6.1 million, a decrease of 5.0% over the prior year period, primarily due to lower orders from a US distributor who purchased a portion of its KORU product from one of our international distributors, as well as an inventory reduction by such US distributor, partially offset by market growth from new patient starts and share gains in key accounts. International core revenues were $3.7 million, an increase of 229.6% over the prior year period, primarily due to supplying a distributor in a strategic market to meet anticipated demands of prefilled conversion from vials, new patient starts within existing markets, and product purchases by an international distributor who subsequently sold into the US market, as mentioned above. Pharma services and clinical trials net revenues were $0.6 million, a decrease of 4.4% over the prior year period, primarily driven by staging of NRE work versus the prior year period, reflecting the inherent variability of this business.

Gross Profit

Our gross profit for the three months ended September 30, 2025 and 2024 is as follows:

	Three Months Ended September 30,		Change from Prior Year	
	2025	2024	$	%
Gross Profit	$ 6,264,571	$ 5,185,991	$ 1,078,580	20.8%
Gross Margin	60.2%	63.4%		

Gross profit increased $1.1 million, or 20.8%, to $6.3 million in the three months ended September 30, 2025, as compared to $5.2 million in the prior year period. Gross margin decreased to 60.2% in the three months ended September 30, 2025, as compared to 63.4% in the prior year period. The decrease in gross margin was primarily driven by higher manufacturing costs, geographic sales mix from outside the United States, and tariff-related charges.

Operating Expenses

Our selling, general and administrative, research and development and depreciation and amortization expenses for the three months ended September 30, 2025 and 2024 are as follows:

	Three Months Ended September 30,		Change from Prior Year	
	2025	2024	$	%
Selling, general and administrative	$ 5,994,661	$ 5,127,659	$ 867,002	16.9%
Research and development	933,107	1,533,845	(600,738)	(39.2%)
Depreciation and amortization	204,482	227,785	(23,303)	(10.2%)
Total Operating Expenses	$ 7,132,250	$ 6,889,289	$ 242,961	3.5%

Selling, general and administrative expenses increased $0.9 million, or 16.9%, to $6.0 million during the three months ended September 30, 2025, as compared to $5.1 million in the prior year period. The increase in selling, general and administrative expenses was primarily driven by increases in compensation and benefits, mostly due to higher bonus accruals and commissions due to higher revenues, legal fees, and facility expense.

Research and development expenses decreased $0.6 million, or 39.2%, to $0.9 million during the three months ended September 30, 2025, as compared to $1.5 million in the prior year period, primarily due to severance occurring in the prior year, and lower project spend in the current period.

Depreciation and amortization expense remained flat at $0.2 million during the three months ended September 30, 2024, as compared to $0.2 million in the prior year period.

Net Loss

	Three Months Ended September 30,		Change from Prior Year	
	2025	2024	$	%
Net Loss	$ (777,966)	$ (1,580,817)	$ 802,851	50.8%

Our net loss decreased to $0.8 million in the three months ended September 30, 2025, as compared to the prior year period, primarily driven by an increase in gross profit of $1.1 million due to increased revenues, partially offset by an increase in operating expense $0.2 million.

Nine months ended September 30, 2025, compared to September 30, 2024

Net Revenues

The following table summarizes our net revenues for the nine months ended September 30, 2025, and 2024:

	Nine Months Ended September 30,		Change from Prior Year		% of Net Revenues	
	2025	2024	$	%	2025	2024
Net Revenues						
Domestic Core	$ 20,147,615	$ 18,557,431	$ 1,590,184	8.6%	66.6%	74.8%
International Core	8,304,297	4,539,871	3,764,426	82.9%	27.5%	18.3%
Total Core	28,451,912	23,097,302	5,354,610	23.2%	94.1%	93.1%
Pharma Services and Clinical Trials	1,780,126	1,710,562	69,564	4.1%	5.9%	6.9%
Total	$ 30,232,038	$ 24,807,864	$ 5,424,174	21.9%	100%	100%

Total net revenues increased $5.4 million, or 21.9% to $30.2 million, for the nine months ended September 30, 2025, as compared with the same prior year period. Domestic core revenues increased by 8.6% to $20.1 million, primarily due to market growth from new patient starts and share gains in key accounts, partially offset by lower orders from a US distributor who purchased a portion of its quarterly KORU product from one of our international distributors, as well as an inventory reduction by such US distributor. International core revenues increased by 82.9% to $8.3 million, primarily due to supplying a distributor in a strategic market to meet anticipated demands of prefilled conversion from vials, new patient starts within existing markets, and product purchases by an international distributor who subsequently sold into the US market, as mentioned above. Pharma services and clinical trials net revenues increased by $0.1 million, or 4.1% to $1.8 million in the nine months ended September 30, 2025, driven by Phase 3 clinical trial orders.

Gross Profit

Our gross profit for the nine months ended September 30, 2025 and 2024 is as follows:

	Nine Months Ended September 30,		Change from Prior Year	
	2025	2024	$	%
Gross Profit	$ 18,786,676	$ 15,769,038	$ 3,017,638	19.1%
Gross Margin	62.1%	63.6%		

Gross profit increased by $3.0 million or 19.1% in the nine months ended September 30, 2025, as compared with the same prior year period. Gross margin decreased to 62.1% in the nine months ended September 30, 2025, as compared with 63.6% in the prior year period. The decrease in gross margin was primarily driven by geographic sales mix from outside the United States, product sales mix, and tariff-related charges.

Operating Expenses

Our selling, general and administrative, research and development and depreciation and amortization expenses for the nine months ended September 30, 2025 and 2024 are as follows:

	Nine Months Ended September 30,		Change from Prior Year	
	2025	2024	$	%
Selling, general and administrative	$ 17,338,183	$ 15,804,866	$ 1,533,317	9.7%
Research and development	3,242,505	4,143,752	(901,247)	(21.7%)
Depreciation and amortization	631,326	677,019	(45,693)	(6.7%)
Total Operating Expenses	$ 21,212,014	$ 20,625,637	$ 586,377	2.8%

Selling, general and administrative expenses increased $1.5 million, or 9.7%, during the nine months ended September 30, 2025, as compared with the prior year period, primarily due to increases in compensation and benefits, new hires, and legal fees.

Research and development expenses decreased $0.9 million, or 21.7%, during the nine months ended September 30, 2025, as compared with the same prior year period, primarily due to lower severance related expenses and project spend due to shifting timelines related to new product development projects.

Depreciation and amortization expense decreased $0.05 million, or 6.7%, during the nine months ended September 30, 2025, as compared with $0.7 million in the same prior year period, primarily due to a prior year fixed asset reclass.

Net Loss

	Nine Months Ended September 30,		Change from Prior Year	
	2025	2024	$	%
Net Loss	$ (2,151,070)	$ (4,505,490)	$ 2,354,420	52.3%
Stated as a Percentage of Net Revenues	(7.1%)	(18.2%)		

Our net loss decreased $2.4 million in the nine months ended September 30, 2025, as compared with the same prior year period, mostly driven by an increase in gross profit of $3.0 million or 19.1%, partially offset by an increase in operating expenses of $0.6 million or 2.8%.

LIQUIDITY AND CAPITAL RESOURCES

Our principal source of liquidity is our cash on hand of approximately $8.5 million as of September 30, 2025. Our principal source of operating cash inflows is from sales of our products. Our principal cash outflows relate to selling, general and administrative expenses, the purchase and production of inventory, and funding of research and development.

Our inventory position was $4.4 million at September 30, 2025, which reflects an increase of $1.6 million from December 31, 2024.

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 utilize a combination of the above. 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:

	Nine Months Ended September 30, 2025	Nine Months Ended September 30, 2024
Net cash used in operating activities	$ (632,351)	$ (1,259,333)
Net cash used in investing activities	$ (528,135)	$ (1,383,780)
Net cash used in financing activities	$ 43,558	$ (32,817)

Operating Activities

Net cash used in operating activities was $0.6 million for the nine months ended September 30, 2025, as compared to $1.3 million in the prior year period. This net cash usage of $0.6 million was primarily due to the net loss of $2.2 million, working capital increases of $0.9 million, consisting of increases in inventory of $1.6 million, and an increase in prepaid expenses of $0.2 million partially offset by decrease in accounts receivable and contract assets of $0.3 million, an increase in accounts payable of $0.2 million, and an increase in accrued expenses of $0.4 million . Additional offsets to the net loss were non-cash items including stock-based compensation expense of $1.7 million, and depreciation and amortization expense of $0.6 million.

Net cash used in operating activities was $1.3 million for the nine months ended September 30, 2024, as compared to $6.0 million in the same period in 2023. This net cash usage of $1.3 million was primarily due to the net loss of $4.5 million, working capital decreases of $0.6 million, consisting of an increase in accounts receivable of $1.2 million, and increases in inventory of $0.4 million, partially offset by increases in accounts payable and payroll bonus accruals of $1.9 million, and decreases in pre-paid expenses of $0.3 million. Additional offsets to the net loss were non-cash items including stock-based compensation expense of $1.9 million, and depreciation and amortization expense of $0.7 million.

Investing Activities

Net cash used in investing activities of $0.5 million for the nine months ending September 30, 2025, was due to capital expenditures related to purchases of manufacturing equipment for our new consumable and pump production lines.

Net cash used in investing activities of $1.4 million for the nine months ending September 30, 2024, was for capital expenditures for manufacturing equipment related to our new consumables production lines.

Financing Activities

Net cash gained from financing activities of $0.04 million for the nine months ended September 30, 2025 was primarily due to cash receipts related to the exercise of employee stock options, mostly offset by payments on our note payable for insurance premium financing.

Net cash used in financing activities of $0.03 million for the nine months ended September 30, 2024 was due to payments on our note payable for insurance premium financing, partially offset by new borrowings for a subsequent insurance premium financing agreement.

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 nine months ended September 30, 2025, 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, 2024 and our Quarterly Report on Form 10-Q for the quarter ending March 31, 2025, 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
3.1(i)	Certificate of Incorporation of KORU Medical Systems, Inc. (incorporated by reference to our Form 8-K filed with the SEC on May 17, 2023).
3.1(ii)	Bylaws of KORU Medical Systems, Inc. (incorporated by reference to our Form 8-K filed with the SEC on May 17, 2023).
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.

November 12, 2025

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

November 12, 2025

/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: November 12, 2025

/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: November 12, 2025

/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 September 30, 2025 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: November 12, 2025

/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 September 30, 2025 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: November 12, 2025

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