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, 2023

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 8, 2023, 45,669,362 shares of common stock, $0.01 par value per share, were outstanding, which excludes 3,420,502 shares of treasury stock.

KORU MEDICAL SYSTEMS, INC.
FORM 10-Q
FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2023
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PART I — FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

KORU MEDICAL SYSTEMS, INC.
BALANCE SHEETS
(UNAUDITED)

	September 30, 2023	December 31, 2022
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 10,772,178	$ 17,408,257
Accounts receivable less allowance for doubtful accounts of $24,777 as of September 30, 2023 and $21,459 as of December 31, 2022	4,050,756	3,558,884
Inventory	4,676,913	6,404,867
Other receivables	813,499	972,396
Prepaid expenses	1,373,348	1,457,232
TOTAL CURRENT ASSETS	21,686,694	29,801,636
Property and equipment, net	3,820,087	3,886,975
Intangible assets, net of accumulated amortization of $373,943 and $325,872 as of September 30, 2023 and December 31, 2022, respectively	758,423	787,182
Operating lease right-of-use assets	3,544,959	3,786,545
Deferred income tax assets, net	5,445,123	3,967,480
Other assets	98,969	102,625
TOTAL ASSETS	$ 35,354,255	$ 42,332,443
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 945,619	$ 2,391,799
Accrued expenses	1,458,529	2,889,941
Note payable	466,026	433,295
Other liabilities	500,620	257,337
Accrued payroll and related taxes	392,527	542,399
Financing lease liability – current	102,470	98,335
Operating lease liability – current	356,349	345,834
TOTAL CURRENT LIABILITIES	4,222,140	6,958,940
Financing lease liability, net of current portion	316,906	394,283
Operating lease liability, net of current portion	3,384,666	3,653,257
TOTAL LIABILITIES	7,923,712	11,006,480
Commitments and Contingencies (Note 7)		
STOCKHOLDERS' EQUITY		
Common stock, $0.01 par value, 75,000,000 shares authorized, 49,059,583 and 48,861,891 shares issued 45,639,081 and 45,441,389 shares outstanding as of September 30, 2023, and December 31, 2022, respectively	490,596	488,619
Additional paid-in capital	46,629,753	44,252,117
Treasury stock, 3,420,502 shares as of September 30, 2023 and December 31, 2022, at cost	(3,843,562)	(3,843,562)
Accumulated deficit	(15,846,244)	(9,571,211)
TOTAL STOCKHOLDERS' EQUITY	27,430,543	31,325,963
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 35,354,255	$ 42,332,443

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,	
	2023	2022	2023	2022
NET REVENUES	$ 7,003,198	$ 7,760,398	$ 21,331,734	$ 20,551,356
Cost of goods sold	2,661,021	3,438,036	8,954,398	9,260,516
Gross Profit	4,342,177	4,322,362	12,377,336	11,290,840
OPERATING EXPENSES				
Selling, general and administrative	4,623,928	4,825,349	15,352,972	15,846,584
Research and development	1,293,256	862,148	4,454,739	3,314,233
Depreciation and amortization	216,014	164,344	642,050	399,479
Total Operating Expenses	6,133,198	5,851,841	20,449,761	19,560,296
Net Operating Loss	(1,791,021)	(1,529,479)	(8,072,425)	(8,269,456)
Non-Operating Income/(Expense)				
Loss on currency exchange	(9,390)	(10,057)	(12,542)	(38,897)
Loss on disposal of fixed assets, net	(3,527)	—	(59,806)	—
Interest income, net	135,429	42,476	392,098	44,579
TOTAL OTHER INCOME/(EXPENSE)	122,512	32,419	319,750	5,682
LOSS BEFORE INCOME TAXES	(1,668,509)	(1,497,060)	(7,752,675)	(8,263,774)
Income Tax Benefit	300,247	271,500	1,477,642	1,579,359
NET LOSS	$ (1,368,262)	$ (1,225,560)	$ (6,275,033)	$ (6,684,415)
NET LOSS PER SHARE				
Basic	$ (0.03)	$ (0.03)	$ (0.14)	$ (0.15)
Diluted	$ (0.03)	$ (0.03)	$ (0.14)	$ (0.15)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING				
Basic	45,639,081	45,038,181	45,578,314	44,877,366
Diluted	45,639,081	45,038,181	45,578,314	44,877,366

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, 2023	For the Nine Months Ended September 30, 2022
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	$ (6,275,033)	$ (6,684,415)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	2,379,613	2,361,085
Depreciation and amortization	642,050	399,479
Deferred income taxes	(1,477,643)	(1,579,569)
Loss on disposal of fixed assets	59,806	—
ROU landlord credit	(16,489)	218,044
Changes in operating assets and liabilities:		
Increase in Accounts receivable	(332,975)	(1,445,079)
Decrease / (Increase) in Inventory	1,727,954	(777,818)
Increase in Prepaid expenses and other assets	87,540	(160,794)
Increase in Other liabilities	243,283	267,491
(Decrease) / Increase in Accounts payable	(1,446,180)	138,077
(Decrease) / Increase in Accrued payroll and related taxes	(149,872)	663,444
Decrease in Accrued expenses	(1,431,412)	(140,958)
NET CASH USED IN OPERATING ACTIVITIES	(5,989,358)	(6,741,013)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property and equipment	(586,897)	(2,541,693)
Purchases of intangible assets	(19,312)	(36,003)
NET CASH USED IN INVESTING ACTIVITIES	(606,209)	(2,577,696)
CASH FLOWS FROM FINANCING ACTIVITIES		
Borrowings from indebtedness	565,172	644,733
Payments on indebtedness	(532,441)	(508,583)
Proceeds from issuance of equity	—	314,000
Payments on finance lease liability	(73,243)	(25,062)
NET CASH (USED IN) PROVIDED BY FINANCING ACTIVITIES	(40,512)	425,088
NET DECREASE IN CASH AND CASH EQUIVALENTS	(6,636,079)	(8,893,621)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	17,408,257	25,334,889
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 10,772,178	$ 16,441,268
Supplemental Information		
Cash paid during the periods for:		
Interest	$ 34,773	$ 15,700
Income taxes	$ 3,160	$ —
Schedule of Non-Cash Operating, Investing and Financing Activities:		
Issuance of common stock as compensation	$ 348,849	$ 355,505

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

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

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Treasury Stock	Total Stockholders' Equity
	Shares	Amount				
Three and Nine Months Ended September 30, 2023						
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
Accrued compensation paid in shares	25,931	259	82,567	—	—	82,826
Compensation expense related to stock options	—	—	551,250	—	—	551,250
Compensation expense related to restricted stock awards	—	—	63,582	—	—	63,582
Net loss	—	—	—	(1,368,262)	—	(1,368,262)
BALANCE, SEPTEMBER 30, 2023	49,059,583	$ 490,596	$ 46,629,753	$ (15,846,244)	$ (3,843,562)	$ 27,430,543

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Treasury Stock	Total Stockholders' Equity
Three and Nine Months Ended September 30, 2022						
BALANCE, DECEMBER 31, 2021	48,044,162	$ 480,441	$ 40,774,245	$ (910,069)	$ (3,843,562)	$ 36,501,055
Accrued compensation paid in shares	47,500	475	142,025	—	—	142,500
Compensation expense related to stock options	—	—	524,670	—	—	524,670
Compensation expense related to restricted stock awards	—	—	170,386	—	—	170,386
Issuance upon options exercised	29,627	296	(296)	—	—	—
Net loss	—	—	—	(2,537,514)	—	(2,537,514)
BALANCE, MARCH 31, 2022	48,121,289	$ 481,212	$ 41,611,030	$ (3,447,583)	$ (3,843,562)	$ 34,801,097
Accrued compensation paid in shares	69,707	697	114,808	—	—	115,505
Compensation expense related to stock options	—	—	527,736	—	—	527,736
Compensation expense related to restricted stock awards	50,000	500	231,011	—	—	231,511
Issuance upon options exercised	166,623	1,667	(134,825)	—	—	(133,158)
Net loss	—	—	—	(2,921,341)	—	(2,921,341)
BALANCE, JUNE 30, 2022	48,407,619	$ 484,076	$ 42,349,760	$ (6,368,924)	$ (3,843,562)	$ 32,621,350
Accrued compensation paid in shares	45,936	460	97,041	—	—	97,501
Compensation expense related to stock options	—	—	514,047	—	—	514,047
Compensation expense related to restricted stock awards	—	—	170,387	—	—	170,387
Issuance upon options exercised	203,468	2,034	311,966	—	—	314,000
Net loss	—	—	—	(1,225,560)	—	(1,225,560)
BALANCE, SEPTEMBER 30, 2022	48,657,023	$ 486,570	$ 43,443,201	$ (7,594,484)	$ (3,843,562)	$ 32,491,725

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

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, 2022 (“Annual Report”). In accordance with the rules and regulations of the U.S. Securities and Exchange Commission (“SEC”), the Company has omitted footnote disclosures that would substantially duplicate the disclosures contained in the audited financial statements of the Company. The accompanying interim financial statements are unaudited and reflect all adjustments which are in the opinion of management necessary for a fair statement of the Company’s financial position, results of operations, and cash flows for the periods presented. All such adjustments are of a normal, recurring nature. The Company’s results of operations and cash flows for the interim periods are not necessarily indicative of the results of operations and cash flows that it may achieve in future periods.

CASH AND CASH EQUIVALENTS

For purposes of the statements of cash flows, the Company considers all short-term investments with an original maturity of three months or less to be cash equivalents. The Company has historically held cash balances in excess of $250,000 at its primary commercial bank, which exceeds FDIC insurance limits. To reduce the risk of uninsured deposits, the Company entered an insured cash sweep program with KeyBank during the second quarter of 2023 to automatically invest its uninsured bank cash balances over $250,000 into FDIC insured banks so there is no more than $250,000 maintained at any one bank. Further, as of September 30, 2023 the Company had invested $10.1 million in a US Treasury bill that matures every 90 days.

PATENTS

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

STOCK-BASED COMPENSATION

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

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

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

NET LOSS PER COMMON SHARE

Basic net loss per common share is calculated by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted net loss per common share is computed by dividing net loss by the weighted average number of common and common equivalent shares outstanding during the period. The Company's potentially dilutive common shares are those that result from diluted common stock options and unvested restricted stock awards. The calculation of diluted loss per share excluded stock options of zero and 72,347, respectively, in weighted-average shares for each of the three months ended September 30, 2023 and 2022 and 4,047 and 81,723 respectively in weighted-average shares for each of the nine months ended September 30, 2023 and 2022, respectively, as their effect was anti-diluted as a result of the net loss incurred for those periods.

The calculation of diluted loss per share excluded stock options, performance-based restricted stock and performance-based restricted stock units (PSUs) of 904,496 and 1,022,347 respectively, in weighted-average shares for each of the three months ended September 30, 2023 and 2022 and 908,543 and 1,031,723 respectively in weighted-average shares for the nine months ended September 30, 2023 and 2022, respectively, as their effect was anti-diluted as a result of the net loss incurred for those periods.

The following securities were not included in the computation of diluted shares outstanding for the three and nine months ended September 30, 2023, and 2022 because the effect would be anti-dilutive:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Common stock options	$ —	$ 72,347	$ 4,047	$ 81,723
PSUs	54,496	—	54,496	—
Restricted stock	850,000	950,000	850,000	950,000
Total	$ 904,496	$ 1,022,347	$ 908,543	$ 1,031,723

Therefore, diluted weighted average number of shares outstanding and diluted net loss per share were the same as basic weighted average number of shares outstanding and net loss per share for the three and nine months ended September 30, 2023 and 2022.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Net loss	$ (1,368,262)	$ (1,225,560)	$ (6,275,033)	$ (6,684,415)
Weighted Average Outstanding Shares:				
Basic weighted average shares outstanding	45,639,081	45,038,181	45,578,314	44,877,366
Dilutive effect of outstanding stock options and unvested restricted stock	—	—	—	—
Diluted weighted average shares outstanding	45,639,081	45,038,181	45,578,314	44,877,366
Net loss per share				
Basic	$ (0.03)	$ (0.03)	$ (0.14)	$ (0.15)
Diluted	$ (0.03)	$ (0.03)	$ (0.14)	$ (0.15)

USE OF ESTIMATES IN THE FINANCIAL STATEMENTS

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates. Important estimates include but are not limited to asset lives, deferred tax valuation allowances, inventory valuation, and customer rebate and incentive accruals. The results of operations for the three and nine months ended September 30, 2023 are not necessarily indicative of the results that may be expected for the entire 2023 fiscal year.

REVENUE RECOGNITION

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

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

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

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

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

Contracts are often modified to account for changes in contract specifications and requirements. Contract modifications exist when the modification either creates new, or changes existing, enforceable rights and obligations. Generally, when contract modifications create new performance obligations, the modification is considered to be a separate contract and revenue is recognized prospectively. When contract modifications change existing performance obligations, the impact on the existing transaction price and measure of progress for the performance obligation to which it relates is generally recognized as an adjustment to revenue (either as an increase in or a reduction of revenue) on a cumulative catch-up basis. Contract assets primarily represent revenue earnings over time that are not yet billable based on the terms of the contracts. Contract liabilities (i.e., deferred revenue) consist of fees invoiced or paid by the Company's customers for which the associated performance obligations have not been satisfied and revenue has not been recognized based on the Company's revenue recognition criteria described above. As of September 30, 2023, the Company has recognized a contract asset of 36,095 which is included in other accounts receivable in the accompanying balance sheet.

The following table summarizes net revenues by geography for the three and nine months ended September 30, 2023, and 2022:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Revenues				
Domestic	$ 5,929,071	$ 6,661,196	$ 17,899,463	$ 17,475,083
International	1,074,127	1,099,202	3,432,271	3,076,273
Total	$ 7,003,198	$ 7,760,398	$ 21,331,734	$ 20,551,356

ACCOUNTING PRONOUNCEMENTS RECENTLY ADOPTED

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

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

FAIR VALUE MEASUREMENTS

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

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

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

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

The carrying amounts of cash and cash equivalents, including investments in short-term U.S. Treasury bills, accounts receivable, prepaid expenses, accounts payable and accrued expenses are considered to be representative of their fair values because of the short-term nature of those instruments. There were no transfers between levels in the fair value hierarchy during the three and nine months ended September 30, 2023 and 2022.

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 September 30, 2023.

NOTE 2 — PROPERTY AND EQUIPMENT

Property and equipment consists of the following at:

	September 30, 2023	December 31, 2022
Furniture and office equipment	$ 1,366,553	$ 1,456,745
Leasehold improvements	1,939,833	2,413,820
Manufacturing equipment and tooling	3,023,031	2,810,813
Total property and equipment	6,329,417	6,681,378
Less: accumulated depreciation and amortization	(2,509,330)	(2,794,403)
Property and equipment, net	$ 3,820,087	$ 3,886,975

Leasehold improvements and accumulated amortization each decreased of $0.5 million is due to the closure of the Company's former Chester, New York office and manufacturing site.

Depreciation and amortization expense was $199,880 and $148,635 for the three months ended September 30, 2023 and 2022, respectively, and $593,979 and $353,197 for the nine months ended September 30, 2023 and 2022, respectively.

NOTE 3 — STOCK-BASED COMPENSATION

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

As of September 30, 2023, there were options to purchase 2,600,000 shares of the Company's common stock outstanding to certain executives, key employees and consultants under the 2015 Plan, of which zero were issued during the three months ended September 30, 2023 and 40,000 were issued during the nine months ended September 30, 2023. Additional options may be issued under the 2015 Plan as outstanding options are forfeited, subject to a maximum 124,250 available for issuance under the 2015 Plan as of September 30, 2023.

The 2021 Plan provides for the grant of up to 1,000,000 incentive stock options, nonqualified stock options, stock awards, restricted stock awards, restricted stock units and/or stock appreciation rights to employees, consultants and directors. During the three months ended September 30, 2023, there were 100,000 option awards issued under the 2021 Plan. As of September 30, 2023, there had been 196,236 shares of common stock issued as directors fees, 21,100 executive bonus shares and 620,000 shares issued as executive and key employee compensation, and 54,496 in PSUs to an executive under the 2021 Plan in total. Additional equity incentive awards may be issued under the 2021 Plan as outstanding awards are forfeited, subject to a maximum 120,398 shares available for issuance under the 2021 Plan as of September 30, 2023.

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. From May 18, 2021 to May 6, 2022, non-employee director compensation was paid pursuant to the 2021 Plan. Since May 6, 2022, non-employee director compensation has been paid pursuant to the Non-Employee Director Compensation Plan. All payments were and are pro-rated for partial service.

The per share weighted average fair value of stock options granted during the nine months ended September 30, 2023 and September 30, 2022 was $2.23 and $2.03, respectively. The fair value of each award is estimated on the grant date using the Black-Scholes option pricing model with the following weighted average assumptions used for grants in the nine months ended September 30, 2023 and September 30, 2022. Historical information was the primary basis for the selection of the expected volatility, expected dividend yield and the expected lives of the options. The risk-free interest rate was selected based upon yields of the U.S. Treasury issues with a term equal to the expected life of the option being valued. We have recognized tax benefits associated with stock-based compensation of $191,126 and $172,413 for the nine months ended September 30, 2023 and 2022, respectively.

The following table summarizes the activities for our Plans for the nine months ended September 30, 2023, and 2022.

	September 30, 2023	September 30, 2022
Dividend yield	0.00%	0.00%
Expected Volatility	54.8% - 61.3%	65.9% - 77.5%
Weighted-average volatility	—	—
Expected dividends	—	—
Expected term (in years)	10	10
Risk-free rate	3.50% - 4.05%	1.81% - 2.99%

The following table summarizes the status of the stock options:

	Nine Months Ended September 30, 2023		Nine Months Ended September 30, 2022	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at January 1	3,035,000	$ 3.93	3,672,500	$ 3.42
Granted	185,000	$ 3.18	770,000	$ 2.68
Exercised	—	$ —	831,250	$ 1.57
Forfeited	—	$ —	486,250	$ 2.73
Outstanding at September 30	3,220,000	$ 3.88	3,125,000	$ 3.84
Options exercisable at September 30	1,333,750	$ 4.57	825,000	$ 4.41
Weighted average fair value of options granted during the period	—	$ 2.23	—	$ 2.03
Stock-based compensation expense	—	$ 1,626,408	—	$ 1,564,027

Total stock-based compensation expense was $1,626,408 and $1,564,027 for the nine months ended September 30, 2023, and 2022, respectively. No cash was received from option exercises for the nine months ended September 30, 2023, and $314,000 for 2022.

The weighted-average grant-date fair value of options granted during the nine months ended September 30, 2023, and 2022 was $0.4 million and $1.6 million, respectively. There were no options exercised during the nine months ended September 30, 2023 and 831,250 options exercised during the nine months ended September 30, 2022.

The following table presents information pertaining to options outstanding at September 30, 2023:

Range of Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$2.25-$9.49	3,220,000	8.3 years	$ 3.88	1,333,750	$ 4.57

As of September 30, 2023, there was $3,871,986 of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the Plans. That cost is expected to be recognized over a weighted-average period of 46 months. The total fair value of shares vested as of September 30, 2023, and September 30, 2022, was $4,536,052 and $2,679,152, respectively.

RESTRICTED STOCK AWARDS AND PSUs

The following table summarizes the activities for our restricted stock awards and PSUs for the nine months ended September 30, 2023, and 2022.

	Nine Months Ended September 30,			
	2023		2022	
	Shares	Weighted Average Grant-Date Fair Value	Shares	Weighted Average Grant-Date Fair Value
Unvested at January 1	950,000	$ 3.04	—	$ —
Granted	54,496	$ 3.68	1,000,000	$ 3.01
Vested	100,000	$ 3.31	50,000	$ 3.31
Forfeited/canceled	—	$ —	—	$ —
Unvested at September 30	904,496	$ 2.97	950,000	$ 2.99

Total stock-based compensation expense was $404,386 and $572,284 for the nine months ended September 30, 2023, and 2022, respectively.

As of September 30, 2023, and 2022, there was $1,215,518 and $1,788,565 of unrecognized compensation cost related to unvested employee restricted stock units. This amount is expected to be recognized over a weighted-average period of 21 months. We have recognized tax benefits associated with restricted stock award compensation of $84,921 and $107,344 for the nine months ended September 30, 2023 and 2022, respectively.

NOTE 4 — DEBT OBLIGATIONS

On July 28, 2023, the Company entered into a commercial insurance premium finance and security agreement with AON Premium Finance, LLC in the aggregate principal amount of $0.57 million bearing an annual percentage rate of 9.5%, to finance its insurance premiums. Monthly payments are due on the first of each month beginning August 1, 2023 through June 1, 2024. The balance of AON note was $433,295 as of December 31, 2022 and $466,026 as of September 30, 2023, respectively.

NOTE 5 — LEASES

The Company has an operating lease for its corporate office, and finance leases for certain office and computer equipment. Our operating lease has remaining lease term of 8.9 years. Our finance leases, which were entered into in June 2022 and October 2022, respectively, have remaining lease terms of 3.7 and 3.8 years, respectively, as of September 30, 2023.

The components of lease expense were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating lease cost	$ 112,038	$ 157,076	$ 336,839	$ 396,658
Short-term lease cost	42,844	18,300	120,881	96,588
Total lease cost	$ 154,882	$ 175,376	$ 457,720	$ 493,246
Finance lease cost:				
Amortization of right-of-use assets	$ 27,223	$ 17,754	$ 81,670	$ 23,672
Interest on lease liabilities	6,050	1,381	19,157	1,381
Total finance lease cost	$ 33,273	$ 19,135	$ 100,827	$ 25,053

Supplemental cash flow information related to leases was as follows:

	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 345,946	$ 301,150
Financing cash flows from finance leases	92,399	26,443

Supplemental balance sheet information related to leases was as follows:

	September 30, 2023	December 31, 2022
Operating Leases		
Operating lease right-of-use assets	$ 3,544,959	$ 3,786,545
Operating lease current liabilities	356,349	345,834
Operating lease long term liabilities	3,384,666	3,653,257
Total operating lease liabilities	$ 3,741,015	$ 3,999,091
Finance Leases		
Property and equipment, at cost	$ 544,468	$ 544,468
Accumulated depreciation	(132,565)	(50,895)
Property and equipment, net	$ 411,903	$ 493,573
Finance lease current liabilities	102,470	98,335
Finance lease long term liabilities	316,906	394,283
Total finance lease liabilities	$ 419,376	$ 492,618

	September 30, 2023	December 31, 2022
Weighted Average Remaining Lease Term		
Operating leases	8.9 Years	9.7 Years
Finance leases	3.7 Years	4.6 Years
Weighted Average Discount Rate		
Operating leases	4.00%	4.00%
Finance leases	4.25%	4.25%

Maturities of lease liabilities are as follows:

Year Ending December 31,	Operating Leases	Finance Leases
Remainder of 2023	$ 124,876	30,800
2024	499,503	123,200
2025	499,503	123,200
2026	499,503	123,200
2027	499,503	65,956
Thereafter	2,331,015	—
Total undiscounted lease payments	4,453,903	466,356
Less: imputed interest	(712,888)	(46,980)
Total lease liabilities	$ 3,741,015	$ 419,376

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 benefit of $0.3 million and income tax benefit of $0.3 million for the three months ended September 30, 2023 and 2022, respectively. For the nine months ended September, 30 2023 and 2022, the Company reported income tax benefit of $1.5 million and income tax benefit of $1.6 million, respectively.

Each reporting period, we evaluate the realizability of our net deferred tax assets and perform an assessment of both positive and negative evidence. Based on our evaluation of all available positive and negative evidence, we determined, as of September 30, 2023 and December 31, 2022, that it is more likely than not that our net U.S. deferred tax assets will be realized. Due to estimates and the potential for changes in facts and circumstances, it is reasonably possible that we will be required to record a valuation allowance in future reporting periods that could have a material effect on our results of operations.

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 2023.

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 2019 are no longer subject to examination by tax authorities.

NOTE 7 — COMMITMENTS AND CONTINGENCIES

LEGAL PROCEEDINGS

The Company has been and may again become involved in legal proceedings, claims and litigation arising in the ordinary course of business. KORU Medical 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

None.

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

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

Our actual results may vary materially from the forward-looking statements made in this report due to important factors such as uncertainties associated with global health crises, inflation, war and other geopolitical conflicts, customer ordering patterns, availability and costs of raw materials and labor and our ability to recover such costs, our ability to convert inventory to a source of cash, future operating results, growth of new patient starts and the SCIg market, our ability to partner with biopharmaceutical companies in our novel therapies business, Food and Drug Administration and foreign authority regulations and the outcome of regulatory audits, introduction of competitive products, acceptance of and demand for new and existing products, ability to penetrate new markets, success in enforcing and obtaining patents, reimbursement related risks, government regulation of the home health care industry, success of our research and development effort, expanding the market of FREEDOM system demand in the SCIg market, availability of sufficient capital if or when needed, dependence on key personnel, and the impact of recent accounting pronouncements, as well as those risks and uncertainties described in Part II.— Item IA. "Risk Factors" in this report and from time to time in our past and future reports filed with the Securities and Exchange Commission, including in our Annual Report on Form 10-K for the year ended December 31, 2022 in addition to others. When used in this report, the words "estimate," "project," "believe," "may," "will," "anticipate," "intend," "expect" and similar expressions are intended to identify forward-looking statements, which include, without limitation, statements regarding reduction of inventory, and need for additional financing. Such statements reflect current views with respect to future events based on currently available information and are subject to risks and uncertainties that could cause actual results to differ materially from those contemplated in such forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. The Company does not undertake any obligation to release publicly any revision to these forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.

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

OVERVIEW

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

Our revenues derive from three business sources: (i) domestic core (consisting 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 cleared by FDA and other applicable global regulatory authorities (e.g. EU Competent Authorities) for use with the FREEDOM System, with the primary use being for the delivery for immunoglobulin to treat Primary Immunodeficiency Diseases ("PIDD") and Chronic Inflammatory Demyelinating Polyneuropathy ("CIDP"). Novel therapies 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. Our novel therapies revenues can fluctuate and may not be consistent from period to period. Engineering work performed on our product may be specialized and tailored to the specific needs of each independent clinical trial and not uniform in nature. The clinical trial size and scope of protocols may also range greatly from customer to customer, and there is no expectation of repeat customers on a consistent basis compared to our core business.

The Company ended the 2023 third fiscal quarter with $7.0 million in net revenues, a 9.8% decrease, compared with $7.8 million in the same period last year primarily driven by a decrease in novel therapies net revenues of $0.6 million. The decrease was driven primarily by a large clinical trial order of $0.5 million in the prior year quarter. The Company had lower domestic core revenues of $0.1 million in the third quarter of 2023 compared to the prior year quarter primarily resulting from the clearing of a $0.3 million backorder in the prior year. International core net revenues for the quarter ended September 30, 2023 decreased $0.03 million.

Gross profit for the three months ended September 30, 2023, was flat compared to the same period last year despite lower revenues and, stated as a percentage of net revenues was 62.0%, an increase from 55.7% in the prior year period.

Operating expenses for the three months ended September 30, 2023, were $6.1 million, up from $5.9 million for the same period last year, driven primarily by an increase of $0.4 million in research and development expenses offset by a reduction of $0.2 million in selling, general and administrative expenses.

RESULTS OF OPERATIONS

Three months ended September 30, 2023, compared to September 30, 2022

Net Revenues

The following table summarizes our net revenues for the three months ended September 30, 2023, and 2022:

	Three Months Ended September 30,		Change from Prior Year		% of Net Revenues	
	2023	2022	$	%	2023	2022
Net Revenues						
Domestic Core	$ 5,773,863	$ 5,900,042	$ (126,179)	(2.1%)	82.5%	76.0%
International Core	1,066,567	1,096,746	(30,179)	(2.8%)	15.2%	14.1%
Novel Therapies	162,768	763,610	(600,842)	(78.7%)	2.3%	9.9%
Total	$ 7,003,198	$ 7,760,398	$ (757,200)	(9.8%)		

Total net revenues decreased $0.8 million, or 9.8%, for the three months ended September 30, 2023, as compared with the same period last year. Novel therapies net revenues declined by 78.7% primarily driven by a large clinical trial order of $0.5 million in the prior period and timing of collaborations. Domestic core revenues declined by 2.1% driven by lower consumable volumes as compared to prior period which included a clearing of a $0.3 million consumable backorder, as well as a lower US market prescriptions for subcutaneous immunoglobulin drugs in the current year period, partially offset by an increase in pump units sold. International core revenues declined by 2.8%, driven largely by a tender order in the prior period partially offset by volume growth in several countries.

Gross Profit

Our gross profit for the three months ended September 30, 2023 and 2022 is as follows:

	Three Months Ended September 30,		Change from Prior Year	
	2023	2022	$	%
Gross Profit	$ 4,342,177	$ 4,322,362	$ 19,815	0.5%
Stated as a Percentage of Net Revenues	62.0%	55.7%		

Gross profit was mostly flat in the three months ended September 30, 2023, compared to the same period in 2022. Gross profit as a percentage of revenues increased to 62.0% compared to 55.7% in the third quarter of 2022. The increase in the gross profit as a percentage of revenues was primarily driven by production efficiencies from the outsourced manufacturing initiative and Chester site exit when compared to the prior year.

Selling, general and administrative and research and development

Our selling, general and administrative and research and development costs for the three months ended September 30, 2023 and 2022 are as follows:

	Three Months Ended September 30,		Change from Prior Year	
	2023	2022	$	%
Selling, general and administrative	$ 4,623,928	$ 4,825,349	$ (201,421)	(4.2%)
Research and development	1,293,256	862,148	431,108	50.0%
	$ 5,917,184	$ 5,687,497	$ 229,687	4.0%

Selling, general and administrative expenses decreased $0.2 million, or 4.2%, during the three months ended September 30, 2023 compared with the same period last year, primarily due to $0.2 million of compensation and benefits related to executive management restructuring costs that took place in the prior year.

Research and development expenses increased $0.4 million, or 50.0% during the three months ended September 30, 2023 compared with the same period last year, primarily due to increases in expenses associated with the support of our innovation efforts for both core and novel therapies businesses.

Depreciation and amortization

Depreciation and amortization expense increased by 31.4% to $216,014 in the three months ended September 30, 2023 compared with $164,344 in the three months ended September 30, 2022 from commissioning of our in-house manufacturing space, research and development laboratories, and equipment commencing in the fourth quarter of 2022.

Net Loss

	Three Months Ended September 30,		Change from Prior Year	
	2023	2022	$	%
Net Loss	$ (1,368,262)	$ (1,225,560)	$ (142,702)	(11.6%)

Our net loss increased $0.1 million in the three months ended September 30, 2023 compared with the same period last year, mostly driven by a decrease in net revenues of $0.8 million offset by improved gross margins of $0.8 million. Operating expenses increased by $0.3 million which were partially offset by $0.1 million due to higher interest and dividend income from our treasury bill investments.

A tax benefit of $0.3 million resulting from the loss was also recorded during the three months ended September 30, 2023.

Nine months ended September 30, 2023, compared to September 30, 2022

Net Revenues

The following table summarizes our net revenues for the nine months ended September 30, 2023, and 2022:

	Nine Months Ended September 30,		Change from Prior Year		% of Net Revenue	
	2023	2022	$	%	2023	2022
Net Revenues						
Domestic Core	$ 16,881,170	$ 15,890,369	$ 990,801	6.2%	79.1%	77.3%
International Core	3,281,061	2,943,173	337,888	11.5%	15.4%	14.3%
Novel Therapies	1,169,503	1,717,814	(548,311)	(31.9%)	5.5%	8.4%
Total	$ 21,331,734	$ 20,551,356	$ 780,378	3.8%		

Total net revenues increased $0.8 million, or 3.8%, for the nine months ended September 30, 2023, as compared with the same period last year. Domestic core growth of 6.2% was primarily driven by volume growth in consumables and pumps attributed to new accounts, and increased prefilled syringe adoptions despite a decline in US market prescriptions for subcutaneous immunoglobulin drugs. International core growth of 11.5%, was driven by increased volume across several EU markets. Novel therapies net revenues declined by 31.9% driven primarily by higher clinical trial supply shipments in the prior period.

Gross Profit

Our gross profit for the nine months ended September 30, 2023 and 2022 is as follows:

	Nine Months Ended September 30,		Change from Prior Year	
	2023	2022	$	%
Gross Profit	$ 12,377,336	$ 11,290,894	$ 1,086,442	9.6%
Stated as a Percentage of Net Revenues	58.0%	54.9%		

Gross profit increased $1.1 million or 9.6% in the nine months ended September 30, 2023, compared to the same period in 2022 driven by the increase in net revenues of $0.8 million as described above. Gross profit as a percentage of revenues increased to 58.0% in the first nine months of 2023 compared to 54.9% from the first nine months of 2022 primarily driven by increased manufacturing efficiencies versus the prior year.

Selling, general and administrative and research and development

Our selling, general and administrative and research and development costs for the nine months ended September 30, 2023 and 2022 are as follows:

	Nine Months Ended September 30,		Change from Prior Year	
	2023	2022	$	%
Selling, general and administrative	$ 15,352,972	$ 15,846,584	$ (493,612)	(3.1%)
Research and development	4,454,739	3,314,233	1,140,506	34.4%
	$ 19,807,711	$ 19,160,817	$ 646,894	3.4%

Selling, general and administrative expenses decreased $0.5 million, or 3.1%, during the nine months ended September 30, 2023 compared with the same period last year, primarily due to $0.7 million in compensation and benefits related to executive management restructuring costs that took place in the prior year, and a decrease in recruiting costs of $0.2 million, partially offset by $0.4 million increase in compensation costs related to medical affairs and business development in the current year.

Research and development expenses increased $1.1 million, or 34.4% during the nine months ended September 30, 2023 compared with the same period last year, primarily due to $0.3 million in compensation and benefits, $0.1 million in stock compensation and $0.6 million in expenses to support acceleration of our innovation efforts.

Depreciation and amortization

Depreciation and amortization expense increased by 60.7% to $642,050 in the nine months ended September 30, 2023 compared with $399,479 in the nine months ended September 30, 2022 resulting from prior year investments in our Mahwah corporate facility which includes our corporate office, in-house manufacturing, and research and development labs.

Net Loss

	Nine Months Ended September 30,		Change from Prior Year	
	2023	2022	$	%
Net Loss	$ (6,275,033)	$ (6,684,415)	$ 409,382	6.1%

Our net loss decreased $0.4 million in the nine months ended September 30, 2023 compared with the same period last year mostly driven by an increase in net revenues of $0.8 million and associated higher gross profit of $1.1 million, an increase in other income of $0.3 million due to higher interest and dividend income from our treasury bill investments, which was partially offset by higher operating expenses of $0.9 million and $0.1 million unfavorable change in tax benefit.

A tax benefit of $1.5 million resulting from the loss was also recorded during the nine months ended September 30, 2023.

LIQUIDITY AND CAPITAL RESOURCES.

Our principal source of liquidity is our cash and cash equivalents on hand of $10.8 million as of September 30, 2023. Our principal source of operating cash inflows is from sales of our products and NRE services to customers. 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 tooling and equipment for new products.

Our inventory position was $4.7 million as of September 30, 2023, which reflected a decrease of $1.7 million from December 31, 2022. We have completed the transition of our manufacturing operations to Command and expect to continue to reduce our inventory position during the final quarter of 2023.

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") was signed into law. The CARES Act contains a provision known as the Employee Retention Credit ("ERC"), a refundable payroll tax credit for qualified wages paid to retained full-time employees between March 13, 2020, and December 31, 2020. The Consolidations Appropriations Act (CAA), signed into law on December 27, 2020, significantly modified and expanded the provisions of the ERC to include wages paid in 2021. For 2021, the ERC provides employers a refundable federal tax credit equal to 70% of the first $10,000 of qualified wages and benefits paid to retained employees between January 1, 2021, and December 31, 2021. Credits may be claimed immediately by reducing payroll taxes sent to the Internal Revenue Service. To the extent that the credit exceeds employment withholdings, the employer may request a refund of prior taxes paid. The Company determined that it qualified for this credit and anticipated utilizing benefits under this act to aid its liquidity position and as a result recorded a receivable of $0.7 million as of December 31, 2021. We collected the credit in October 2023.

We expect that our cash on hand, cash flows from operations and available financing sources will be sufficient to meet our requirements at least the next twelve months from the issuance of this Form 10-Q. Continued execution on our longer-term strategic plan may require the Company to take on additional debt. The Company is actively exploring potential debt financing sources in the event additional cash is needed beyond twelve months. Alternatively, or in addition, we may need to raise capital through issuance of equity or other securities. Our future capital requirements may vary from those currently planned and will depend on many factors, including our rate of revenue 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, rising interest rates, increased demand for equity investor capital 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 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, 2023		Nine Months Ended September 30, 2022	
Net cash used in operating activities	$	(5,989,358)	$	(6,741,013)
Net cash used in investing activities	$	(606,209)	$	(2,577,696)
Net cash (used in) provided by financing activities	$	(40,512)	$	425,088

Operating Activities

Net cash used in operating activities was $6.0 million for the nine months ended September 30, 2023. This net cash usage was primarily due to the net loss of $6.3 million, plus cash flows used to reduce accrued expenses of $1.4 million, primarily from the payment of 2023 bonuses, and a decrease in accounts payable of $1.4 million, offset by cash flows generated from a decrease in inventory of $1.7 million, and an increase in accounts receivable of $0.3 million. Further contributing to this change were non-cash items including an increase in deferred tax assets of $1.5 million offset by stock-based compensation expense of $2.4 million, depreciation and amortization expense of $0.6 million and a loss on disposal of fixed assets of $0.1 million.

Net cash used in operating activities of $6.7 million for the nine months ended September 30, 2022 was primarily due to the net loss of $6.7 million, working capital changes which included an increase in accounts receivable of $1.4 million, an increase in inventory of $0.7 million, an increase in prepaid expense of 0.2 million, and a decrease in accrued expenses of $0.1 million, offset by an increase in accrued payroll of $0.7 million and an increase in accounts payable and other liabilities of $0.4 million. Further contributing were deferred tax assets of $1.6 million increased for book to tax differences related to stock option expense. Offsetting these were primarily non-cash charges for stock-based compensation of $2.7 million, and depreciation and amortization of $0.4 million.

Investing Activities

Net cash used in investing activities of $0.6 million for the nine months ending September 30, 2023, was for capital expenditures for research and development and manufacturing equipment.

Net cash used in investing activities of $2.6 million for the nine months ending September 30, 2022, was for capital expenditures for manufacturing and office equipment for our corporate office and manufacturing facilities move.

Financing Activities

Net cash used in financing activities for the nine months ended September 30, 2023 is $0.05 million, a net between borrowings and payments on our note payable for insurance premium financing, and $0.1 million for payments on our finance leases.

The $0.4 million provided by financing activities for the nine months ended September 30, 2022, is from $0.3 million in option exercises and $0.1 million net borrowings on our indebtedness for a note payable for insurance premium financing.

ACCOUNTING PRONOUNCEMENTS NOT YET ADOPTED

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

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

There have been no changes in the Company's internal control over financial reporting during the nine months ended September 30, 2023, 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, 2022, our Quarterly Report on Form 10-Q for the quarter ended September 30, 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.
November 8, 2023	/s/ Linda Tharby Linda Tharby, President and Chief Executive Officer (Principal Executive Officer)
November 8, 2023	/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 8, 2023

/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 8, 2023

/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, 2023 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 8, 2023

/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, 2023 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 8, 2023

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