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, 2022

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)

New York	**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 9, 2022, 45,279,948 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, 2022
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PART I — FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

KORU MEDICAL SYSTEMS, INC.
BALANCE SHEETS
(UNAUDITED)

	September 30, 2022	December 31, 2021
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 16,441,268	$ 25,334,889
Accounts receivable less allowance for doubtful accounts of $24,471 for September 30, 2022, and December 31, 2021	5,070,077	3,592,886
Inventory	6,884,156	6,106,338
Other Receivables	686,108	718,220
Prepaid expenses	1,660,655	1,568,821
TOTAL CURRENT ASSETS	30,742,264	37,321,154
Property and equipment, net	3,318,612	1,106,445
Intangible assets, net of accumulated amortization of $310,011 and $263,729 at September 30, 2022 and December 31, 2021, respectively	798,534	808,813
Operating lease right-of-use assets	3,865,370	95,553
Finance lease right -of-use, net accumulated depreciation of $23,671 at September 30, 2022	331,400	—
Deferred income tax assets, net	3,520,823	1,941,254
Other assets	88,772	19,812
TOTAL ASSETS	$ 42,665,775	$ 41,293,031
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 1,365,610	$ 1,227,533
Accrued expenses	2,568,746	2,709,704
Note Payable	644,733	508,583
Other Liabilities	357,491	90,000
Accrued payroll and related taxes	824,047	160,603
Financing lease liability – current	64,467	—
Operating lease liability – current	342,399	95,553
TOTAL CURRENT LIABILITIES	6,167,493	4,791,976
Financing lease liability, net of current portion	265,542	—
Operating lease liability, net of current portion	3,741,015	—
TOTAL LIABILITIES	10,174,050	4,791,976
STOCKHOLDERS' EQUITY		
Common stock, $0.01 par value, 75,000,000 shares authorized, 48,657,023 and 48,044,162 shares issued 45,236,521 and 44,623,660 shares outstanding at September 30, 2022, and December 31, 2021, respectively	486,570	480,441
Additional paid-in capital	43,443,201	40,774,245
Treasury stock, 3,420,502 shares at September 30, 2022 and December 31, 2021, respectively, at cost	(3,843,562)	(3,843,562)
Retained deficit	(7,594,484)	(910,069)
TOTAL STOCKHOLDERS' EQUITY		

	32,491,725	36,501,055
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 42,665,775	$ 41,293,031

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
NET SALES	$ 7,760,398	$ 6,040,544	$ 20,551,356	$ 16,999,669
Cost of goods sold	3,438,036	2,544,794	9,260,516	7,061,881
Gross Profit	4,322,362	3,495,750	11,290,840	9,937,788
OPERATING EXPENSES				
Selling, general and administrative	4,825,349	3,901,830	15,846,584	12,980,604
Research and development	862,148	800,020	3,314,233	1,523,739
Depreciation and amortization	164,344	115,934	399,479	349,822
Total Operating Expenses	5,851,841	4,817,784	19,560,296	14,854,165
Net Operating Loss	(1,529,479)	(1,322,034)	(8,269,456)	(4,916,377)
Non-Operating Income/(Expense)				
Loss on currency exchange	(10,057)	(7,283)	(38,897)	(21,761)
Gain on disposal of fixed assets, net	—	273	—	1,009
Interest income (expense), net	42,476	(2,838)	44,579	16,883
TOTAL OTHER INCOME/(EXPENSE)	32,419	(9,848)	5,682	(3,869)
LOSS BEFORE INCOME TAXES	(1,497,060)	(1,331,882)	(8,263,774)	(4,920,246)
Income Tax Benefit	271,500	238,104	1,579,359	1,425,781
NET LOSS	$ (1,225,560)	$ (1,093,778)	$ (6,684,415)	$ (3,494,465)
NET LOSS PER SHARE				
Basic	$ (0.03)	$ (0.02)	$ (0.15)	$ (0.08)
Diluted	$ (0.03)	$ (0.02)	$ (0.15)	$ (0.08)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING				
Basic	45,038,181	44,322,335	44,877,366	44,510,021
Diluted	45,038,181	44,322,335	44,877,366	44,510,021

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

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

	For the Nine Months Ended September 30,	
	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	$ (6,684,415)	$ (3,494,465)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	2,361,085	1,967,632
Depreciation and amortization	399,479	349,822
Deferred income taxes	(1,579,569)	(1,440,060)
Loss on disposal of fixed assets	—	(1,009)
ROU landlord credit	218,044	—
Changes in operating assets and liabilities:		

Increase in accounts receivable	(1,445,079)	(549,711)
Increase in inventory	(777,818)	(138,160)
Increase in prepaid expenses and other assets	(160,794)	(529,039)
Increase in other Liabilities	267,491	—
Increase in accounts payable	138,077	760,493
Increase in accrued payroll and related taxes	663,444	45,684
Decrease in accrued expenses	(140,958)	(573,565)
NET CASH USED IN OPERATING ACTIVITIES	(6,741,013)	(3,602,378)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property and equipment	(2,541,693)	(301,720)
Proceeds from disposal of property and equipment	—	9,065
Purchases of intangible assets	(36,003)	(25,838)
NET CASH USED IN INVESTING ACTIVITIES	(2,577,696)	(318,493)
CASH FLOWS FROM FINANCING ACTIVITIES		
Borrowings from indebtedness	644,733	924,389
Payments on indebtedness	(508,583)	(251,255)
Proceeds from issuance of equity	314,000	1,230,000
Common stock issuance as settlement for litigation	—	938,094
Payments on finance lease liability	(25,062)	(2,232)
NET CASH PROVIDED BY FINANCING ACTIVITIES	425,088	2,838,996
NET DECREASE IN CASH AND CASH EQUIVALENTS	(8,893,621)	(1,081,875)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	25,334,889	27,315,286
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 16,441,268	$ 26,233,411
Supplemental Information		
Cash paid during the periods for:		
Interest	$ 15,700	$ 6,194
Income Taxes	$ —	$ 850
Schedule of Non-Cash Operating, Investing and Financing Activities:		
Issuance of common stock as compensation	$ 355,505	$ 295,947
Issuance of common stock as settlement for litigation	$ —	$ 938,094

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

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

	Common Stock		Additional Paid-in	Retained Earnings	Treasury	Total Stockholders'
	Shares	Amount	Capital	(Deficit)	Stock	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
Issuance of stock-based compensation	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
Issuance of stock-based compensation	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
Issuance of stock-based compensation	45,936	460	97,041	—	—	97,501
Compensation expense related to stock	—	—	514,047	—	—	514,047

options						
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

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	Common Stock		Additional Paid-in	Retained Earnings	Treasury	Total Stockholders'
	Shares	Amount	Capital	(Deficit)	Stock	Equity
Three and Nine Months Ended September 30, 2021						
BALANCE, DECEMBER 31, 2020	46,680,119	$ 466,801	$ 35,880,986	$ 3,652,754	$ (3,843,562)	$ 36,156,979
Issuance of stock-based compensation	10,124	101	56,149	—	—	56,250
Compensation expense related to stock options	—	—	677,934	—	—	677,934
Litigation settlement share issuance	95,238	952	937,142	—	—	938,094
Issuance upon options exercised	1,110,580	11,106	1,218,894	—	—	1,230,000
Net loss	—	—	—	(1,276,138)	—	(1,276,138)
BALANCE, MARCH 31, 2021	47,896,061	$ 478,960	$ 38,771,105	$ 2,376,616	$ (3,843,562)	$ 37,783,119
Issuance of stock-based compensation	14,615	146	97,050	—	—	97,196
Compensation expense related to stock options	—	—	441,841	—	—	441,841
Compensation expense related to restricted stock awards	—	—	66,135	—	—	66,135
Net loss	—	—	—	(1,124,549)	—	(1,124,549)
BALANCE, JUNE 30, 2021	47,910,676	$ 479,106	$ 39,376,131	$ 1,252,067	$ (3,843,562)	$ 37,263,742
Issuance of stock-based compensation	20,988	211	142,290	—	—	142,501
Compensation expense related to stock options	—	—	406,414	—	—	406,414
Compensation expense related to restricted stock awards	—	—	79,362	—	—	79,362
Net loss	—	—	—	(1,093,778)	—	(1,093,778)
BALANCE, SEPTEMBER 30, 2021	47,931,664	$ 479,317	$ 40,004,197	$ 158,289	$ (3,843,562)	$ 36,798,241

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

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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 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, 2021 ("Annual Report"). Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with United States generally accepted accounting principles ("GAAP") have been condensed or omitted from the accompanying financial statements. The accompanying year-end balance sheet was derived from the audited financial statements included in the Annual Report. 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 statement 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 holds cash in excess of $250,000 at its depository, which exceeds the FDIC insurance limits and is, therefore, uninsured.

INVENTORY

Inventories of raw materials are stated at the lower of standard cost, which approximates average cost, or market value including allocable overhead. Work-in-process and finished goods are stated at the lower of standard cost or market value and include direct labor and allocable overhead.

PATENTS

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

INCOME TAXES

Deferred income taxes are provided using the liability method whereby deferred tax assets are recognized for deductible temporary differences and operating loss and tax credit carry forwards and deferred tax liabilities are recognized for taxable temporary differences.

The Company believes that it has no uncertain tax positions requiring disclosure or adjustment. Generally, tax years starting with 2019 are subject to examination by income tax authorities.

PROPERTY, EQUIPMENT, AND DEPRECIATION

Property and equipment is stated at cost and is depreciated using the straight-line method over the estimated useful lives of the respective assets.

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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. 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 earnings per share are computed on the weighted average of common shares outstanding during each year. Diluted earnings per share include only an increase in the weighted average shares by the common shares issuable upon exercise of employee and consultant stock options. See “NOTE 4 — STOCK-BASED COMPENSATION” for further detail.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Net loss	$ (1,225,560)	$ (1,093,778)	$ (6,684,415)	$ (3,494,465)
Weighted Average Outstanding Shares:				
Outstanding shares	45,038,181	44,322,335	44,877,366	44,510,021
Option shares includable	—(a)	—(a)	—(a)	—(a)
	45,038,181	44,322,335	44,877,366	44,510,021
Net loss per share				
Basic	$ (0.03)	$ (0.02)	$ (0.15)	$ (0.08)
Diluted	$ (0.03)	$ (0.02)	$ (0.15)	$ (0.08)

(a) For the three months ended September 30, 2022, and 2021, option shares of 72,347 and 296,504 respectively, were not included as the impact is anti-dilutive. For the nine months ended September 30, 2022, and 2021, option shares of 81,723 and 244,422 respectively, were not included as the impact is anti-dilutive.

For the three months ended September 30, 2022 and 2021, restricted shares of 950,000 and 1,000,000 respectively, were not included as the impact is anti-dilutive. For the nine months ended September 30, 2022, and 2021, restricted shares of 950,000 and 1,000,000 respectively, were not included as the impact is anti-dilutive.

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, valuation allowances, inventory valuation, and accruals.

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REVENUE RECOGNITION

Our revenues are derived from three business sources: (i) domestic core, (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 PIDD and 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.

For Product Revenues, 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 sales.

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.

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. 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 (ie completion milestone). The input method that we use is based on costs incurred.

The following table summarizes net sales by geography for the three and nine months ended September 30, 2022, and 2021:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Sales				
Domestic	$ 6,661,196	$ 5,254,336	$ 17,475,083	$ 14,346,895
International	1,099,202	786,208	3,076,273	2,652,774
Total	$ 7,760,398	$ 6,040,544	$ 20,551,356	$ 16,999,669

LEASES

In February 2016, the FASB issued a standard related to leases to increase transparency and comparability among organizations by requiring the recognition of right-of-use ("ROU") assets and lease liabilities on the balance sheet. Most prominent among the changes in the standard is the recognition of ROU assets and lease liabilities by the Company for those leases classified as operating leases under current GAAP, while our accounting for capital leases remains substantially unchanged. Under the standard, disclosures are required to meet the objective of enabling users of financial statements to assess the amount, timing, and uncertainty of cash flows arising from leases. The standard became effective for us on January 1, 2019. The standard had a material impact on our balance sheets but did not have a material impact on our statements of operations. See "NOTE 6 — LEASES" for further detail.

ACCOUNTING PRONOUNCEMENTS RECENTLY ADOPTED

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*. The amendments in this ASU simplify the accounting for income taxes by removing several exceptions including the exception to the general methodology for calculating income taxes in an interim period when a year-to-date loss exceeds the anticipated loss for the year. The amendments also improve consistent application of and simplify GAAP for other areas of Topic 740 by clarifying and amending existing guidance. The amendments in this ASU are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. The Company adopted this standard on January 1, 2021, and it has had no impact on our financial statement disclosures.

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ACCOUNTING PRONOUNCEMENTS NOT YET ADOPTED

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 amendments in this update are effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. The Company is assessing the impact of the adoption of the ASU on its financial statements, disclosure requirements and methods of adoption.

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.

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, 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 nine months ended September 30, 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. No impairment losses have been recorded through September 30, 2022.

RECLASSIFICATION

Certain reclassifications have been made to conform prior period data to the current presentation. These reclassifications had no effect on reported net income.

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NOTE 2 — PROPERTY AND EQUIPMENT

Property and equipment consists of the following at:

	September 30, 2022	December 31, 2021
Furniture and office equipment	$ 896,655	$ 818,897
Construction in progress	803,931	—
Leasehold improvements	1,598,037	556,907
Manufacturing equipment and tooling	2,646,962	2,042,675
Total property and equipment	5,945,585	3,418,479
Less: accumulated depreciation and amortization	(2,626,973)	(2,312,034)
Property and equipment, net	$ 3,318,612	$ 1,106,445

Construction in progress and leasehold improvement increases of $0.8 million and $1.0 million, respectively are due to the new corporate headquarters and manufacturing facility buildout.

Depreciation expense was $130,882 and $100,502 for the three months ended September 30, 2022 and 2021, respectively, and $329,526 and $301,469 for the nine months ended September 30, 2022 and 2021, respectively.

NOTE 3 — 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 4 — 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 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, 2022, there were options to purchase 2,650,000 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, 2022 and 295,000 were issued during the nine months ended September 30, 2022. Additional options may be issued under the 2015 Plan as outstanding options are forfeited, subject to a maximum 6,000,000 available for issuance under the 2015 Plan.

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 and nine months ended September 30, 2022, there were issued zero and 97,100 shares of common stock, respectively, as director compensation and 475,000 options to purchase shares of common stock as executive compensation under the 2021 Plan. As of September 30, 2022, there had been issued 20,988 shares of common stock as directors fees under the 2021 Plan.

Effective January 1, 2021, each non-employee director of the Company (other than the Chairman of the Board) and Board advisor were eligible to receive of $75,000 annually, to be paid quarterly $12,500 in cash and $6,250 in common stock. The Chairman of the Board is eligible to receive $100,000 annually, to be paid quarterly $12,500 in cash and $12,500 in common stock. Effective May 18, 2021, each non-employee director of the Company (other than the Chairman of the Board) and Board advisor are eligible to receive of $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.

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2015 STOCK OPTION PLAN, as amended

Time Based Stock Options

The per share weighted average fair value of stock options granted during the nine months ended September 30, 2022 and September 30, 2021 was $2.10 and $2.93, 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, 2022 and September 30, 2021. 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 $151,736 and $56,102 for the nine months ended September 30, 2022 and 2021, respectively.

	September 30,	
	2022	2021
Dividend yield	0.00%	0.00%
Expected Volatility	65.9% - 77.5%	74.01% - 76.77%
Weighted-average volatility	—	—
Expected dividends	—	—
Expected term (in years)	10	10
Risk-free rate	1.81% - 2.99%	1.20% - 1.62%

The following table summarizes the status of the 2015 Plan with respect to time based stock options:

	Nine Months Ended September 30,			
	2022		2021	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at January 1	3,672,500	$ 3.42	2,922,494	$ 2.46
Granted	295,000	$ 2.70	1,650,000	$ 3.75
Exercised	831,250	$ 1.57	1,000,000	$ 1.23
Forfeited	486,250	$ 2.73	187,494	$ 3.36
Outstanding at September 30	2,650,000	$ 4.05	3,385,000	$ 3.39
Options exercisable at September 30	825,000	$ 4.41	1,005,625	$ 2.65
Weighted average fair value of options granted during the period	—	$ 2.10	—	$ 2.93
Stock-based compensation expense	—	$ 1,465,567	—	$ 1,934,935

Total stock-based compensation expense was $1,465,567 and $1,934,935 for the nine months ended September 30, 2022, and 2021, respectively. Cash received from option exercises for the nine months ended September 30, 2022, and 2021 was $314,000 and

$1,230,000, respectively.

The weighted-average grant-date fair value of options granted during the nine months ended September 30, 2022, and 2021 was $0.6 million and $4.8 million, respectively. There were 831,250 options exercised during the nine months ended September 30, 2022, and 1.0 million during the nine months ended September 30, 2021.

The following table presents information pertaining to options outstanding at September 30, 2022:

Range of Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$1.57-$9.49	2,650,000	8.1 years	$ 4.05	825,000	$ 4.41

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As of September 30, 2022, there was $4,581,923 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the Plan. That cost is expected to be recognized over a weighted-average period of 45 months. The total fair value of shares vested as of September 30, 2022, and September 30, 2021, was $2,679,152 and $1,909,141, respectively.

Performance Based Stock Options

There were no performance based stock options granted during the nine months ended September 30, 2022, and 2021.

The following table summarizes the status of the 2015 Plan with respect to performance based stock options:

	Nine Months Ended September 30,			
	2022		2021	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at January 1	—	$ —	1,000,000	$ 1.70
Granted	—	$ —	—	$ —
Exercised	—	$ —	—	$ —
Forfeited	—	$ —	—	$ —
Outstanding at September 30	—	$ —	1,000,000	$ 1.70
Options exercisable at September 30	—	$ —	—	$ —
Weighted average fair value of options granted during the period	—	$ —	—	$ —
Stock-based compensation expense	—	$ —	—	$ (408,747)

Total performance stock-based compensation expense totaled zero and ($408,747) for the nine months ended September 30, 2022, and 2021, respectively. All performance based stock options were forfeited as of September 30, 2021, and there was no unrecognized compensation cost remaining.

2021 STOCK OPTION PLAN, as amended

Time Based Stock Options

The per share weighted average fair value of stock options granted during the nine months ended September 30, 2022 and September 30, 2021 was $1.99 and $0 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, 2022 and September 30, 2021. 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 $20,677 and $0 for the nine months ended September 30, 2022 and 2021, respectively.

	September 30,	
	2022	2021
Dividend yield	0.00%	0.00%
Expected Volatility	65.9%	0% - 0%
Weighted-average volatility	—	—
Expected dividends	—	—
Expected term (in years)	10	0
Risk-free rate	2.99%	0% - 0%

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The following table summarizes the status of the 2021 Plan with respect to time based stock options:

	Nine Months Ended September 30,			
	2022		2021	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at January 1	0	$ 0	—	$ —
Granted	475,000	$ 2.67	—	$ —
Exercised	0	$ —	—	$ —
Forfeited	0	$ —	—	$ —
Outstanding at September 30	475,000	$ 2.67	—	$ —
Options exercisable at September 30	0	$ —	—	$ —
Weighted average fair value of options granted during the period	—	$ 1.99	—	$ —
Stock-based compensation expense	—	$ 98,460	—	$ —

Total stock-based compensation expense was $98,460 and $0 for the nine months ended September 30, 2022, and 2021, respectively. There were no options exercised during the nine months ended September 30, 2022 and September 30, 2021.

The weighted-average grant-date fair value of options granted during the nine months ended September 30, 2022, and 2021 was $0.95 million and $0 million, respectively. There were zero options exercised during the nine months ended September 30, 2022, and September 30, 2021.

The following table presents information pertaining to options outstanding at September 30, 2022:

Range of Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$2.67	475,000	9.6 years	$ 2.67	0	$ 0

As of September 30, 2022, there was $846,755 of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the 2021 Plan. That cost is expected to be recognized over a weighted-average period of 48 months. The total fair value of shares vested as of September 30, 2022, and September 30, 2021, was zero and zero, respectively.

RESTRICTED STOCK AWARDS

The following table summarizes the activities for our restricted stock awards for the nine months ended September 30, 2022, and 2021.

	Nine Months Ended September 30,			
	2022		2021	
	Shares	Weighted Average Grant-Date Fair Value	Shares	Weighted Average Grant-Date Fair Value
Unvested at January 1	—	$ —	—	$ —
Granted	1,000,000	$ 3.01	1,000,000	$ 3.01
Vested	50,000	$ 3.31	—	$ —
Forfeited/canceled	—	$ —	—	$ —
Unvested at September 30	950,000	$ 2.99	1,000,000	$ 3.01

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As of September 30, 2022, and 2021, there was $1,788,565 and $2,379,089 of unrecognized compensation cost related to unvested employee restricted shares. 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 $107,344 and $30,554 for the nine months ended September 30, 2022 and 2021, respectively.

NOTE 5 — DEBT OBLIGATIONS

On June 29, 2022, the Company entered into a Loan Modification Extension Agreement (the "Modification Agreement") with Keybank National Association ("Lender") to modify its revolving line of credit with Lender in the amount of $3,500,000 (the "Loan") that was originally made available on April 14, 2020 and renewed on June 24, 2021. Among other things, the Modification Agreement: (i) extends the maturity date of the Loan from June 1, 2022 to June 1, 2023; (ii) changes the interest rate applicable to the Loan from Prime – 1.50% to Prime + 0%; (iii) releases the Company from its obligations under a certain security agreement dated June 24, 2021 pursuant to which the Company had previously granted the Lender a first priority security interest in all equipment, inventory, accounts, instruments, chattel paper and general intangibles of the Company (the "Security Agreement"); and (iv) replaces the Security Agreement with a new pledge security agreement dated June 29, 2022 by and between the Company and Lender (the "Pledge Agreement"), which Pledge Agreement grants Lender a first priority security interest in certain of the Company's bank accounts as collateral security for the Loan. The Company had no amount outstanding against the line of credit as of September 30, 2022.

On August 5, 2022, the Company entered into a commercial insurance premium finance and security agreement with AON Premium Finance, LLC in the aggregate principal amount of $0.8 million bearing an annual percentage rate of 6.5%, to finance its insurance premiums. Monthly payments were due on the first of each month beginning August 1, 2022 through June 1, 2023.

NOTE 6 — LEASES

We have finance and operating leases for our corporate office and certain office and computer equipment. Our two operating leases have remaining lease terms of ten years and 6 months, respectively. On September 29, 2022, we extended our existing lease in Chester NY through March 31, 2023 with the same payment terms. Our finance lease, which was entered into in June 2022 has a remaining lease term of 5 years.

The components of lease expense were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating lease cost	$ 157,076	$ 37,093	$ 396,658	$ 112,383
Short-term lease cost	18,300	35,960	96,588	104,396
Total lease cost	$ 175,376	$ 73,053	$ 493,246	$ 216,779
Finance lease cost:				
Amortization of right-of-use assets	$ 17,754	$ 597	$ 23,672	$ 2,188
Interest on lease liabilities	1,381	10	1,381	57
Total finance lease cost	$ 19,135	$ 607	$ 25,053	$ 2,245

Supplemental cash flow information related to leases was as follows:

	Nine Months Ended September 30,	
	2022	2021
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 301,150	$ 105,618
Financing cash flows from finance leases	26,443	2,232

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Supplemental balance sheet information related to leases was as follows:

	September 30, 2022	December 31, 2021
Operating Leases		
Operating lease right-of-use assets	$ 3,865,370	$ 95,553
Operating lease current liabilities	342,399	95,553
Operating lease long term liabilities	3,741,015	—
Total operating lease liabilities	$ 4,083,414	$ 95,553
Finance Leases		
Property and equipment, at cost	$ 355,071	$ 12,725
Accumulated depreciation	23,671	(12,725)
Property and equipment, net	$ 331,400	$ —
Finance lease current liabilities	64,467	—
Finance lease long term liabilities	265,542	—
Total finance lease liabilities	$ 330,009	$ —

	September 30, 2022	December 31, 2021
Weighted Average Remaining Lease Term		
Operating leases	10.1 Years	0.6 Years
Finance leases	4.9 Years	0 Years
Weighted Average Discount Rate		
Operating leases	4.02%	4.75%
Finance leases	4.25%	4.75%

Maturities of lease liabilities are as follows:

Year Ending December 31,	Operating Leases	Finance Leases
2022 (excluding the nine months ended September 30, 2022)	124,876	19,832
2023	499,503	79,329
2024	499,503	79,329
2025	499,503	79,329
2026	499,503	79,329
Thereafter	2,830,519	33,052
Total undiscounted lease payments	4,953,407	370,200
Less: imputed interest	(869,993)	(40,191)
Total lease liabilities	$ 4,083,414	$ 330,009

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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 COVID-19, 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, 2021 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 transition to our secondary manufacturing source, reduction of inventory, move of our manufacturing facility, need for additional financing, and 2022 expenses and capital expenditures. 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 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 standards for quality system management.

Our revenues derive from three business sources: (i) domestic core, (ii) international core, and (iii) novel therapies. Our domestic core and international core revenues consist of sales of our products for the delivery of subcutaneous drugs that are FDA cleared for use with the KORU Medical infusion system, with the primary use being for the delivery for immunoglobulin to treat PIDD and 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.

We have experienced and continue to experience supply chain issues and inflationary impacts on raw materials and labor resulting from the COVID-19 pandemic. We cannot predict whether current trends will continue and what impact they may have on our business, our customers or our financial results.

The Company continued its transition of finished goods manufacturing of our needle and tubing sets to Command Medical Products, a third-party contract manufacturing organization, which began in 2021 and expects to complete the implementation before the end of first quarter 2023. This move is intended to create a dual source of manufacturing and improve costs.

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The Company entered into a lease commencing March 1, 2022 for a new corporate headquarters and manufacturing facility located in Mahwah, NJ. During the quarter ended June 30, 2022, the Company completed the first phase of the move, the headquarters and office staff to the new location, and expects to complete the move of manufacturing before the end of the first quarter 2023.

The Company ended the 2022 third fiscal quarter with $7.8 million in net sales, a 28.5% increase, compared with $6.0 million in the same period last year driven by growth in all three of our business sources.

Gross profit, for the three months ended September 30, 2022, was $4.3 million, an increase of 23.7% from the same period last year, and stated as a percentage of net sales was 55.7%, a decline from 57.9% in the prior year period.

Operating expenses for the three months ended September 30, 2022, were $5.9 million, up from $4.8 million for the same period last year, driven primarily by research and development, and for selling, general and administrative for new hires to support commercialization, business development, quality, and regulatory capabilities.

RESULTS OF OPERATIONS

Three months ended September 30, 2022, compared to September 30, 2021

Net Sales

The following table summarizes our net sales for the three months ended September 30, 2022, and 2021:

	Three Months Ended September 30,		Change from Prior Year		% of Net Sales	
	2022	2021	$	%	2022	2021
Net Sales						
Domestic Core	$ 5,900,042	$ 5,076,294	$ 823,748	16.2%	76.0%	84.0%
International Core	1,096,746	747,281	349,465	46.8%	14.1%	12.4%
Novel Therapies	763,610	216,969	546,641	251.9%	9.9%	3.6%
Total	$ 7,760,398	$ 6,040,544	$ 1,719,854	28.5%		

Total net sales increased $1.7 million, or 28.5%, for the three months ended September 30, 2022, as compared with the same period last year as we saw double digit growth across all businesses. Domestic core growth was primarily driven by increased volume attributed to SCIg market growth and label expansions including prefill syringes, as well as clearing of $0.3 million in backorders from the second quarter of 2022. Novel therapies sales grew by 252% in the third quarter of 2022 related to services performed on an NRE innovation development agreement for a pharmaceutical customer and increases in clinical trial product sales for several pharmaceutical customers. Sales growth in our international core business was driven by volume growth in certain EU markets compared with prior year.

Gross Profit

Our gross profit for the three months ended September 30, 2022 and 2021 is as follows:

	Three Months Ended September 30,		Change from Prior Year	
	2022	2021	$	%
Gross Profit	$ 4,322,362	$ 3,495,750	$ 826,612	23.7%
Stated as a Percentage of Net Sales	55.7%	57.9%		

Gross profit increased $0.8 million or 23.7% in the three months ended September 30, 2022, compared to the same period in 2021. This increase in the 2022 third quarter was driven by volume increase in net sales of $1.7 million as described above. Gross profit as a percent of sales decreased to 55.7% compared to 57.9% from the third quarter of 2021. The decline in the gross profit percent was primarily caused by higher manufacturing costs associated with labor and materials, and production rework completed in the current quarter. Product mix had a negative impact as we saw increased consumable sales across our core domestic business, and NRE service revenue mix contributed to a lower gross profit as a percentage of sales. Partially offsetting these declines was an increase in average selling prices.

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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, 2022 and 2021 are as follows:

	Three Months Ended September 30,		Change from Prior Year	
	2022	2021	$	%

Selling, general and administrative	$ 4,825,349	$ 3,901,830	$ 923,519	23.7%
Research and development	862,148	800,020	62,128	7.8%
	$ 5,687,497	$ 4,701,850	$ 985,647	21.1%
Stated as a Percentage of Net Sales	73.3%	77.8%		

Selling, general and administrative expenses increased $0.9 million, or 23.7%, during the three months ended September 30, 2022 compared to the same period last year, primarily due to $0.7 million in compensation and benefits associated with new hires, $0.2 million in severance relating to the employment termination of the Chief Operating Officer, $0.2 million in building expenses related to our manufacturing move, $0.1 million in stock compensation partially offset by lower consulting costs of $0.1 million and lower recruitment costs of $0.2 million.

Research and development expenses increased $0.1 million during the three months ended September 30, 2022 compared with the same period last year, primarily due to $0.3 million in new hires to support our innovation efforts, which was partially offset by lower testing material costs of $0.2 million and lower recruiting costs of $0.1 million.

Depreciation and amortization

Depreciation and amortization expense increased by 41.8% to $164,344 in the three months ended September 30, 2022 compared with $115,934 in the three months ended September 30, 2021 resulting from investment in our corporate office and manufacturing site move.

Net Loss

	Three Months Ended September 30,		Change from Prior Year	
	2022	2021	$	%
Net Loss	$ (1,225,560)	$ (1,093,778)	$ (131,782)	12.1%
Stated as a Percentage of Net Sales	(15.8%)	(18.1%)		

Our net loss increased $0.1 million in the three months ended September 30, 2022 compared with the same period last year mostly driven by higher operating expenses due to higher selling, general and administrative and research and development expenses related to our strategy to build our novel therapies business and innovation. A tax benefit of $0.3 million resulting from the loss was also recorded during the period.

Nine months ended September 30, 2022 compared to September 30, 2021

Net Sales

The following table summarizes our net sales for the nine months ended September 30, 2022 and 2021:

	Nine Months Ended September 30,		Change from Prior Year		% of Net Sales	
	2022	2021	$	%	2022	2021
Net Sales						
Domestic Core	$ 15,890,369	$ 14,084,552	$ 1,805,817	12.8%	77.3%	82.9%
International Core	2,943,173	2,585,881	357,292	13.8%	14.3%	15.2%
Novel Therapies	1,717,814	329,236	1,388,578	421.8%	8.4%	1.9%
Total	$ 20,551,356	$ 16,999,669	$ 3,551,687	20.9%		

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Total net sales increased $3.6 million or 20.9% for the nine months ended September 30, 2022, as compared to the prior year period, driven primarily by higher domestic core net sales of $1.8 million driven by volume growth in our consumables and pump business resulting from our label expansions including prefills, existing customers, and an overall SCIg market growth. Further contributing were higher novel therapies sales of $1.4 million compared with last year due to completion of two NRE product innovation milestones and clinical product sales for an expanded pharmaceutical pipeline. International core net sales were higher by $0.4 million in the first nine months of 2022, driven by volume growth in our consumables and pump business.

Gross Profit

Our gross profit for the nine months ended September 30, 2022 and 2021 is as follows:

	Nine Months Ended September 30,		Change from Prior Year	
	2022	2021	$	%
Gross Profit	$ 11,290,840	$ 9,937,788	$ 1,353,052	13.6%
Stated as a Percentage of Net Sales	54.9%	58.5%		

Gross profit increased $1.4 million or 13.6% in the nine months ended September 30, 2022, compared to the same period last year. This increase in the first nine months of 2022 was mostly driven by the increase in net sales of $3.5 million as described above. Gross profit, stated as a percentage of net sales, was impacted by higher manufacturing costs due to supply chain issues, labor and material costs, and higher NRE revenue at lower margins recorded in the nine months of 2022, partially offset by increased average selling prices.

Selling, general and administrative and Research and development

Our selling, general and administrative expenses and research and development costs for the nine months ended September 30, 2022 and 2021 are as follows:

	Nine Months Ended September 30,	Change from Prior Year

	2022	2021	$	%
Selling, general and administrative	$ 15,846,584	$ 12,980,604	$ 2,865,980	22.1%
Research and development	3,314,233	1,523,739	1,790,494	117.5%
	$ 19,160,817	$ 14,504,343	$ 4,656,474	32.1%
Stated as a Percentage of Net Sales	93.2%	85.3%		

Selling, general and administrative expenses increased $2.9 million, or 22.1%, during the nine months ended September 30, 2022 compared to the same period last year, primarily due to $2.1 million in compensation and benefits related mostly to new hires in sales, quality and regulatory to support our strategic growth initiatives, $0.3 million in recruitment fees, $0.3 million in stock compensation, $0.3 million in building related expense, $0.2 million in travel related costs and $0.1 million in liability insurance, which was partially offset by lower restructuring costs of $0.4 million.

Research and development expenses increased $1.8 million during the nine months ended September 30, 2022 compared with the same period last year primarily due to $1.0 million in consulting fees and $0.8 million in compensation and benefits for new hires to support product development for novel therapies, and $0.1 million in stock compensation, which was partially offset by $0.1 million in reduced testing material expense.

Depreciation and amortization

Depreciation and amortization expense increased by 14.2% to $399,479 the nine months ended September 30, 2022 compared with $349,822 in the nine months ended September 30, 2021 due to investment in our corporate office and manufacturing site move.

Net Loss

	Nine Months Ended September 30,		Change from Prior Year	
	2022	2021	$	%
Net Loss	$ (6,684,415)	$ (3,494,465)	$ (3,189,950)	91.3%
Stated as a Percentage of Net Sales	(32.5%)	(20.6%)		

Our net loss for the nine months ended September 30, 2022 was $6.7 million compared to net loss of $3.5 million for the nine months ended September 30, 2021, driven by higher selling, general and administrative and research and development expenses.

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LIQUIDITY AND CAPITAL RESOURCES

Our principal source of liquidity is our cash on hand of $16.4 million as of September 30, 2022. 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, 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 manufacturing technologies, facilities and equipment, and research and development. We estimate operating expenses to be between $26.5 million and $27.5 million in 2022.

Our 2022 capital investments for manufacturing and leasehold improvements for our new facility is expected to be in the aggregate between $1.5 million and $2.0 million, net of pre-approved financing arrangements and leasehold improvement credits totaling $0.9 million and $0.2 million respectively, which are expected to be fully executed in the fourth quarter of 2022.

Our accounts receivable balance was $5.1 million at September 30, 2022, which reflected a $1.5 million increase since the beginning of the year. Supply chain issues which caused back-orders in the second quarter of 2022 that were cleared at the end of the third quarter of 2022, resulted in higher receivable balances due to end of quarter shipments.

Our inventory position was $6.9 million at September 30, 2022, which reflects an excess of work in process inventory when compared to prior periods that could not be converted to finished goods as a result of supply chain issues, labor shortages, and our second quarter 2022 backorder. We expect to reduce this excess inventory and convert it to a source of cash by the end of 2022. We further expect to reduce our inventory position when the transition to our secondary manufacturing source is completed, which we expect by March 31, 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. As of September 30, 2022, the credit has not been received.

We expect that our cash on hand and cash flows from operations will be sufficient to meet our requirements at least through the next 12 months. Continued execution on our longer-term strategic plan may require the Company to take on additional debt or raise capital through issuance of equity, or a combination of both in the periods post 12/31/2023. 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, 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 and COVID-19 on the global financial markets. To the extent that current and anticipated future sources of liquidity are 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, 2022	Nine Months Ended September 30, 2021
Net cash used in operating activities	$ (6,741,013)	$ (3,602,378)
Net cash used in investing activities	$ (2,577,696)	$ (318,493)
Net cash provided by financing activities	$ 425,088	$ 2,838,996

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Operating Activities

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.

Net cash used in operating activities of $3.6 million for the nine months ended September 30, 2021 was primarily due to the net loss of $3.5 million, working capital changes which included an increase in accounts receivable of $0.5 million due to timing, an increase in prepaids of $0.5 million due to insurance renewals, and a decrease in accrued expenses of $0.6 million most of which was non-cash activity related to the issuance of common stock in settlement of litigation. Further contributing were deferred tax assets of $1.4 million mostly increased for book to tax differences related to stock option expense. Offsetting these were an increase in accounts payable of $0.8 million, non-cash charges for stock-based compensation of $2.0 million, and depreciation and amortization of $0.3 million.

Investing Activities

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.

Net cash used in investing activities of $0.3 million for the nine months ending September 30, 2021, was for capital expenditures for manufacturing and office equipment.

Financing Activities

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.

The $2.8 million provided by financing activities for the nine months ended September 30, 2021, is from options exercised, the non-cash activity related to the issuance of common stock in settlement of litigation and 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 three months ended September 30, 2022, that have materially affected, or are reasonably likely to materially affect, the Company’s internal control over financial reporting.

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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, 2021 and in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, 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)

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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 9, 2022

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

(Principal Executive Officer)

November 9, 2022

/s/ Thomas Adams
Thomas Adams, Interim 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 9, 2022

/s/ Linda Tharby
Linda Tharby
President and Chief 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 9, 2022

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

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, 2022 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 9, 2022

/s/ Linda Tharby
Linda Tharby
President and Chief 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, 2022 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 9, 2022

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