

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

FORM 10-Q

(Mark One)

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

For the Quarterly Period Ended March 31, 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)

New York

(State or other jurisdiction of incorporation or organization)

13-3044880

(I.R.S. Employer Identification No.)

100 Corporate Drive, Mahwah, New Jersey

(Address of principal executive offices)

07430

(Zip Code)

(845) 469-2042

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

| <u>Title of each class</u> | <u>Trading Symbol(s)</u> | <u>Name of each exchange on which registered</u> |
|--------------------------------|--------------------------|--|
| 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. ☒ 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). ☒ 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 ☐
Non-accelerated filer ☒

Accelerated filer ☐
Smaller reporting company ☒
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 ☒ No

As of May 4, 2023, 45,613,150 shares of common stock, \$0.01 par value per share, were outstanding, which excludes 3,420,502 shares of treasury stock.

KORU MEDICAL SYSTEMS, INC.
FORM 10-Q
FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2023
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PART I — FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

**KORU MEDICAL SYSTEMS, INC.
BALANCE SHEETS
(UNAUDITED)**

| | March 31, 2023 | December 31, 2022 |
|---|---------------------------|------------------------------|
| ASSETS | | |
| CURRENT ASSETS | | |
| Cash and cash equivalents | \$ 12,224,865 | \$ 17,408,257 |
| Accounts receivable less allowance for doubtful accounts of \$ 21,459 for March 31, 2023, and for December 31, 2022 | 4,164,513 | 3,558,884 |
| Inventory | 6,638,418 | 6,404,867 |
| Other Receivables | 1,014,761 | 972,396 |
| Prepaid expenses | 1,172,101 | 1,457,232 |
| TOTAL CURRENT ASSETS | 25,214,658 | 29,801,636 |
| Property and equipment, net | 3,906,067 | 3,886,975 |
| Intangible assets, net of accumulated amortization of \$ 341,755 and \$ 325,872 at March 31, 2023 and December 31, 2022, respectively | 782,531 | 787,182 |
| Operating lease right-of-use assets | 3,706,874 | 3,786,545 |
| Deferred income tax assets, net | 4,544,880 | 3,967,480 |
| Other assets | 98,970 | 102,625 |
| TOTAL ASSETS | \$ 38,253,980 | \$ 42,332,443 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| CURRENT LIABILITIES | | |
| Accounts payable | \$ 1,503,120 | \$ 2,391,799 |
| Accrued expenses | 1,591,737 | 2,889,941 |
| Note Payable | 218,403 | 433,295 |
| Other Liabilities | 261,544 | 257,337 |
| Accrued payroll and related taxes | 500,415 | 542,399 |
| Financing lease liability – current | 99,694 | 98,335 |
| Operating lease liability – current | 349,304 | 345,834 |
| TOTAL CURRENT LIABILITIES | 4,524,217 | 6,958,940 |
| Financing lease liability, net of current portion | 368,844 | 394,283 |
| Operating lease liability, net of current portion | 3,564,619 | 3,653,257 |
| TOTAL LIABILITIES | 8,457,680 | 11,006,480 |
| STOCKHOLDERS' EQUITY | | |
| Common stock, \$0.01 par value, 75,000,000 shares authorized, 48,960,766 and 48,861,891 shares issued 45,540,264 and 45,441,389 shares outstanding at March 31, 2023, and December 31, 2022, respectively | 489,608 | 488,619 |
| Additional paid-in capital | 45,132,350 | 44,252,117 |
| Treasury stock, 3,420,502 shares at March 31, 2023 and December 31, 2022, at cost | (3,843,562) | (3,843,562) |
| Retained deficit | (11,982,096) | (9,571,211) |
| TOTAL STOCKHOLDERS' EQUITY | 29,796,300 | 31,325,963 |
| TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY | \$ 38,253,980 | \$ 42,332,443 |

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 March 31, | |
|--|---------------------------------|----------------|
| | 2023 | 2022 |
| NET SALES | \$ 7,392,605 | \$ 6,244,330 |
| Cost of goods sold | 3,245,570 | 2,622,025 |
| Gross Profit | 4,147,035 | 3,622,305 |
| OPERATING EXPENSES | | |
| Selling, general and administrative | 5,425,877 | 5,491,213 |
| Research and development | 1,564,869 | 1,148,355 |
| Depreciation and amortization | 213,117 | 109,252 |
| Total Operating Expenses | 7,203,863 | 6,748,820 |
| Net Operating Loss | (3,056,828) | (3,126,515) |
| Non-Operating Income/(Expense) | | |
| Loss on currency exchange | (680) | (7,135) |
| Loss on disposal of fixed assets, net | (56,279) | — |
| Interest income (expense), net | 125,502 | (1,463) |
| TOTAL OTHER INCOME/(EXPENSE) | 68,543 | (8,598) |
| LOSS BEFORE INCOME TAXES | (2,988,285) | (3,135,113) |
| Income Tax Benefit | 577,400 | 597,599 |
| NET LOSS | \$ (2,410,885) | \$ (2,537,514) |
| NET LOSS PER SHARE | | |
| Basic | \$ (0.05) | \$ (0.06) |
| Diluted | \$ (0.05) | \$ (0.06) |
| WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING | | |
| Basic | 45,487,593 | 44,667,977 |
| Diluted | 45,487,593 | 44,667,977 |

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 Three Months Ended March 31, | |
|---|--|----------------|
| | 2023 | 2022 |
| CASH FLOWS FROM OPERATING ACTIVITIES | | |
| Net Loss | \$ (2,410,885) | \$ (2,537,514) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Stock-based compensation expense | 881,222 | 837,556 |
| Depreciation and amortization | 213,117 | 109,252 |
| Deferred income taxes | (577,400) | (597,599) |
| Loss on disposal of fixed assets | 56,279 | — |
| ROU landlord credit | (5,497) | — |
| Changes in operating assets and liabilities: | | |
| (Increase)/Decrease in accounts receivable | (647,994) | 447,489 |
| Decrease in other receivables | — | 38,145 |
| (Increase)/Decrease in inventory | (233,551) | 88,601 |
| Decrease/(Increase) in prepaid expenses and other assets | 288,786 | (11,805) |
| Increase in other Liabilities | 4,207 | 25,625 |
| (Decrease)/Increase in accounts payable | (888,679) | 40,447 |
| (Decrease)/Increase in accrued payroll and related taxes | (41,984) | 345,712 |
| Decrease in accrued expenses | (1,298,204) | (537,981) |
| NET CASH USED IN OPERATING ACTIVITIES | (4,660,583) | (1,752,072) |
| CASH FLOWS FROM INVESTING ACTIVITIES | | |
| Purchases of property and equipment | (272,605) | (750,908) |
| Purchases of intangible assets | (11,232) | (1,694) |
| NET CASH USED IN INVESTING ACTIVITIES | (283,837) | (752,602) |
| CASH FLOWS FROM FINANCING ACTIVITIES | | |
| Payments on indebtedness | (214,892) | (252,968) |
| Payments on finance lease liability | (24,080) | — |
| NET CASH USED IN FINANCING ACTIVITIES | (238,972) | (252,968) |

| | | |
|---|----------------------|----------------------|
| NET DECREASE IN CASH AND CASH EQUIVALENTS | (5,183,392) | (2,757,642) |
| CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD | 17,408,257 | 25,334,889 |
| CASH AND CASH EQUIVALENTS, END OF PERIOD | <u>\$ 12,224,865</u> | <u>\$ 22,577,247</u> |
| Supplemental Information | | |
| Cash paid during the periods for: | | |
| Interest | \$ 12,326 | \$ 4,425 |
| Income Taxes | <u>\$ —</u> | <u>\$ —</u> |
| Schedule of Non-Cash Operating, Investing and Financing Activities: | | |
| Issuance of common stock as compensation | <u>\$ 175,776</u> | <u>\$ 142,500</u> |

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

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

Three Months Ended March 31, 2023

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

Three Months Ended March 31, 2022

| | <u>Common Stock</u> | | <u>Additional</u> | <u>Retained</u> | <u>Treasury</u> | <u>Total</u> |
|---|---------------------|-------------------|---------------------|----------------------|----------------------|----------------------|
| | <u>Shares</u> | <u>Amount</u> | <u>Paid-in</u> | <u>Deficit</u> | <u>Stock</u> | <u>Stockholders'</u> |
| | | | <u>Capital</u> | | | <u>Equity</u> |
| 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 related to Restricted Stock | — | — | 170,386 | — | — | 170,386 |
| Issuance upon options exercised | 29,627 | 296 | (296) | — | — | — |
| Net loss | — | — | — | (2,537,514) | — | (2,537,514) |
| BALANCE, MARCH 31, 2022 | <u>48,121,289</u> | <u>\$ 481,212</u> | <u>\$41,611,030</u> | <u>\$(3,447,583)</u> | <u>\$(3,843,562)</u> | <u>\$ 34,801,097</u> |

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, 2022 ("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 March 31, | |
|--------------------------------------|---------------------------------|-------------------|
| | 2023 | 2022 |
| Net loss | \$ (2,410,885) | \$ (2,537,514) |
| Weighted Average Outstanding Shares: | | |
| Outstanding shares | 45,487,593 | 44,667,977 |
| Option shares includable | — ^(a) | — ^(a) |
| Restricted stock includable | — ^(b) | — ^(b) |
| | <u>45,487,593</u> | <u>44,667,977</u> |
| Net loss per share | | |
| Basic | \$ (0.05) | \$ (0.06) |
| Diluted | \$ (0.05) | \$ (0.06) |

(a) For the three months ended March 31, 2023, and 2022, option shares of 14,626 and 346,020 respectively, were not included as the impact is anti-dilutive.

(b) For the three months ended March 31, 2023, and 2022, Linda Tharby's 900,000 and 1,000,000 shares of restricted stock, 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 across multiple drug categories.

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 revenues.

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 revenues by geography for the three months ended March 31, 2023, and 2022:

| | Three Months Ended March 31, | | % of Total Revenues | |
|---------------|------------------------------|---------------------|---------------------|------|
| | 2023 | 2022 | 2023 | 2022 |
| Revenues | | | | |
| Domestic | \$ 6,283,965 | \$ 5,301,388 | 85% | 85% |
| International | 1,108,640 | 942,942 | 15% | 15% |
| Total | \$ 7,392,605 | \$ 6,244,330 | | |

LEASES

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. The standard requires 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. See "NOTE 6 — LEASES" for further detail.

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ACCOUNTING PRONOUNCEMENTS RECENTLY 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 Company adopted the pronouncement above on January 1, 2022, and there is no impact on its financial statements.

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 three months ended March 31, 2023.

IMPAIRMENT OF LONG-LIVED ASSETS

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be fully recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than the carrying amount. The impairment loss, if recognized, would be based on the excess of the carrying value of the impaired asset over its respective fair value. The Company did not record any impairment losses through March 31, 2023.

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NOTE 2 — PROPERTY AND EQUIPMENT

Property and equipment consists of the following at:

| | <u>March 31, 2023</u> | <u>December 31, 2022</u> |
|---|-----------------------|--------------------------|
| Furniture and office equipment | \$ 1,325,908 | \$ 1,456,745 |
| Leasehold improvements | 1,888,245 | 2,413,820 |
| Manufacturing equipment and tooling | 2,916,577 | 2,810,813 |
| Total property and equipment | 6,130,730 | 6,681,378 |
| Less: accumulated depreciation and amortization | (2,224,663) | (2,794,403) |
| Property and equipment, net | <u>\$ 3,906,067</u> | <u>\$ 3,886,975</u> |

Leasehold improvements decrease of \$0.5 million is due to the write-off of Chester location leasehold improvements resulting from the manufacturing site closure.

Depreciation expense was \$197,233 and \$94,085 for the three months ended March 31, 2023 and 2022, 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 March 31, 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 40,000 were issued during the three months ended March 31, 2023. 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 months ended March 31, 2023, there were no awards under the 2021 Plan. As of March 31, 2023, there had been 156,758 shares of common stock issued as directors fees and 475,000 shares issued as executive compensation under the 2021 Plan in total.

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.

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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 three months ended March 31, 2023 and March 31, 2022 was \$2.83 and \$2.45, 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 three months ended March 31, 2023 and March 31, 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 \$49,817 and \$49,406 for the three months ended March 31, 2023 and 2022, respectively.

| | March 31, | |
|-----------------------------|-----------|---------------|
| | 2023 | 2022 |
| Dividend yield | 0.00% | 0.00% |
| Expected Volatility | 61.3% | 76.1% - 77.5% |
| Weighted-average volatility | — | — |
| Expected dividends | — | — |
| Expected term (in years) | 10 | 10 |
| Risk-free rate | 3.53% | 1.81% - 1.87% |

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

| | Three Months Ended March 31, | | | |
|--|------------------------------|---------------------------------|-----------|---------------------------------|
| | 2023 | | 2022 | |
| | Shares | Weighted Average Exercise Price | Shares | Weighted Average Exercise Price |
| Outstanding at January 1 | 2,560,000 | \$ 4.15 | 3,672,500 | \$ 3.42 |
| Granted | 40,000 | \$ 3.91 | 135,000 | \$ 3.07 |
| Exercised | — | \$ — | 75,000 | \$ 1.60 |
| Forfeited | — | \$ — | 93,750 | \$ 1.57 |
| Outstanding at March 31 | 2,600,000 | \$ 4.15 | 3,638,750 | \$ 3.49 |
| Options exercisable at March 31 | 1,010,000 | \$ 4.63 | 1,358,750 | \$ 2.83 |
| Weighted average fair value of options granted during the period | — | \$ 2.83 | — | \$ 2.45 |
| Stock-based compensation expense | — | \$ 475,983 | — | \$ 524,670 |

Total stock-based compensation expense was \$475,983 and \$524,670 for the three months ended March 31, 2023, and 2022, respectively. No cash was received from option exercises for the three months ended March 31, 2023, and 2022.

The weighted-average grant-date fair value of options granted during the three months ended March 31, 2023, and 2022 was \$0.1 million and \$0.3 million, respectively. There were no options exercised during the three months ended March 31, 2023 and 75,000 options exercised during the three months ended March 31, 2022, respectively.

The following table presents information pertaining to options outstanding at March 31, 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 | 2,600,000 | 8.6 years | \$ 4.15 | 1,010,000 | \$ 4.63 |

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As of March 31, 2023, there was \$3,936,268 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 March 31, 2023, and March 31, 2022, was \$ 3,511,874 and \$2,815,943, respectively.

2021 STOCK OPTION PLAN, as amended

Time Based Stock Options

The per share weighted average fair value of stock options granted during the three months ended March 31, 2023 and March 31, 2022 was zero and zero 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 three months ended March 31, 2023 and March 31, 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 \$12,406 and zero for the three months ended March 31, 2023 and 2022, respectively.

| | March 31, | |
|-----------------------------|-----------|-------|
| | 2023 | 2022 |
| Dividend yield | 0.00% | 0.00% |
| Expected Volatility | 0.00% | 0.00% |
| Weighted-average volatility | — | — |
| Expected dividends | — | — |
| Expected term (in years) | 0 | 0 |
| Risk-free rate | 0.00% | 0.00% |

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

| | Three Months Ended March 31, | | | |
|--|------------------------------|---------------------------------|--------|---------------------------------|
| | 2023 | | 2022 | |
| | Shares | Weighted Average Exercise Price | Shares | Weighted Average Exercise Price |
| Outstanding at January 1 | 475,000 | \$ 2.67 | — | \$ — |
| Granted | — | \$ — | — | \$ — |
| Exercised | — | \$ — | — | \$ — |
| Forfeited | — | \$ — | — | \$ — |
| Outstanding at March 31 | 475,000 | \$ 2.67 | — | \$ — |
| Options exercisable at March 31 | — | \$ — | — | \$ — |
| Weighted average fair value of options granted during the period | — | \$ — | — | \$ — |
| Stock-based compensation expense | — | \$ 59,076 | — | \$ — |

Total stock-based compensation expense was \$59,076 and zero for the three months ended March 31, 2023, and 2022, respectively. There were no options exercised during the three months ended March 31, 2023 and March 31, 2022.

The weighted-average grant-date fair value of options granted during the three months ended March 31, 2023, and 2022 was zero million and zero million, respectively. There were zero options exercised during the three months ended March 31, 2023, and March 31, 2022.

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The following table presents information pertaining to options outstanding at March 31, 2023:

| 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 | 9.1 years | \$ 2.67 | — | \$ — |

As of March 31, 2023, there was \$728,603 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 March 31, 2023, and March 31, 2022, was zero and zero, respectively.

RESTRICTED STOCK AWARDS

The following table summarizes the activities for our restricted stock awards for the three months ended March 31, 2023, and 2022.

| | Three Months Ended March 31, | | | |
|-----------------------|------------------------------|--|-----------|--|
| | 2023 | | 2022 | |
| | Shares | Weighted Average Grant-Date Fair Value | Shares | Weighted Average Grant-Date Fair Value |
| Unvested at January 1 | 950,000 | \$ 3.04 | 1,000,000 | \$ 3.01 |
| Granted | — | \$ — | — | \$ — |
| Vested | 50,000 | \$ 3.31 | — | \$ — |
| Forfeited/canceled | — | \$ — | — | \$ — |
| Unvested at March 31 | 900,000 | \$ 2.93 | 1,000,000 | \$ 3.01 |

As of March 31, 2023, and 2022, there was \$1,447,790 and \$2,129,339 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 \$35,781 and \$35,781 for the three months ended March 31, 2023 and 2022, 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 March 31, 2023.

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 are due on the first of each month beginning August 1, 2022 through June 1, 2023. The balance of AON note was \$433,295 and \$218,403 at December 31, 2022 and March 31, 2023, respectively.

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NOTE 6 — LEASES

We have an operating lease for our corporate office, and 2 finance leases for certain office and computer equipment. Our operating lease has remaining lease term of nine years and 4 months. Our finance leases, which were entered into in June 2022 and October 2022, respectively, have remaining lease terms of 4.2 and 4.5 years, respectively.

The components of lease expense were as follows:

| | Three Months Ended March 31, | |
|-------------------------------------|---------------------------------|-------------------|
| | 2023 | 2022 |
| Operating lease cost | \$ 112,522 | \$ 78,442 |
| Short-term lease cost | 52,894 | 49,709 |
| Total lease cost | <u>\$ 165,416</u> | <u>\$ 128,151</u> |
| Finance lease cost: | | |
| Amortization of right-of-use assets | \$ 27,223 | \$ — |
| Interest on lease liabilities | 6,720 | — |
| Total finance lease cost | <u>\$ 33,943</u> | <u>\$ —</u> |

Supplemental cash flow information related to leases was as follows:

| | Three Months Ended March 31, | |
|---|---------------------------------|-----------|
| | 2023 | 2022 |
| Cash paid for amounts included in the measurement of lease liabilities: | | |
| Operating cash flows from operating leases | \$ 113,813 | \$ 63,193 |
| Financing cash flows from finance leases | 30,800 | — |

Supplemental balance sheet information related to leases was as follows:

| | March 31, 2023 | December 31, 2022 |
|---------------------------------------|---------------------|----------------------|
| Operating Leases | | |
| Operating lease right-of-use assets | \$ 3,706,874 | \$ 3,786,545 |
| Operating lease current liabilities | 349,304 | 345,834 |
| Operating lease long term liabilities | 3,564,619 | 3,653,257 |
| Total operating lease liabilities | <u>\$ 3,913,923</u> | <u>\$ 3,999,091</u> |
| Finance Leases | | |
| Property and equipment, at cost | \$ 544,468 | \$ 544,468 |
| Accumulated depreciation | (78,118) | (50,895) |
| Property and equipment, net | <u>\$ 466,350</u> | <u>\$ 493,573</u> |
| Finance lease current liabilities | 99,694 | 98,335 |
| Finance lease long term liabilities | 368,844 | 394,283 |
| Total finance lease liabilities | <u>\$ 468,538</u> | <u>\$ 492,618</u> |

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| March 31, 2023 | December 31, 2022 |
|-------------------|----------------------|
|-------------------|----------------------|

| Weighted Average Remaining Lease Term | | |
|--|-----------|-----------|
| Operating leases | 9.4 Years | 9.7 Years |
| Finance leases | 4.3 Years | 4.6 Years |

| Weighted Average Discount Rate | | |
|---------------------------------------|-------|-------|
| Operating leases | 4.00% | 4.0% |
| Finance leases | 4.25% | 4.25% |

Maturities of lease liabilities are as follows:

| Year Ending December 31, | Operating Leases | Finance Leases |
|--|-------------------------|-----------------------|
| 2023 (excluding the three months ended March 31, 2023) | 374,627 | 92,400 |
| 2024 | 499,503 | 123,200 |
| 2025 | 499,503 | 123,200 |
| 2026 | 499,503 | 123,200 |
| 2027 | 499,503 | 65,957 |
| Thereafter | 2,331,014 | — |
| Total undiscounted lease payments | 4,703,653 | 527,957 |
| Less: imputed interest | (789,730) | (59,419) |
| Total lease liabilities | <u>\$ 3,913,923</u> | <u>\$ 468,538</u> |

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 1A. “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 transition to our secondary manufacturing source, reduction of inventory, move of our manufacturing facility, need for additional financing, and 2023 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.

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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 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 Freedom Infusion System, with the primary use being for the delivery for immunoglobulin to treat Primary Immunodeficiency Diseases (“PID”) 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.

In March 2023, the Company completed its transition of finished goods manufacturing of needle and tubing sets to Command Medical Products, a third-party contract manufacturing organization, which began in 2021. The transition provides for dual source manufacturing capability and expected cost improvements.

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 completed the move of manufacturing during the first quarter of 2023.

The Company ended the 2023 first fiscal quarter with \$7.4 million in net revenues, an 18.4% increase, compared with \$6.2 million in the same period last year driven by growth in all three of our business sources.

Gross profit, for the three months ended March 31, 2023, was \$4.1 million, an increase of 14.5% from the same period last year and, stated as a percentage of net revenues was 56.1%, a decline from 58% in the prior year period.

Operating expenses for the three months ended March 31, 2023, were \$7.2 million, up from \$6.7 million for the same period last year, driven primarily by an increase of \$0.4 million in research and development expense and an increase of \$0.1 million in depreciation expense, which was partially offset by a reduction of \$0.07 million in selling, general and administrative expenses.

RESULTS OF OPERATIONS

Three months ended March 31, 2023, compared to March 31, 2022

Net Revenues

The following table summarizes our net revenues for the three months ended March 31, 2023, and 2022:

| | Three Months Ended March 31, | | Change from Prior Year | | % of Net Revenue | |
|---------------------|------------------------------|---------------------|------------------------|--------------|------------------|-------|
| | 2023 | 2022 | \$ | % | 2023 | 2022 |
| Net Revenues | | | | | | |
| Domestic Core | \$ 5,719,135 | \$ 4,993,536 | \$ 725,599 | 14.5% | 77.4% | 80.0% |
| International Core | 1,097,490 | 894,942 | 202,548 | 22.6% | 14.8% | 14.3% |
| Novel Therapies | 575,980 | 355,852 | 220,128 | 61.9% | 7.8% | 5.7% |
| Total | \$ 7,392,605 | \$ 6,244,330 | \$ 1,148,275 | 18.4% | | |

Total net revenues increased \$1.1 million, or 18.4%, for the three months ended March 31, 2023, as compared with the same period last year with double-digit growth across all businesses. Domestic Core growth of 14.5% was primarily driven by increased growth in pumps and consumables from a growing SCIG market, new account wins, increased prefilled syringe adoptions, and increases in average selling prices. International Core growth of 22.6%, was driven by strength across several EU markets, expanded distribution, and growing global Immunoglobulin drug volume availability. Novel Therapies net revenues grew by 61.9% in the first quarter of 2023 primarily related to services performed on an NRE innovation development agreement for a pharmaceutical customer.

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Gross Profit

Our gross profit for the three months ended March 31, 2023 and 2022 is as follows:

| | Three Months Ended March 31, | | Change from Prior Year | |
|--|------------------------------|--------------|------------------------|-------|
| | 2023 | 2022 | \$ | % |
| Gross Profit | \$ 4,147,035 | \$ 3,622,305 | \$ 524,730 | 14.5% |
| Stated as a Percentage of Net Revenues | 56.1% | 58.0% | | |

Gross profit increased \$0.5 million or 14.5% in the three months ended March 31, 2023, compared to the same period in 2022. The 2023 first quarter gross profit increase was driven by the increase in net revenues of \$1.1 million as described above. Gross profit as a percentage of revenues decreased to 56.1% in the first quarter of 2023 compared to 58% from the first quarter of 2022. The decline in the gross profit as a percentage of revenues was primarily caused by higher manufacturing costs associated with labor and materials partially offset by an increase in average selling prices.

Selling, general and administrative and research and development

Our selling, general and administrative and research and development costs for the three months ended March 31, 2023 and 2022 are as follows:

| | Three Months Ended March 31, | | Change from Prior Year | |
|--|------------------------------|---------------------|------------------------|-------------|
| | 2023 | 2022 | \$ | % |
| Selling, general and administrative | \$ 5,425,877 | \$ 5,491,213 | \$ (65,336) | -1.2% |
| Research and development | 1,564,869 | 1,148,355 | 416,514 | 36.3% |
| | \$ 6,990,746 | \$ 6,639,568 | \$ 351,178 | 5.3% |
| Stated as a Percentage of Net Revenues | 94.6% | 106.3% | | |

Selling, general and administrative expenses decreased \$0.07 million, or 1%, during the three months ended March 31, 2023 compared to the same period last year, primarily due to a \$0.1 million decrease in liability insurance, a \$0.1 million decrease in stock compensation, and a \$0.1 million decrease in sales commissions, partially offset by a \$0.1 million increase in travel and entertainment expense and \$0.1 million in building expense and tax.

Research and development expenses increased \$0.4 million, or 36% during the three months ended March 31, 2023 compared with the same period last year, primarily due to \$0.2 million in compensation and benefits, \$0.1 million in stock compensation and \$0.1 million in recruiting associated with new hires to support our innovation efforts.

Depreciation and amortization

Depreciation and amortization expense increased by 95.07% to \$213,117 in the three months ended March 31, 2023 compared with \$109,252 in the three months ended March 31, 2022 resulting from prior year investments in support of our corporate office and manufacturing site relocation.

Net Loss

| | Three Months Ended March 31, | | Change from Prior Year | |
|--|------------------------------|----------------|------------------------|------|
| | 2023 | 2022 | \$ | % |
| Net Loss | \$ (2,410,885) | \$ (2,537,514) | \$ 126,629 | 5.0% |
| Stated as a Percentage of Net Revenues | (32.6%) | (40.6%) | | |

Our net loss decreased \$0.1 million in the three months ended March 31, 2023 compared with the same period last year mostly driven by higher net revenues of \$1.1 million and associated higher gross margin of \$0.5 million, offsetting operating expenses of \$0.4 million, and higher other income of \$0.1 million due to higher interest income from our treasury bill investments. A tax benefit of \$0.6 million resulting from the loss was also recorded during the period.

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LIQUIDITY AND CAPITAL RESOURCES

Our principal source of liquidity is our cash on hand of \$12.2 million as of March 31, 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, manufacturing technologies, and equipment.

Our inventory position was \$6.6 million at March 31, 2023, which reflected an increase of \$0.2 million from December 31, 2022. We have completed the transition of our manufacturing operations to Command and expect to significantly reduce our inventory position during the future quarters 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 expect the credit to be received before the end of 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 through March 31, 2024. 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. 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:

| | Three Months Ended March 31, 2023 | Three Months Ended March 31, 2022 |
|---------------------------------------|--------------------------------------|--------------------------------------|
| Net cash used in operating activities | \$ (4,660,583) | \$ (1,752,072) |
| Net cash used in investing activities | \$ (283,837) | \$ (752,602) |
| Net cash used in financing activities | \$ (238,972) | \$ (252,968) |

Operating Activities

Net cash used in operating activities of \$4.7 million for the three months ended March 31, 2023 was primarily due to the net loss of \$2.4 million, working capital changes which included an increase in accounts receivable of \$0.6 million, an increase in inventory of \$0.2 million, a decrease in accrued expenses of \$1.3 million, a decrease in accounts payable of \$0.9 million and a decrease in prepaid expense of \$0.3 million. Further contributing was an increase in deferred tax assets of \$0.6 million.

Offsetting these were primarily non-cash charges for stock-based compensation of \$0.9 million, depreciation and amortization of \$0.2 million and a loss on disposal of fixed assets of \$0.1 million.

Net cash used in operating activities of \$1.8 million for the three months ended March 31, 2022, was primarily due to the net loss of \$2.5 million and the deferred tax asset of \$0.6 million, offset by favorable net working capital of \$0.4 million driven by accounts receivable collections and non-cash charges for stock-based compensation of \$0.8 million, and depreciation and amortization of \$0.1 million.

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Investing Activities

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

Net cash used in investing activities of \$0.8 million for the three months ended March 31, 2022, was for capital improvement expenditures for our new location and manufacturing and office equipment.

Financing Activities

Net cash used in financing activities for the three months ended March 31, 2023, is from \$0.2 million of net borrowings on our indebtedness for a note payable for insurance premium financing.

The \$0.3 million used in financing activities for the three months ended March 31, 2022, was for financed director and officer liability insurance.

ACCOUNTING PRONOUNCEMENTS NOT YET ADOPTED

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

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

There have been no changes in the Company's internal control over financial reporting during the three months ended March 31, 2023, 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, 2022 and described below, which could adversely affect our business, financial condition, results of operations, cash flows, and the trading price of our common stock.

Bank failures or other events affecting financial institutions could have a material adverse effect on our business, results of operations or financial condition, or have other adverse consequences.

All of our cash deposits are held by Federal Deposit Insurance Corporation ("FDIC") insured banks, which amounts exceed the FDIC insurance limits. Through various overnight "sweep account" programs, we also invest a significant portion of our cash balances in U.S. Treasury-based funds, which are invested through brokerage firms affiliated with the banks at which our deposits are held. The failure of a bank or related brokerage firm that we use, or events involving limited liquidity, non-performance or other adverse conditions in the financial or credit markets impacting financial institutions at which we maintain balances, or concerns or rumors about such events, may lead to disruptions in access to our cash balances, adversely impact our liquidity, including our ability to borrow under our credit facility, or limit our ability to pay our vendors. In the event of a failure of a bank or other financial institution that holds our cash deposits, there can be no assurance that our deposits in excess of the FDIC or other comparable insurance limits will be recoverable or, even if ultimately recoverable, there may be significant delays in our ability to access those funds. Furthermore, bank failures, non-performance, or other adverse developments that affect financial institutions could impair the ability of one or more of the banks participating in our credit facility from honoring their commitments. Such events could have a material adverse effect on our financial condition or results of operations.

PART II – ITEM 6. EXHIBITS.

Exhibit No. Description

| | |
|---------|---|
| 31.1 | <u>Certification of Principal Executive Officer Pursuant to Section 302 of Sarbanes-Oxley Act 2002</u> |
| 31.2 | <u>Certification of Principal Financial Officer Pursuant to Section 302 of Sarbanes-Oxley Act 2002</u> |
| 32.1 | <u>Certification of Principal Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act 2002</u> |
| 32.2 | <u>Certification of Principal Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act 2002</u> |
| 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.

May 4, 2023

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

May 4, 2023

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

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EXHIBIT 31.1

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

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

- 1) I have reviewed this Quarterly Report on Form 10-Q of KORU Medical Systems, Inc. (the "Report");
- 2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing this equivalent function):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 4, 2023

/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: May 4, 2023

/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 March 31, 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: May 4, 2023

/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 March 31, 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: May 4, 2023

/s/ Thomas Adams

Thomas Adams

Interim Chief Financial Officer and Treasurer
