

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported) March 8, 2023

KORU Medical Systems, Inc.

(Exact name of registrant as specified in its charter)

<u>New York</u> (State or other jurisdiction of incorporation)	<u>0-12305</u> (Commission File Number)	<u>13-3044880</u> (IRS Employer Identification No.)
<u>100 Corporate Drive, Mahwah, NJ</u> (Address of principal executive offices)	<u>07430</u> (Zip Code)	

Registrant's telephone number, including area code (845) 469-2042

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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 is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.

ITEM 2.02 RESULTS OF OPERATIONS AND FINANCIAL CONDITION.

On March 8, 2023, KORU Medical Systems, Inc. ("KORU Medical" or "we") issued a press release announcing its financial results for the fourth quarter and year ended December 31, 2023 and financial guidance for the fiscal year ended December 31, 2023. A related conference call will be held on March 8, 2023 at 4:30 pm Eastern Time.

KORU Medical is making reference to non-GAAP financial measures in both the press release and the conference call. Our management believes that investors' understanding of KORU Medical's performance is enhanced by disclosing the non-GAAP financial measures of Adjusted EBITDA and Adjusted EPS (each as defined below) as a reasonable basis for comparison of our ongoing results of operations. KORU Medical strongly encourages investors to review its consolidated financial statements and publicly filed reports in their entirety and cautions investors that the non-GAAP measures used by KORU Medical may differ from similar measures used by other companies, even when similar terms are used to identify such measures. Non-GAAP measures should not be considered replacements for, and should be read together with, the most comparable GAAP financial measures. A reconciliation of GAAP to non-GAAP results is provided in the attached Exhibit 99.1 press release.

We define Adjusted EBITDA as earnings (net (loss)/income) before interest expense/(income), net, income tax (benefit)/expense, depreciation and amortization, reorganization charges, discontinued product expense, litigation expenses, manufacturing initiative expenses and stock-based compensation expense. We believe that Adjusted EBITDA is used by investors and other users of our financial statements as a supplemental financial measure that, when viewed with our GAAP results and the accompanying reconciliation, we believe provides additional information that is useful to gain an understanding of the factors and trends affecting our business. We also believe the disclosure of Adjusted EBITDA helps investors meaningfully evaluate and compare our cash flow generating capacity from quarter to quarter and year to year. Adjusted EBITDA is used by management as a supplemental internal measure for planning and forecasting overall expectations and for evaluating actual results against such expectations.

We present diluted earnings per share after eliminating items that we believe are not part of our ordinary operations and affect the comparability of the periods presented (“Adjusted EPS”). Adjusted EPS includes adjustments for reorganization charges, discontinued product expense, litigation expenses, manufacturing initiative expenses, stock-based compensation expense, and tax (expense). We believe adjustments for these items allow investors to better understand our underlying operating results and facilitate comparisons between the periods shown. Management uses Adjusted EPS as a supplemental internal measure for planning and forecasting overall expectations and for evaluating actual results against such expectations.

The information in Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1, is furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated March 8, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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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 hereunto duly authorized.

KORU Medical Systems, Inc.

(Registrant)

Date: March 8, 2023

By: /s/ Thomas Adams
Thomas Adams

Interim Chief Financial Officer

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EXHIBIT 99.1



**KORU MEDICAL SYSTEMS ANNOUNCES 2022 Q4 AND FULL YEAR FINANCIAL RESULTS,
ACCELERATING TO 19% REVENUE GROWTH IN 2022**

MAHWAH, NJ – March 8, 2023 –KORU Medical Systems, Inc. (NASDAQ: KRMD) ("KORU Medical" or the "Company"), a leading medical technology company focused on the development, manufacturing, and commercialization of innovative and easy-to-use subcutaneous drug delivery systems that improve quality of life for patients, today reported financial results for the fourth quarter and full year ended December 31, 2022. The Company also issued guidance for the full year 2023.

Recent Highlights:

- Fourth quarter net revenue growth of 13% to \$7.3 million, marking the fifth consecutive quarter of double-digit growth, and full year net revenue growth of 19% to \$27.9 million
- Novel Therapies business finished the year with 14 total collaborations to date – growing pre-commercial revenue from \$0.5 million in 2021 to \$2.5 million for full year 2022
- 11% Core business growth (U.S. and International) for the year driven by overall SCIG market growth and market share gains through prefilled syringe adoptions
- Improved cash position to \$17.4 million ending the fourth quarter via strong working capital management
- 2023 net revenues expected to be between \$32.5 and \$33.5 million, representing growth in the range of 17-20%

"2022 was a very impactful year for KORU Medical, as we executed on the first year of our Vision 2026 strategy and strengthened our position as a leading provider of drug delivery in the home," said Linda Tharby, KORU Medical's President and CEO. "We grew revenue by 19%, more than doubled our novel therapies revenues and pipeline, and delivered double-digit revenue growth in our Core business. We continued to build a strong team, and we are excited by the momentum we carry into 2023. We anticipate another strong year of growth across both our Novel Therapies and Core businesses, as well as completion of our operational improvements to drive our gross margin profile. We look forward to continuing to build value for our patients, customers and shareholders."

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2022 Fourth Quarter Financial Results

	Three Months		Change from Prior Year	
	2022	2021	\$	%
Net Revenues				
Domestic Core	\$ 5,314,836	\$ 5,004,192	\$ 310,644	6.2%
International Core	1,221,540	1,261,731	(40,191)	(3.2)%
Novel Therapies	808,305	224,584	583,721	259.9%
Total	\$ 7,344,681	\$ 6,490,507	\$ 854,174	13.2%

Total net revenues increased \$0.9 million, or 13.2%, for the three months ended December 31, 2022 compared to the same period in 2021. Novel Therapies net revenues grew by 259.9% in the fourth quarter of 2022 driven by significant progress related to a non-recurring engineering (NRE) innovation services agreement and revenues in support of ongoing clinical trials. Domestic Core growth of 6.2% was driven by growth in Freedom Edge pumps to support prefilled syringe adoption and increases in average selling prices, offset by store consolidations in a large specialty pharmacy account and the impact of lower SCIG script volumes in the third quarter of 2022. International Core net revenues were lower by 3.2% driven by prior year timing of orders from two distributors, partially offset by new distributor revenue growth in Germany and growth in other markets related to new label indications.

Gross profit increased \$0.2 million or 6.4% in the three months ended December 31, 2022, compared to the same period in 2021. This increase in gross profit was primarily driven by the increase in net revenues of \$0.9 million, as described above. Gross profit as a percentage of net revenues decreased to 55.5% compared to 59.0% from the fourth quarter of 2021. The decline in the gross profit as a percentage of revenues was primarily due to higher year on year manufacturing costs associated with labor and materials, and expenses related to our manufacturing transition as we prepare to exit our Chester facility and complete the transition to our Mahwah facility and outsourced manufacturing organization. Offsetting these increases was a higher margin for Novel Therapies NRE service revenue mix and an increase in Core average selling price and product mix.

Total operating expenses for the fourth quarter of 2022 were \$6.6 million, compared to \$5.9 million for the same period in 2021. The increase in operating expenses was primarily due to innovation investments in research and development.

Net loss for the fourth quarter of 2022 was \$2.0 million, or \$(0.04) per diluted share, compared to a net loss of \$1.1 million, or \$(0.02) per diluted share for the same period of 2021. Net loss included a tax benefit of \$0.5 million for the fourth quarter of 2022.

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2022 Full Year Financial Results

	Twelve Months Ended December 31,		Change from Prior Year	
	2022	2021	\$	%
Net Revenues				
Domestic Core	\$ 21,205,204	\$ 19,045,512	\$ 2,159,692	\$ 11.3%
International Core	4,164,714	3,856,972	307,742	8.0%
Novel Therapies	2,526,119	587,691	1,938,428	329.8%
Total	\$ 27,896,037	\$ 23,490,175	\$ 4,405,862	\$ 18.8%

Total net revenues increased \$4.4 million, or 18.8%, for the year ended December 31, 2022, as compared with the same period last year. Double-digit revenue growth was achieved in our Domestic Core and Novel Therapies businesses. Domestic Core growth was primarily driven by increased volume attributed to SCIG market growth and new label indications, including prefilled syringes, and increases in average selling prices. Novel Therapies revenues grew by 329.8% for the year ended 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. Revenues growth in our International Core business was driven by volume growth in several EU markets compared with prior year.

Gross profit increased \$1.6 million or 11.6% for the year ended December 31, 2022, compared to the same period in 2021. Gross profit as a percent of revenues decreased to 55.1% compared to 58.6% from the prior year. The decline in the gross profit as a percentage of revenues was primarily due to higher manufacturing costs associated with labor and materials, and expenses related to our manufacturing transition as we prepare to exit our Chester facility to complete the transition to our Mahwah facility and outsourced manufacturing organization, and a lower Novel Therapies service revenue margin. Partially offsetting these declines was an increase in core average selling price and product mix.

Selling, general and administrative expenses increased \$2.7 million, or 15.4%, during the year ended December 31, 2022 compared to the same period last year, primarily due to \$2.5 million in investments for new hires in commercial for Domestic Core and Novel Therapies businesses, as well as quality and regulatory to support our strategic growth initiatives.

Research and development expenses increased \$2.5 million, or 100.4%, during the year ended December 31, 2022 compared with the same period last year primarily due to new product development initiatives.

Net loss for the full year 2022 was \$8.6 million, or \$(0.19) per diluted share, compared to a net loss of \$4.6 million, or \$(0.10) per diluted share for the same period of 2021. Net loss included a tax benefit of \$2.0 million for the full year 2022.

Cash and cash equivalents were \$17.4 million as of December 31, 2022.

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Assumptions and Guidance for Full Year 2023

KORU Medical's guidance for full year 2023 reflects numerous assumptions that could affect its business, based on the information management has as of this date, which includes, SCIG market growth rate of ~10% , prefilled syringe penetration of 15-20%, plasma supply, clinical trial activity and expansion of the novel therapies pipeline, inflationary impact (including labor and supply price increases), third party contractor execution, supply chain and labor shortage impacts, and timely receipt of other receivable credits. Management will discuss its outlook and several of its assumptions on its fourth quarter 2022 earnings call.

KORU Medical expects:

- Full year 2023 net revenue between \$32.5 and \$33.5 million, representing growth in the range of 17%-20%
 - o To sign 6 new Novel Therapies collaborations
 - o Two 510(k) filings submitted in second half
- Gross margins between 58% and 60% on a full year, with first half margins expected between 55% to 57% and a planned exit between 60% and 62%
 - o Chester, NY site closure Q1; completion of manufacturing outsourcing transition Q2
- Cash balance at year-end 2023 greater than \$10.0 million

- o Operating expenses of approximately \$30.0 million, inclusive of stock compensation expense
- o Working capital improvements in inventory of approximately \$2.0 million
- o Breakeven in second half of 2024 based on current strategic outlook

Conference Call and Webcast Details

The Company will host a live conference call and webcast to discuss these results and provide a corporate update on Wednesday, March 8, 2023, at 4:30 PM ET.

To participate in the call, please dial (877)-407-0784 (domestic) or (201)-689-8560 (international) and provide conference ID: 13736062. The live webcast will be available on the IR Calendar on the News/Events page of the Investors section of KORU Medical's website.

Non-GAAP Measures

This press release includes the non-GAAP financial measures "Adjusted EBITDA" and "Adjusted Diluted earnings per share" that are not in accordance with, nor an alternate to, generally accepted accounting principles and may be different from non-GAAP measures used by other companies. These non-GAAP measures are not based on any comprehensive set of accounting rules or principles. Non-GAAP financial measures should not be considered a substitute for, or superior to, measures of financial performance prepared in accordance with GAAP. They are limited in value because they exclude charges that have a material effect on KORU Medical's reported results and, therefore, should not be relied upon as the sole financial measures to evaluate the Company's financial results. Non-GAAP financial measures are meant to supplement, and to be viewed in conjunction with, GAAP financial results. Reconciliations of the Company's non-GAAP measures are included at the end of this press release.

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About KORU Medical Systems

KORU Medical Systems develops, manufactures, and commercializes innovative and easy-to-use subcutaneous drug delivery systems that improve quality of life for patients around the world. The FREEDOM Syringe Infusion System currently includes the FREEDOM60® and FreedomEdge® Syringe Infusion Drivers, Precision Flow Rate Tubing™ and HigH-Flo Subcutaneous Safety Needle Sets™. These devices are used for infusions administered in the home and alternate care settings. For more information, please visit www.korumedical.com.

Forward-looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties. All statements that are not historical fact are forward-looking statements, including, but not limited to, expected financial outlook and operating performance for fiscal 2023. Forward-looking statements discuss the Company's current expectations and projections relating to its financial position, results of operations, plans, objectives, future performance and business. Forward-looking statements can be identified by words such as "guidance," "outlook", "expect", "plan", "believe" and "will". Actual results may differ materially from the results predicted and reported results should not be considered as an indication of future performance. The potential risks and uncertainties that could cause actual results to differ from the results predicted include, among others, those referenced under "Assumptions and Outlook for Full Year 2023" in this press release, uncertainties associated with the shift to increased healthcare delivery in the home, new patient diagnoses, customer ordering patterns, innovation and competition, labor and supply price increases, inflationary impacts, labor supply, and those risks and uncertainties included under the captions "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2022 which is on file with the SEC and available on our website at www.korumedical.com/investors and on the SEC website at www.sec.gov. All information provided in this release and in the attachments is as of March 8, 2023. Undue reliance should not be placed on the forward-looking statements in this press release, which are based on information available to us on the date hereof. We undertake no duty to update this information unless required by law.

Investor Contact:

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investor@korumedical.com

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KORU MEDICAL SYSTEMS, INC. STATEMENTS OF OPERATIONS

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2022	2021	2022	2021
NET REVENUES	\$ 7,344,681	\$ 6,490,507	\$ 27,896,037	23,490,175
Cost of goods sold	3,266,535	2,658,718	12,527,051	9,720,597

Gross Profit	4,078,146	3,831,789	15,368,986	13,769,578
OPERATING EXPENSES				
Selling, general and administrative	4,761,173	4,881,709	20,606,507	17,862,314
Research and development	1,640,732	949,930	4,956,215	2,473,669
Depreciation and amortization	187,658	113,308	587,137	463,130
Total Operating Expenses	6,589,563	5,944,947	26,149,859	20,799,113
Net Operating Loss	(2,511,417)	(2,113,158)	(10,780,873)	(7,029,535)
Non-Operating Income				
Loss on foreign currency exchange	(977)	(7,144)	(39,874)	(28,905)
Gain on disposal of fixed assets, net	—	—	—	1009
Other Income	—	679,907	—	679,907
Interest (expense)/income, net	101,008	(3,800)	145,587	13,083
TOTAL OTHER INCOME	100,031	668,963	105,713	665,094
LOSS BEFORE TAXES	(2,411,386)	(1,444,195)	(10,675,160)	(6,364,441)
Income Tax Benefit	434,659	375,837	2,014,018	1,801,618
NET LOSS	<u>\$ (1,976,727)</u>	<u>\$ (1,068,358)</u>	<u>\$ (8,661,142)</u>	<u>(4,562,823)</u>
NET LOSS PER SHARE				
Basic	<u>\$ (0.04)</u>	<u>\$ (0.02)</u>	<u>\$ (0.19)</u>	<u>(0.10)</u>
Diluted	<u>\$ (0.04)</u>	<u>\$ (0.02)</u>	<u>\$ (0.19)</u>	<u>(0.10)</u>
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING				
Basic	<u>45,372,132</u>	<u>44,571,079</u>	<u>45,002,074</u>	<u>44,385,032</u>
Diluted	<u>45,372,132</u>	<u>44,571,079</u>	<u>45,002,074</u>	<u>44,385,032</u>

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**KORU MEDICAL SYSTEMS, INC.
BALANCE SHEETS**

	<u>December 31, 2022</u>	<u>December 31, 2021</u>
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 17,408,257	\$ 25,334,889
Accounts receivable less allowance for doubtful accounts of \$21,459 and \$24,271 for December 31, 2022, and December 31, 2021, respectively	3,558,884	3,592,886
Inventory	6,404,867	6,106,338
Other receivables	972,396	718,220
Prepaid expenses and other	1,457,232	1,568,821
TOTAL CURRENT ASSETS	<u>29,801,636</u>	<u>37,321,154</u>
Property and equipment, net	3,886,975	1,106,445
Intangible assets, net of accumulated amortization of \$325,872 and \$263,729 at December 31, 2022 and December 31, 2021, respectively	787,182	808,813
Operating lease right-of-use assets	3,786,545	95,553
Deferred income tax assets, net	3,967,480	1,941,254
Other assets	102,625	19,812
TOTAL ASSETS	<u>\$ 42,332,443</u>	<u>\$ 41,293,031</u>

LIABILITIES AND STOCKHOLDERS' EQUITY

CURRENT LIABILITIES		
Accounts payable	\$ 2,391,799	\$ 1,227,533
Accrued expenses	2,889,941	2,709,704
Note Payable	433,295	508,583
Other liabilities	257,337	90,000
Accrued payroll and related taxes	542,399	160,603
Finance lease liability – current	98,335	—
Operating lease liability – current	345,834	95,553
TOTAL CURRENT LIABILITIES	<u>6,958,940</u>	<u>4,791,976</u>
Finance lease liability, net current portion	394,283	—

Operating lease liability, net of current portion	3,653,257	—
TOTAL LIABILITIES	11,006,480	4,791,976
Commitments and contingencies		
STOCKHOLDERS' EQUITY		
Common stock, \$0.01 par value, 75,000,000 shares authorized, 48,861,891 and 48,044,162 shares issued; 45,441,389 and 44,623,660 shares outstanding at December 31, 2022, and December 31, 2021, respectively	488,619	480,441
Additional paid-in capital	44,252,117	40,774,245
Treasury stock, 3,420,502 shares at December 31, 2022 and December 31, 2021, at cost	(3,843,562)	(3,843,562)
Retained deficit	(9,571,211)	(910,069)
TOTAL STOCKHOLDERS' EQUITY	31,325,963	36,501,055
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 42,332,443	\$ 41,293,031

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**KORU MEDICAL SYSTEMS, INC.
STATEMENTS OF CASH FLOWS**

	For the Years Ended December 31,	
	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	\$ (8,661,142)	\$ (4,562,823)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	3,079,427	2,707,554
Depreciation and amortization	587,137	463,130
Loss on disposal of fixed assets	—	(1,009)
Deferred income taxes	(2,026,226)	(1,815,980)
ROU landlord credit	212,546	—
Changes in operating assets and liabilities:		
Decrease/(Increase) in accounts receivable	34,002	(1,019,932)
(Increase)/Decrease in inventory	(298,529)	723,434
Increase in other receivables	(254,176)	(718,220)
Decrease/(Increase) in prepaid expenses and other assets	28,776	(761,041)
Increase in accounts payable	1,164,266	602,613
Increase/(Decrease) in accrued payroll and related taxes	381,796	(126,527)
Increase in other liabilities	167,337	90,000
Increase in accrued expenses	180,237	99,291
NET CASH USED IN OPERATING ACTIVITIES	(5,404,549)	(4,319,510)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property and equipment	(2,761,056)	(346,178)
Purchases of intangible assets	(40,512)	(29,056)
Proceeds from disposal of property and equipment	—	9,065
NET CASH USED IN INVESTING ACTIVITIES	(2,801,568)	(366,169)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of equity	406,623	1,261,251
Common stock issuance settlement of litigation	—	938,094
Borrowings from indebtedness	783,799	924,389
Payments on indebtedness	(859,087)	(415,806)
Payments on finance lease liability	(51,850)	(2,646)
NET CASH PROVIDED BY FINANCING ACTIVITIES	279,485	2,705,282
NET DECREASE IN CASH AND CASH EQUIVALENTS	(7,926,632)	(1,980,397)
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR	25,334,889	27,315,286
CASH AND CASH EQUIVALENTS, END OF YEAR	\$ 17,408,257	\$ 25,334,889
Supplemental Information		
Cash paid during the years for:		
Interest	\$ 28,490	\$ 13,241
Income taxes	\$ —	\$ 1,903
Schedule of Non-Cash Operating, Investing and Financing Activities:		
Issuance of common stock as compensation	\$ 513,082	\$ 433,654
Issuance of common stock as settlement for litigation	\$ —	\$ 938,094

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A reconciliation of our non-GAAP measures is below:

Reconciliation of GAAP Net (Loss) to Non-GAAP Adjusted EBITDA:	Three Months Ended		Twelve Months Ended	
	December 31,		December 31,	
	2022	2021	2022	2021
GAAP Net Loss	\$ (1,976,728)	(1,068,358)	\$ (8,661,142)	\$ (4,562,823)
Tax (Benefit)	(434,659)	(375,837)	(2,014,018)	(1,801,618)
Depreciation and Amortization	187,658	113,308	587,137	463,130
Interest (Income)/Expense, Net	(101,009)	3,800	(145,587)	(13,083)
Reorganization Charges	—	—	765,433	1,192,618
Manufacturing Initiative Expenses	184,343	1,883	293,229	239,216
Stock-based Compensation Expense	588,654	739,922	3,079,426	2,707,544
Non-GAAP Adjusted EBITDA	<u>\$ (1,551,741)</u>	<u>\$ (585,282)</u>	<u>\$ (6,095,522)</u>	<u>\$ (1,775,016)</u>

Reconciliation of Reported Diluted EPS to Non-GAAP Adjusted Diluted EPS:	Three Months Ended		Twelve Months Ended	
	December 31,		December 31,	
	2022	2021	2022	2021
Reported Diluted Earnings Per Share	\$ (0.04)	(0.02)	\$ (0.19)	\$ (0.10)
Reorganization Charges	—	—	0.02	0.03
Manufacturing Initiative Expenses	—	—	0.01	0.01
Stock-based Compensation Expense	—	—	—	0.01
Tax (Expense) Adjustment	—	—	—	(0.01)
Non-GAAP Adjusted Diluted Earnings Per Share	<u>\$ (0.04)</u>	<u>\$ (0.02)</u>	<u>\$ (0.16)</u>	<u>\$ (0.06)</u>

*Numbers presented are rounded to the nearest whole cent

Reorganization Charges. We have excluded the effect of reorganization charges in calculating our non-GAAP measures. In 2021 we incurred significant expenses in connection with the departure and replacement of our chief executive officer and the recruiting of two new board members, which we would not have otherwise incurred in periods presented as part of our continuing operations. In 2022 we incurred further severance expense related to the reorganization of the leadership team and the departure of our chief financial officer, which we would not have otherwise incurred in periods presented as part of continuing operations.

Manufacturing Initiative Expenses. We have excluded the effect of expenses related to creating manufacturing efficiencies, in calculating our non-GAAP measures. We incurred expenses in connection with these initiatives which we would not have otherwise incurred in periods presented as part of our continuing operations. We expect to incur related expenses for the next three to six months.

Stock-based Compensation Expense. We have excluded the effect of stock-based compensation expense in calculating our non-GAAP measures. We record non-cash compensation expense related to grants of options and restricted shares for executives, employees and consultants, and grants of shares to our board of directors. Depending upon the size, timing and the terms of the grants, the non-cash compensation expense may vary significantly but will recur in future periods.