

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 2, 2022

**REPRO MED SYSTEMS, INC.**

(Exact name of registrant as specified in its charter)

New York  
(State or other jurisdiction  
of incorporation)

0-12305  
(Commission  
File Number)

13-3044880  
(IRS Employer  
Identification No.)

24 Carpenter Road, Chester, New York  
(Address of principal executive offices)

10918  
(Zip Code)

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

not applicable  
(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>
<b>common stock, \$0.01 par value</b>	<b>KRMD</b>	<b>The Nasdaq Stock Market</b>

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 2, 2022, Repro Med Systems, Inc. dba KORU Medical Systems ("KORU Medical") issued a press release announcing its financial results for the fourth quarter and year ended December 31, 2021 and its financial outlook for the fiscal year ended December 31, 2022. A related conference call will be held on March 2, 2022 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, Adjusted EPS and Adjusted Net Revenues (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 present net revenues after adjusting for net revenues that we believe would have been made during periods other than those in which they were made, due to the pandemic and an early order in the third quarter of 2020 ("Adjusted Net Revenues"). We believe adjustments for these items allow investors to better understand our underlying net revenues results and facilitate comparisons between the periods shown. Management uses Adjusted Net Revenues as a supplemental internal measure for planning and forecasting overall expectations and for evaluating actual results against such expectations.

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	<a href="#">Press release dated March 2, 2022</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

- 2 -

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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.

REPRO MED SYSTEMS, INC.  
(Registrant)

Date: March 2, 2022

By: /s/ Karen Fisher  
Karen Fisher  
Chief Financial Officer

- 3 -

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## **KORU MEDICAL SYSTEMS ANNOUNCES 2021 Q4 AND FULL YEAR FINANCIAL RESULTS**

CHESTER, NY – March 2, 2022 – Repro Med Systems, Inc. dba KORU Medical Systems (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 specialty infusion solutions that improve quality of life for patients, today reported financial results for the fourth quarter and full year ended December 31, 2021.

### **Highlights:**

- Fourth quarter net revenues of \$6.5 million, compared to \$4.1 million in Q4 2020, 60% growth as reported, 27.6% growth when adjusted for customer inventory stocking impacting Q4 2020
- Fourth quarter year-over-year revenue growth was driven by positive momentum across all three businesses, including increased pump placements and consumables growth in the U.S., higher consumables in Europe, and a strengthened novel therapies pipeline
- Full year net revenues of \$23.5 million, compared to \$24.2 million last year, with core revenue growth offset by lower novel therapies revenues due to a large clinical trial order in 2020
- Expanded on label indications with three new 510(k) clearances, including use of the FreedomEdge<sup>®</sup> infusion pump to deliver Hizentra<sup>®</sup> 20 mL prefilled syringes, and use of the FREEDOM60<sup>®</sup> Infusion System with two additional SCIG drugs, Cutaquig and Xembify
- Announced five-year strategic plan to achieve significant expansion of pipeline value through extending leading position in subcutaneous (SC) IG therapy to new subcutaneous drug therapies, multiple new product introductions and \$60 million in revenues by 2026

“We are very pleased to finish 2021 with a strong fourth quarter. Driven by the efforts of our team, KORU Medical has seen momentum in all three areas of our business – domestic and international core business and novel therapies,” said Linda Tharby, KORU Medical’s CEO. “During the fourth quarter, we hit several key milestones, including three new 510(k) clearances, increased pump placements in our U.S. business, and four new agreements in our novel therapies pipeline. In addition, we announced our new strategic plan, including milestones that will drive accelerated revenue growth, margin improvement, and expansion of our total addressable market. We look forward to continued execution of our plan and driving long-term growth and value for our patients, customers, employees, and shareholders.”

### **2021 Fourth Quarter Financial Results**

	<b>Three Months Ended December 31,</b>		<b>Change from Prior Year</b>	
	<b>2021</b>	<b>2020</b>	<b>\$</b>	<b>%</b>
Domestic Core	5,004,192	4,207,504	796,688	18.9%
International Core	1,261,731	828,575	433,156	52.3%
Novel Therapies	224,584	52,141	172,443	330.7%
<b>Non-GAAP Adjusted Net Revenues</b>	<b>\$ 6,490,507</b>	<b>\$ 5,088,220</b>	<b>\$ 1,402,287</b>	<b>27.6%</b>

*\*This table represents Non-GAAP adjusted net revenues. See reconciliation to GAAP table below.*

Net revenues for the fourth quarter of 2021 were \$6.5 million, compared with \$4.1 million in the prior-year period, a 60% increase. Adjusting for net inventory stocking of \$1.0 million last year, net revenues grew 27.6%, reflecting growth in all areas of the Company’s business; domestic core growth driven by pumps and consumables, international driven by consumables and increased novel therapies revenues from expansion of its pipeline.

Gross margin was 59.0% for the fourth quarter of 2021, an increase from prior year of 56.6%. The majority of the increase was driven by a mid-year price increase.

Total operating expenses for the fourth quarter of 2021 were \$5.9 million, compared to \$3.5 million for the same period in 2020. The increase in operating expenses is due to strategic investments in commercialization, quality and regulatory, and research and development.

Net loss for the fourth quarter of 2021 was \$1.1 million, or \$(0.02) per diluted share, compared with a net loss of \$0.8 million, or \$(0.02) per diluted share for the same period in 2020. Non-GAAP adjusted EBITDA for the fourth quarter of 2021 was \$(0.6) million, compared with \$(0.3) million in the fourth quarter of 2020. On a non-GAAP basis, adjusted diluted earnings per share was \$(0.02) per diluted share in both periods.

### **2021 Full Year Financial Results**

Net revenues for 2021 were \$23.5 million, 2.8% lower compared with \$24.2 million in the prior year. On an adjusted basis, net revenues were lower by 1.6%. The shortfall was driven by lower year-over-year novel therapies revenues due to a large clinical trial order in 2020. Domestic core net revenues for 2021 were 0.8% higher than last year mostly driven by price in the second half of the year and international core net revenues were up 14.5% compared to the previous year, driven by growth in key customers.

Gross margin was 58.6% in 2021 compared to 61.8% in 2020. The decrease was primarily driven by the delay in the transition to a secondary manufacturing source.

Total operating expenses increased 28.5%, or \$4.6 million compared to last year. The increase was primarily driven by investments

associated with building the Company's leadership and extended team, commercialization and regulatory efforts, and research and development.

Net loss for the full year 2021 was \$4.6 million, or \$(0.10) per diluted share, compared with a net loss of \$1.2 million, or \$(0.03) per diluted share for the same period in 2020. Non-GAAP adjusted EBITDA for the full year 2021 was \$(1.8) million, compared with \$3.7 million for the same period in 2020. On a non-GAAP basis, adjusted diluted earnings per share was \$(0.07) for the full year 2021, compared with \$0.02 diluted earnings per share for the same period in 2020.

The Company ended the year with \$25.3 million of cash and believes it has sufficient resources to execute its strategic plan over the next several years.

### **Assumptions and Outlook for Full Year Fiscal 2022**

KORU Medical's outlook for fiscal year 2022 reflects numerous assumptions that could affect its business, based on the information management has as of this date, which includes assumptions regarding the continued recovery from the COVID-19 pandemic related to new SCIg patient starts, plasma supply, clinical trial activity, and supply chain impacts. Management will discuss its outlook and several of its assumptions on its fourth fiscal quarter 2021 earnings call.

For fiscal year 2022, KORU Medical expects the subcutaneous immunoglobulin (SCIg) market to recover and grow high single digits. Assuming this market growth holds, the Company expects revenue growth in the low to mid double digits, or \$26.0 to \$27.0 million on a full year basis. Gross margin will be impacted by the supplier transition, which the Company estimates will be completed in the third quarter of 2022 and expects to exit the year at a 60% run rate. The Company expects operating expenses to increase to roughly \$27.0 to \$28.0 million for full year 2022 in support of the strategic plan, including investments in building the team, research and development and commercialization efforts supporting new product introductions, novel therapies pipeline expansion, and SCIg market penetration.

### **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 2, 2022, 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 13726808. The live webcast will be available on the Events & Presentations page of the Investors section of KORU Medical's website.

- 2 -

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### **Non-GAAP Measures**

This press release includes the non-GAAP financial measures of "Adjusted Net Revenues," "Adjusted EBITDA" and "Adjusted Diluted EPS" 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.

### **About KORU Medical Systems**

KORU Medical Systems develops, manufactures, and commercializes innovative and easy-to-use specialty infusion solutions that improve quality of life for patients around the world. The FREEDOM Syringe Infusion System currently includes the FREEDOM60<sup>®</sup> and FreedomEdge<sup>®</sup> Syringe Infusion Drivers, Precision Flow Rate Tubing<sup>™</sup> and HiG-Flo Subcutaneous Safety Needle Sets<sup>™</sup>. These devices are used for infusions administered in the home and alternate care settings. For more information, please visit [www.korumedical.com](http://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 2022, expected market growth and availability of resources to execute the strategic plan. 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 "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, uncertainties associated with the shift to increased healthcare delivery in the home, new patient diagnoses, customer ordering patterns, COVID-19, innovation and competition, 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, 2021, which is on file with the SEC and is available on our website at [www.korumedical.com/investors](http://www.korumedical.com/investors) and on the SEC website at [www.sec.gov](http://www.sec.gov). All information provided in this release and in the attachments is as of March 2, 2022. 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:**

Greg Chodaczek  
347-620-7010  
[investor@korumedical.com](mailto:investor@korumedical.com)

- 3 -

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2021	2020	2021	2020
NET REVENUES	\$ 6,490,507	\$ 4,057,220	\$ 23,490,175	\$ 24,176,448
Cost of goods sold	2,658,718	1,759,946	9,720,597	9,240,362
Gross Profit	3,831,789	2,297,274	13,769,578	14,936,086
OPERATING EXPENSES				
Selling, general and administrative	4,881,709	2,988,795	17,862,314	12,028,309
Litigation	—	—	—	2,447,213
Research and development	949,930	352,116	2,473,669	1,296,754
Depreciation and amortization	113,308	120,794	463,130	418,595
Total Operating Expenses	5,944,947	3,461,706	20,799,113	16,190,871
Net Operating Loss	(2,113,158)	(1,164,432)	(7,029,535)	(1,254,785)
Non-Operating (Expense)/Income				
(Loss)/Gain on currency exchange	(7,144)	12,699	(28,905)	1,536
Gain on disposal of fixed assets, net	—	—	1,009	16,591
Other Income	679,907	—	679,907	—
Interest (expense)/income, net	(3,800)	18,705	13,083	42,395
TOTAL OTHER (EXPENSE)/INCOME	668,963	31,404	665,094	60,522
LOSS BEFORE INCOME TAXES	(1,444,195)	(1,133,028)	(6,364,441)	(1,194,263)
Income Tax Benefit/(Expense)	375,837	298,400	1,801,618	(17,800)
NET LOSS	\$ (1,068,358)	\$ (834,628)	\$ (4,562,823)	\$ (1,212,063)
NET LOSS PER SHARE				
Basic	\$ (0.02)	\$ (0.02)	\$ (0.10)	\$ (0.03)
Diluted	\$ (0.02)	\$ (0.02)	\$ (0.10)	\$ (0.03)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING				
Basic	44,571,079	43,732,728	44,385,032	41,929,736
Diluted	44,571,079	43,732,728	44,385,032	41,929,736

- 4 -

**REPRO MED SYSTEMS, INC.  
BALANCE SHEETS**

	December 31, 2021	December 31, 2020
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 25,334,889	\$ 27,315,286
Accounts receivable less allowance for doubtful accounts of \$24,271 and \$24,469 for December 31, 2021, and December 31, 2020, respectively	3,592,886	2,572,954
Inventory	6,106,338	6,829,772
Other receivables	718,220	—
Prepaid expenses and other	1,568,821	807,780
<b>TOTAL CURRENT ASSETS</b>	<b>37,321,154</b>	<b>37,525,792</b>
Property and equipment, net	1,106,445	1,167,623
Intangible assets, net of accumulated amortization of \$263,729 and \$199,899 at December 31, 2021 and December 31, 2020, respectively	808,813	843,587
Operating lease right-of-use assets	95,553	236,846
Deferred income tax assets, net	1,941,254	125,274
Other assets	19,812	19,812
<b>TOTAL ASSETS</b>	<b>\$ 41,293,031</b>	<b>\$ 39,918,934</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable	\$ 1,227,533	\$ 624,920
Accrued expenses	2,709,704	2,610,413
Note Payable	508,583	—
Deferred Revenue	90,000	—
Accrued payroll and related taxes	160,603	287,130
Finance lease liability – current	—	2,646
Operating lease liability – current	95,553	141,293
<b>TOTAL CURRENT LIABILITIES</b>	<b>4,791,976</b>	<b>3,666,402</b>
Operating lease liability, net of current portion	—	95,553
<b>TOTAL LIABILITIES</b>	<b>4,791,976</b>	<b>3,761,955</b>

Commitments and contingencies		
<b>STOCKHOLDERS' EQUITY</b>		
Common stock, \$0.01 par value, 75,000,000 shares authorized, 48,044,162 and 46,680,119 shares issued; 44,623,660 and 43,259,617 shares outstanding at December 31, 2021, and December 31, 2020, respectively	480,441	466,801
Additional paid-in capital	40,774,245	35,880,986
Treasury stock, 3,420,502 shares at December 31, 2021 and December 31, 2020, at cost	(3,843,562)	(3,843,562)
Retained earnings	(910,069)	3,652,754
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<b>36,501,055</b>	<b>36,156,979</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 41,293,031</b>	<b>\$ 39,918,934</b>

- 5 -

**REPRO MED SYSTEMS, INC.  
STATEMENTS OF CASH FLOWS**

	<b>For the Years Ended December 31,</b>	
	<b>2021</b>	<b>2020</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net Loss	\$ (4,562,823)	\$ (1,212,063)
Adjustments to reconcile net (loss) to net cash used in operating activities:		
Stock-based compensation expense	2,707,554	1,618,732
Stock-based litigation settlement expense	—	1,285,102
Depreciation and amortization	463,130	418,595
Gain on disposal of fixed assets	(1,009)	(16,591)
Deferred income taxes	(1,815,980)	62,967
Provision for doubtful accounts	—	(8,176)
Abandonment of intangible assets	—	41,919
Changes in operating assets and liabilities:		
(Increase)/Decrease in accounts receivable	(1,019,932)	669,743
Decrease/(Increase) in inventory	723,434	(4,441,295)
Increase in other receivables	(718,220)	—
Increase in prepaid expenses and other assets	(761,041)	(420,614)
Increase in accounts payable	602,613	52,264
(Decrease)/Increase in accrued payroll and related taxes	(126,527)	96,865
Increase in deferred revenue	90,000	—
Increase in accrued expenses	99,291	1,313,801
Decrease in accrued tax liability	—	(204,572)
<b>NET CASH USED IN OPERATING ACTIVITIES</b>	<b>(4,319,510)</b>	<b>(743,323)</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchases of property and equipment	(346,178)	(920,604)
Purchases of intangible assets	(29,056)	(140,548)
Proceeds from disposal of property and equipment	9,065	25,000
<b>NET CASH USED IN INVESTING ACTIVITIES</b>	<b>(366,169)</b>	<b>(1,036,152)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Proceeds from issuance of equity	1,261,251	26,728,486
Common stock issuance settlement of litigation	938,094	—
Purchase of treasury stock	—	(3,499,358)
Borrowings from indebtedness	924,389	4,976,508
Payments on indebtedness	(415,806)	(4,976,508)
Payments on finance lease liability	(2,646)	(5,296)
<b>NET CASH PROVIDED BY FINANCING ACTIVITIES</b>	<b>2,705,282</b>	<b>23,223,832</b>
<b>NET (DECREASE)/INCREASE IN CASH AND CASH EQUIVALENTS</b>	<b>(1,980,397)</b>	<b>21,444,357</b>
<b>CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR</b>	<b>27,315,286</b>	<b>5,870,929</b>
<b>CASH AND CASH EQUIVALENTS, END OF YEAR</b>	<b>\$ 25,334,889</b>	<b>\$ 27,315,286</b>
<b>Supplemental Information</b>		
<b>Cash paid during the years for:</b>		
Interest	\$ 13,241	\$ 27,736
Income taxes	\$ 1,903	\$ 321,983
<b>Schedule of Non-Cash Operating, Investing and Financing Activities:</b>		
Issuance of common stock as compensation	\$ 433,654	\$ 240,960
Issuance of common stock as settlement for litigation	\$ 938,094	\$ 938,094

- 6 -

**REPRO MED SYSTEMS, INC.  
SUPPLEMENTAL INFORMATION  
(UNAUDITED)**

The following table summarizes our net revenues for the three and twelve months ended December 31, 2021 and 2020:

	<b>Three Months Ended December 31,</b>		<b>Change from Prior Year</b>	
	<b>2021</b>	<b>2020</b>	<b>\$</b>	<b>%</b>
<b>Net Revenues</b>				

Domestic	\$ 5,004,192	\$ 3,176,504	\$ 1,827,687	\$ 57.5%
International	1,261,731	828,575	433,156	52.3%
Novel Therapies	224,584	52,141	172,444	330.7%
<b>Total</b>	<u>\$ 6,490,507</u>	<u>\$ 4,057,220</u>	<u>\$ 2,433,287</u>	<u>\$ 60.0%</u>

	Twelve Months Ended December 31,		Change from Prior Year	
	2021	2020	\$	%
	<b>Net Revenues</b>			
Domestic	\$ 19,045,512	\$ 18,895,923	\$ 149,589	0.8%
International	3,856,972	3,368,519	488,453	14.5%
Novel Therapies	587,691	1,912,006	(1,324,315)	(69.3%)
<b>Total</b>	<u>\$ 23,490,175</u>	<u>\$ 24,176,448</u>	<u>\$ 686,273</u>	<u>\$ (2.8%)</u>

A reconciliation of one of our non-GAAP measures is below:

**Reconciliation of Reported Net Revenues to Non-GAAP Net Revenues**

	Three Months Ended December 31,		Change from Prior Year	
	2021	2020	\$	%
	Reported Net Revenues	\$ 6,490,507	\$ 4,057,220	\$ 2,433,287
Early Order/Inventory Stocking	—	1,031,000	(1,031,000)	100.0%
Non-GAAP Adjusted Net Revenues	<u>\$ 6,490,507</u>	<u>\$ 5,088,220</u>	<u>\$ 1,402,287</u>	<u>27.6%</u>

**Reconciliation of Reported Net Revenues to Non-GAAP Net Revenues**

	Twelve Months Ended December 31,		Change from Prior Year	
	2021	2020	\$	%
	Reported Net Revenues	\$ 23,490,175	\$ 24,176,448	\$ (686,273)
Early Order/Inventory Stocking	—	(304,000)	304,000	100.0%
Non-GAAP Adjusted Net Revenues	<u>\$ 23,490,175</u>	<u>\$ 23,872,448</u>	<u>\$ (382,273)</u>	<u>(1.6%)</u>

*Early Order/Inventory Stocking.* For the quarter, we included the effect of an early order and covid related inventory stocking in calculating our non-GAAP measure. We had an early order from our largest distributor in the three months ended September 30, 2020, which would have otherwise been placed in the three months ended December 31, 2020, as well as higher purchases in the first half of the year that we believe would have been made in the second half of 2020, had it not been for the pandemic. For the twelve months ended December 31, 2020, we excluded what we believe to have been inventory stocking purchased in the first half of the year, had it not been for the pandemic.

- 7 -

A reconciliation of two of our non-GAAP measures is below:

Reconciliation of GAAP Net Loss to Non-GAAP Adjusted EBITDA:	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2021	2020	2021	2020
	GAAP Net Loss	\$ (1,068,358)	\$ (834,628)	\$ (4,562,823)
Tax (Benefit)/Expense	(375,837)	(298,400)	(1,801,618)	17,800
Depreciation and Amortization	113,308	120,794	463,130	418,595
Interest Expense/(Income), Net	3,800	(18,705)	(13,083)	(42,395)
Reorganization Charges	—	95,700	1,192,618	95,700
Discontinued Product Expenses	—	(459)	—	70,859
Litigation Expenses	—	466	—	2,447,213
Manufacturing Initiative Expenses	1,883	51,723	239,216	246,527
Stock-based Compensation Expense	739,922	607,592	2,707,554	1,618,732
Non-GAAP Adjusted EBITDA	<u>\$ (585,282)</u>	<u>\$ (275,917)</u>	<u>\$ (1,775,006)</u>	<u>\$ 3,660,968</u>

Reconciliation of Reported Diluted EPS to Non-GAAP Adjusted Diluted EPS*:	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2021	2020	2021	2020
	Reported Diluted Earnings Per Share	\$ (0.02)	\$ (0.02)	\$ (0.10)
Reorganization Charges	—	—	0.03	—
Discontinued Product Expense	—	—	—	—
Litigation Expenses	—	—	—	0.06
Manufacturing Initiative Expenses	—	—	—	0.01
Stock-based Compensation Expense	—	—	0.01	—
Tax (Expense) Adjustment	—	—	(0.01)	(0.02)
Non-GAAP Adjusted Diluted Earnings Per Share	<u>\$ (0.02)</u>	<u>\$ (0.02)</u>	<u>\$ (0.07)</u>	<u>\$ 0.02</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. 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.

*Discontinued Product Expense.* We have excluded the effect of expenses related to a discontinued product line in calculating our non-GAAP measures. We did not incur any related expense in 2021.

*Litigation.* We have excluded litigation expenses in calculating our non-GAAP measures. Litigation expenses in 2020 included professional fees associated with our litigation with EMED, which discontinued as a result of the settlement on May 20, 2020.

*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 six to nine 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 for executives, employees and consultants, and grants of common stock to our board of directors and our CEO. 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. Adjusted EBITDA for the twelve months ended December 31, 2021 included stock-based compensation expense of \$0.4 million related to the departure and replacement of our chief executive officer. This expense is the only amount included in Stock-based Compensation Expense in calculating Adjusted Diluted EPS.