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) August 3, 2022

KORU Medical Systems, Inc.

(Exact name of registrant as specified in its charter) 0.12305

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TICW TOLK	<u>0-12303</u>	13-3044660
(State or other jurisdiction	(Commission	(IRS Employer
of incorporation)	File Number)	Identification No.)
	100 Corporate Drive, Mahwah, NJ	07430 (7in Code)
	(Address of principal executive offices)	(Zip Code)
Reg	istrant's telephone number, including area	code (845) 469-2042
	<u>not applicable</u> Former name or former address, if change	d since last report)
	the Form 8-K filing is intended to simult (see General Instruction A.2. below):	taneously satisfy the filing obligation of the registrant
_] Written communications pursuan	t to Rule 425 under the Securities Act (17	CFR 230.425)
_] Soliciting material pursuant to R	ıle 14a-12 under the Exchange Act (17 CF	R 240.14a-12)
_] Pre-commencement communicat	ions pursuant to Rule 14d-2(b) under the E	exchange Act (17 CFR 240.14d-2(b))
_] Pre-commencement communicat	ions pursuant to Rule 13e-4(c) under the E	xchange Act (17 CFR 240.13e-4(c))
Securities registered pursuant to Sect	ion 12(b) of the Act:	
<u>Title of each class</u> common stock, \$0.01 par valu	re <u>Trading symbol(s)</u> Trading symbol(s)	Name of each exchange on which registered The Nasdaq Stock Market
		y as defined in as defined in Rule 405 of the Securities e Act of 1934 (§240.12b-2 of this chapter).
		Emerging growth company [_]
		s elected not to use the extended transition period for suant to Section 13(a) of the Exchange Act.
TEM 2.02 RESULTS OF OPERA	ATIONS AND FINANCIAL CONDITIO	DN.

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On August 3, 2022, KORU Medical Systems, Inc. ("KORU Medical" or "we") issued a press release announcing its financial results for the second quarter ended June 30, 2022 and an update to its financial outlook for the fiscal year ended December 31, 2022. A related conference call will be held on August 3, 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 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

Exhibit No. Description

99.1 Press release dated August 3, 2022

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: August 3, 2022 By: /s/ Thomas Adams Thomas Adams

Interim Chief Financial Officer

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KORU MEDICAL SYSTEMS ANNOUNCES 2022 SECOND QUARTER FINANCIAL RESULTS

MAHWAH, NJ – August 3, 2022 – 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 specialty infusion solutions that improve quality of life for patients, today reported financial results for the second quarter ended June 30, 2022.

Highlights:

- Year-over-year net sales growth of 18.4% to \$6.5 million, marking the third consecutive quarter of double-digit growth
- Expanded novel therapies pipeline with two new biopharmaceutical agreements
- Raising the revenue guidance to \$27.0 to 27.5 million
- Completed first phase of move to new corporate headquarters in Mahwah, New Jersey

"We delivered another strong quarter of revenue growth with contribution across all three of our businesses," said Linda Tharby, KORU Medical's President and CEO. "We continue to gain momentum on our strategic objectives with an expansion of our novel therapies pipeline and growth in our domestic and international core businesses. Despite facing some Q2 supply chain challenges, we continue to make meaningful progress towards building a stronger foundation. We are excited about our progress in driving long-term growth and value for patients, customers and shareholders as a leading provider of large volume drug delivery solutions."

2022 Second Quarter Financial Results

	Change from	n Pri	ior Year		
	2022	2021	\$		%
Net Sales					
Domestic Core	\$ 4,996,791	\$ 4,597,797	\$ 398,994	\$	8.7%
International Core	951,485	859,694	91,791		10.7%
Novel Therapies	598,352	70,683	527,669		746.6%
Total	\$ 6,546,628	\$ 5,528,174	\$ 1,018,454	\$	18.4%

Total net sales increased \$1.0 million, or 18.4%, for the three months ended June 30, 2022, as compared with the same period last year. This increase was driven primarily by higher novel therapies sales related to a NRE development milestone for a large pharmaceutical customer, clinical product sales for an expanded pipeline, and increases in average selling prices for our products. Our domestic core business grew by 8.7%, and was impacted by supply chain issues and labor shortages which created backorders estimated to be \$0.3 million that are not included in the reported net sales number. The increase in domestic core demand inclusive of backorders was attributed to volume growth driven by SCIg market growth and label expansions. We define backorders as any non-cancellable open order not shipped before promised delivery date net of rebates, discounts, and other fees. Backorders are expected to be cleared in the third quarter of 2022. International net sales were \$1.0 million for the three months ended June 30, 2022, up 10.7% compared with the same period last year due to volume growth in several European markets driven by key tender wins.

Gross profit increased \$0.14 million or 4.2% in the three months ended June 30, 2022, compared to the same period in 2021, while gross profit as a percentage of net sales decreased by 700 basis points to 51.1%. The decline in the gross profit percent was primarily caused by the accelerated amortization of manufacturing variances in the quarter, due to lower levels of finished goods inventory. This accounting treatment contributed 380 basis points to the reduction and we believe it is a non-recurring event. In addition, the gross profit percent was impacted by manufacturing variances due to supply chain issues in the first quarter of 2022, amortized in the current period. Further contributing to the lower gross profit percent were higher NRE revenues, which are lower gross margin, and a nominal impact from an increase in average selling prices, partially offsetting the aforementioned unfavorable impacts.

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Total operating expenses for the second quarter of 2022 were \$7.0 million, compared to \$4.6 million for the same period in 2021. The increase in operating expenses is due to strategic investments in research and development, and new hires to support business development, commercialization, quality and regulatory capabilities.

Net loss for the second quarter of 2022 was \$2.9 million, or \$(0.07) per diluted share, compared to a net loss of \$1.1 million, or \$(0.03) per diluted share for the same period of 2021. Net loss included a tax benefit of \$0.7 million for the second quarter of 2022. On a non-GAAP basis, adjusted diluted earnings per share was \$(0.06) compared to \$(0.02) in the same period of 2021.

Cash and cash equivalents were \$18.3 million as of June 30, 2022.

Assumptions and Outlook for Full Year 2022

KORU Medical's outlook for full 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, SCIg market growth rate in the high single digits, plasma supply, clinical trial activity and expansion of the

novel therapies pipeline, inflationary impact (including labor and supply price increases), supply chain and labor shortage impacts, timely receipt of equipment financing and credits and planned inventory reductions by year end 2022. Management will discuss its outlook and several of its assumptions on its second quarter 2022 earnings call.

KORU Medical now expects full year 2022 revenue to be in the range of \$27.0 to \$27.5 million (previously \$26.5 to \$27.0 million).

The Company expects to exit the year with a 55-60% gross margin updated from prior guidance of 60%. Supply chain disruptions and labor shortages resulted in unfavorable manufacturing variances in the second quarter of 2022, but are expected to improve in the second half of the year. Transfer of finished goods manufacturing to our third party contract manufacturing source is now expected in Q1 2023 (previously Q4 2022).

The Company is updating its guidance to include a minimum cash balance of \$16.0 million for year end 2022.

The Company has no further updates to prior guidance.

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, August 3, 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 13730791. 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.

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® 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.

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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, growth of novel therapies pipeline, amortization of manufacturing variances, and market growth. 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, labor and supply price increases, inflationary impacts, labor supply, and 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 and our Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, which are 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 August 3, 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

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	_	2022		2021
ASSETS				
ISSETS				
CURRENT ASSETS				
Cash and cash equivalents	\$	18,265,552	\$	25,334,889
Accounts receivable less allowance for doubtful accounts of \$24,471 for June 30, 2022, and				
December 31, 2021		4,084,762		3,592,886
Inventory		6,771,514		6,106,338
Other Receivables		680,796		718,220
Prepaid expenses		1,165,668		1,568,821
TOTAL CURRENT ASSETS		30,968,292		37,321,154
Property and equipment, net		2,823,090		1,106,445
Intangible assets, net of accumulated amortization of \$294,301 and \$263,729 at June 30, 2022 and		,,		, ,
December 31, 2021, respectively		791,781		808,813
Operating lease right-of-use assets		4,190,931		95,553
Finance lease right -of-use, net accumulated depreciation of \$5,918 at June 30, 2022		349,153		
Deferred income tax assets, net		3,249,323		1,941,254
Other assets		88,772		19,812
TOTAL ASSETS	\$	42,461,342	\$	41,293,031
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LIABILITIES AND STOCKHOLDERS' EQUITY				
EMBETTES AND STOCKHOLDERS EQUIT				
CURRENT LIABILITIES				
Accounts payable	\$	2,389,862	\$	1,227,533
Accrued expenses	-	1,974,196	•	2,709,704
Note Payable				508,583
Other Liabilities		240,501		90,000
Accrued payroll and related taxes		696,042		160,603
Financing lease liability – current		66,503		_
Operating lease liability – current		363,030		95,553
TOTAL CURRENT LIABILITIES		5,730,134		4,791,976
Financing lease liability, net of current portion		281,958		- 1,771,770
Operating lease liability, net of current portion		3,827,900		_
TOTAL LIABILITIES	_	9,839,992	_	4,791,976
TO THE EMBERTIES	_	7,037,772	_	1,771,770
STOCKHOLDERS' EQUITY				
Common stock, \$0.01 par value, 75,000,000 shares authorized, 48,407,619 and 48,044,162				
shares issued 44,987,117 and 44,623,660 shares outstanding at June 30, 2022, and December				
31, 2021, respectively		484,076		480,441
Additional paid-in capital		42,349,760		40,774,245
Treasury stock, 3,420,502 shares at June 30, 2022 and December 31, 2021, respectively, at cost		(3,843,562)		(3,843,562)
Retained deficit		(6,368,924)		(910,069)
TOTAL STOCKHOLDERS' EQUITY		32,621,350	-	36,501,055
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$	42,461,342	\$	41,293,031
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KORU MEDICAL SYSTEMS, INC. STATEMENTS OF OPERATIONS (UNAUDITED)

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		Three Moi Jun	Six Months Ended June 30,			
	_	2022	2021	2022		2021
NET SALES	\$	6,546,628	\$ 5,528,174	\$ 12,790,958	\$	10,959,125
Cost of goods sold		3,200,455	2,317,990	5,822,480		4,517,087
Gross Profit		3,346,173	3,210,184	6,968,478		6,442,038
OPERATING EXPENSES						
Selling, general and administrative		5,530,022	4,085,945	11,021,235		9,078,774
Research and development		1,303,731	386,878	2,452,086		723,719
Depreciation and amortization		125,882	118,415	235,134		233,888
Total Operating Expenses	_	6,959,635	4,591,238	13,708,455		10,036,381
Net Operating Loss		(3,613,462)	(1,381,054)	(6,739,977)		(3,594,343)
Non-Operating Income/(Expense)						
(Loss)/Gain on currency exchange		(21,705)	1,239	(28,840)		(14,478)
Gain on disposal of fixed assets, net		_	_	_		736
Interest income, net		3,566	9,950	2,103		19,721
TOTAL OTHER INCOME/(EXPENSE)	_	(18,139)	11,189	(26,737)		5,979
LOSS BEFORE INCOME TAXES		(3,631,601)	(1,369,865)	(6,766,714)		(3,588,364)

Income Tax Benefit	710,260	245,316	1,307,859	1,187,677
NET LOSS	\$ (2,921,341)	\$ (1,124,549)	\$ (5,458,855) \$	(2,400,687)
NET LOSS PER SHARE				
Basic	\$ (0.07)	\$ (0.03)	\$ (0.12) \$	
Diluted	\$ (0.07)	\$ (0.03)	\$ (0.12) \$	(0.05)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING				
Basic	44,921,870	44,489,853	44,795,625	44,226,936
Diluted	44,921,870	44,489,853	44,795,625	44,226,936
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KORU MEDICAL SYSTEMS, INC. STATEMENTS OF CASH FLOWS (UNAUDITED)

		Six Mont	the hs Er	ıded
	_	2022		2021
CASH FLOWS FROM OPERATING ACTIVITIES				
Net Loss	\$	(5,458,855)	\$	(2,400,687)
Adjustments to reconcile net loss to net cash used in operating activities:		(-,,,		(),,
Stock-based compensation expense		1,579,151		1,339,356
Depreciation and amortization		235,134		233,888
Deferred income taxes		(1,308,069)		(1,201,956)
Gain on disposal of fixed assets				(736)
Changes in operating assets and liabilities:				
Increase in accounts receivable		(454,452)		(4,446)
Increase in inventory		(665,176)		(732,978)
Decrease in prepaid expenses and other assets		334,193		346,227
Increase in other Liabilities		150,501		_
Increase in accounts payable		1,162,329		380,733
Increase in accrued payroll and related taxes		535,438		103,196
Decrease in accrued expenses		(735,508)		(838,747)
NET CASH USED IN OPERATING ACTIVITIES	_	(4,625,314)		(2,776,150)
CASH FLOWS FROM INVESTING ACTIVITIES				
Purchases of property and equipment		(1,915,289)		(152,223)
Proceeds from disposal of property and equipment				9,065
Purchases of intangible assets		(13,540)		(23,978)
NET CASH USED IN INVESTING ACTIVITIES		(1,928,829)		(167,136)
CASH FLOWS FROM FINANCING ACTIVITIES				
Payments on indebtedness		(508,583)		_
Proceeds from issuance of equity		_		1,230,000
Common stock issuance as settlement for litigation		_		938,094
Payments on finance lease liability		(6,611)		(1,616)
NET CASH (USED IN) PROVIDED BY FINANCING ACTIVITIES		(515,194)		2,166,478
NET DECREASE IN CASH AND CASH EQUIVALENTS		(7,069,337)		(776,808)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD		25,334,889		27,315,286
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$	18,265,552	\$	26,538,478
Supplemental Information				
Cash paid during the periods for:				
Interest	\$	6,204	\$	47
Income Taxes	\$		\$	850
Schedule of Non-Cash Operating, Investing and Financing Activities:				
Issuance of common stock as compensation	\$	258,005	\$	153,446
Issuance of common stock as settlement for litigation	\$		\$	938,094
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SUPPLEMENTAL INFORMATION (UNAUDITED)

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

	 Three I Ended			Six M Ended		
	2022	2021	2022			2021
Net Sales	 					<u>.</u>
Domestic	\$ 4,996,791	\$ 4,597,797	\$	9,990,327	\$	9,010,214
International	951,485	859,694		1,846,427		1,838,600
Novel Therapies	598,352	70,683		954,204		110,311
Total	\$ 6,546,628	\$ 5,528,174	\$	12,790,958	\$	10,959,125

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KORU MEDICAL SYSTEMS, INC. SUPPLEMENTAL INFORMATION (UNAUDITED)

A reconciliation of our non-GAAP measures is below:

Reconciliation of GAAP Net (Loss)		Three Mor June			Six Months Ended June 30,			
to Non-GAAP Adjusted EBITDA:	2022		2021		2022			2021
GAAP Net Loss	\$	(2,921,341)	\$	(1,124,549)	\$	(5,458,855)	\$	(2,400,687)
Tax (Benefit)/Expense		(710,260)		(245,316)		(1,307,859)		(1,187,677)
Depreciation and Amortization		125,882		118,415		235,134		233,888
Interest (Income)/Expense, Net		(3,566)		(9,950)		(2,103)		(19,721)
Reorganization Charges		270,433		224,605		565,433		1,193,880
Discontinued Product Expense		_		_		_		_
Litigation Expenses		_		_		_		_
Manufacturing Initiative Expenses		50,344		149,718		88,349		201,441
Stock-based Compensation Expense		821,513		605,172		1,659,070		1,339,356
Non-GAAP Adjusted EBITDA	\$	(2,366,995)	\$	(281,905)	\$	(4,220,831)	\$	(639,520)

	Three Months Ended				Six Months Ended					
Reconciliation of Reported Diluted EPS		June	30,		June 30,					
to Non-GAAP Adjusted Diluted EPS:		2022		2021		2022		2021		
Reported Diluted Earnings Per Share	\$	(0.07)	\$	(0.03)	\$	(0.12)	\$	(0.05)		
Reorganization Charges		0.01		0.01		0.01		0.03		
Discontinued Product Expense		_		_		_		_		
Litigation Expenses		_		_		_		_		
Manufacturing Initiative Expenses		_		_		_		_		
Stock-based Compensation Expense		_		_		_		0.01		
Tax (Expense) Adjustment		_		_		_		(0.01)		
Non-GAAP Adjusted Diluted Earnings Per Share	\$	(0.06)	\$	(0.02)	\$	(0.11)	\$	(0.02)		

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 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 restricted 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.