Treace Medical Concepts Reports Third Quarter 2022 Financial Results

November 8, 2022

PONTE VEDRA, Fla., Nov. 08, 2022 (GLOBE NEWSWIRE) -- Treace Medical Concepts, Inc. (“Treace” or the “Company”) (NasdaqGS: TMCI), a medical technology company driving a fundamental shift in the surgical treatment of hallux valgus (commonly known as bunions), today reported financial results for the third quarter ended September 30, 2022.

Recent Highlights:

- Revenue of $33.1 million in the third quarter of 2022, a 53% increase over the same period last year. Blended average revenue per Lapiplasty® procedure kit sold was $5,794, a 6% increase over the same period last year.
- Gross margin of 80.0% in the third quarter 2022.
- Third quarter revenue contribution from direct sales channel, the industry’s only direct bunion-focused salesforce, increased to 74% of sales compared to 53% during the third quarter 2021.
- Showcased next generation Lapiplasty® Micro-Incision instrumentation and complementary SpeedPlate™ fixation implant platform at the September 2022 American Orthopaedic Foot & Ankle Society Annual Meeting. The SpeedPlate™ System is pending FDA 510(k) clearance and not yet available for sale in the United States.
- Presented new interim ALIGN3D™ Lapiplasty® patient data demonstrating an 81% decrease in pain; 82% and 84% improvement in walking/standing and social interaction scores, respectively, at 24 months (n=107); and a low recurrence rate of 1.4% (2 out of 144 patients) observed post-surgery.
- Announced the appointment of two new independent members to the Board of Directors; Lance A. Berry and Jane E. Kiernan.
- Granted two additional U.S. patents in the third quarter on instrumented bunion correction techniques. Patent portfolio expands to 38 granted U.S. patents and over 45 pending U.S. patent applications as of the end of the third quarter.

“We are pleased with the continued momentum of our business as revenue increased 53% in the third quarter and 51% for the first nine months of 2022. Our strong results benefited from our strategic investments in the industry’s only bunion-focused direct sales channel, targeted R&D initiatives and direct-to-consumer programs which we believe continues to position us for sustained growth as we scale our operations,” said John T. Treace, CEO, Founder and Board Member of Treace.

Third Quarter 2022 Financial Results
Revenue for the third quarter of 2022 was $33.1 million, representing an increase of 53% compared to $21.6 million in the third quarter of 2021. The increase was driven by an increased number of Lapiplasty® procedure kits sold as a result of an expanded surgeon customer base and increased blended average selling prices due to increased adoption of our newer technologies and expanding product line.

Gross profit for the third quarter of 2022 was $26.4 million, representing an increase of 52% compared to a gross profit of $17.4 million in the third quarter of 2021. Gross margin decreased to 80.0% in the third quarter of 2022, compared to 80.4% in the third quarter of 2021. The decrease in gross margin was primarily due to an increase in allocations of payroll and related expenses and an increase in capitalized surgical instrument depreciation, which were partially offset by a decrease in royalty expense in relation to products sold in the quarter and lower inventory and obsolescence provisions.

Total operating expenses were $37.7 million in the third quarter of 2022, including sales and marketing (S&M) expenses of $25.0 million, research and development (R&D) expenses of $3.8 million, and general and administrative (G&A) expenses of $8.9 million. This compared to total operating expenses of $22.8 million, including S&M expenses of $16.0 million, R&D expenses of $2.5 million, and G&A expenses of $4.3 million in the third quarter of 2021. Increased operating expenses in the third quarter of 2022 reflect increased investments in our commercial initiatives as well as other G&A investments supporting our growing business.

Third quarter net loss attributable to common stockholders was ($12.1) million, or ($0.22) per share, compared to ($6.4) million, or ($0.12) per share, for the same period of 2021. Adjusted EBITDA was a loss of ($8.2) million in the third quarter, compared to a loss of ($4.4) million for the same period in 2021. See below for additional information and a reconciliation of non-GAAP financial information.

Cash and cash equivalents were $88.5 million as of September 30, 2022.

Financial Outlook
Treace is raising its full-year 2022 revenue guidance to $135 million to $138 million, which represents approximately 43% to 46% growth over the Company’s 2021 revenue. This compares to the prior revenue guidance of $130 million to $134 million.

Webcast and Conference Call Details
Treace will host a conference call today, November 8, 2022, at 4:30 p.m. ET to discuss its third quarter 2022 financial results. Investors interested in listening to the conference call may do so by registering. Once registered, participants will receive dial-in numbers and a unique pin to join the call and ask questions. The live webcast of the conference call will be available on the Investor Relations section of the Company’s website at https://investors.treace.com/. The webcast will be archived on the website following the completion of the call.

Use of Non-GAAP Financial Measures

To supplement the financial results presented in accordance with GAAP, this earnings release presents Adjusted EBITDA, which the Company defines as net loss before depreciation and amortization expense, share-based compensation expense, interest expense, taxes and debt extinguishment loss. This earnings release also presents net loss attributable to common stockholders excluding the debt extinguishment loss on an aggregate and per share basis ("Adjusted Net Loss"). Non-GAAP financial measures such as Adjusted EBITDA and Adjusted Net Loss are presented in addition to, and not as a substitute for, or superior to, financial measures calculated in accordance with GAAP. Management uses these non-GAAP financial measures to evaluate the Company's operating performance and trends, as well as for making planning decisions. The Company believes that Adjusted EBITDA and Adjusted Net Loss help to identify underlying trends in the Company's business that may otherwise be masked by the effect of the expenses and other items that it excludes in Adjusted EBITDA and Adjusted Net Loss. Accordingly, the Company believes these non-GAAP financial measures provide useful information to investors and others in understanding and evaluating the Company's operating results, enhancing the overall understanding of its past performance and future prospects, and allowing for greater transparency with respect to key financial metrics used by the Company's management in their financial and operational decision-making. The Company also presents these non-GAAP financial measures because it believes investors, analysts and rating agencies consider them to be a useful metrics in measuring the Company's performance against other companies and its ability to meet its debt service obligations.

There are limitations related to the use of non-GAAP financial measures such as Adjusted EBITDA and Adjusted Net Loss because they are not prepared in accordance with GAAP, may exclude significant expenses required by GAAP to be recognized in the Company's financial statements, and may not be comparable to non-GAAP financial measures used by other companies. The Company encourages investors to carefully consider its results under GAAP, as well as its supplemental non-GAAP information and the reconciliation between these presentations, to more fully understand its business. Reconciliations between GAAP and non-GAAP results are presented below.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical fact are forward-looking statements, including, but not limited to the Company's belief that it is well positioned for sustained growth; the Company's expectations regarding positive momentum and market penetration; and the Company's expected revenue and revenue growth rates for full year 2022. Forward-looking statements are based on management's current assumptions and expectations of future events and trends, which affect or may affect the Company's business, strategy, operations or financial performance, and actual results and other events may differ materially from those expressed or implied in such statements due to numerous risks and uncertainties. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. Factors that could cause actual results or other events to differ materially from those contemplated in this press release can be found in the Risk Factors section of Treace's public filings with the Securities and Exchange Commission (SEC), including its Annual Report on Form 10-K for the year ended December 31, 2021, which was filed with the SEC on March 4, 2022. Because forward-looking statements are inherently subject to risks and uncertainties, you should not rely on these forward-looking statements as predictions of future events. These forward-looking statements speak only as of their date and, except to the extent required by law, the Company undertakes no obligation to update these statements, whether as a result of any new information, future developments or otherwise. The Company's results for the quarter ended September 30, 2022 are not necessarily indicative of our operating results for any future periods.

About Treace Medical Concepts

Treace Medical Concepts, Inc. is a medical technology company with the goal of advancing the standard of care for the surgical management of bunion deformities and related midfoot correction. Bunions are complex 3-dimensional deformities that originate from an unstable joint in the middle of the foot and affect approximately 65 million Americans, of which Treace estimates 1.1 million are annual surgical candidates. Treace has pioneered and patented the Lapiplasty® 3D Bunion Correction™ system – a combination of instruments, implants, and surgical methods designed to surgically correct all 3 planes of the bunion deformity and secure the unstable joint, addressing the root cause of the bunion and helping patients get back to their active lifestyles. Treace recently expanded its offering with the Adductoplasty™ Midfoot Correction System, designed for reproducible surgical correction of the midfoot to provide further support to hallux valgus patients. For more information, please visit www.treace.com.

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Treace Medical Concepts, Inc.
Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenue	$ 33,055	$ 21,619	$ 92,069	$ 60,980
Cost of goods sold	6,624	4,248	17,781	11,519
Gross profit	26,431	17,371	74,288	49,461
Operating expenses				
Sales and marketing	25,034	15,984	73,207	42,142

Research and development	3,799	2,537	9,835	6,827
General and administrative	8,916	4,310	22,593	11,405
Total operating expenses	37,749	22,831	105,635	60,374
Loss from operations	(11,318)	(5,460)	(31,347)	(10,913)
Interest and other income, net	375	5	514	12
Interest expense	(1,190)	(963)	(3,087)	(3,032)
Debt extinguishment loss	—	—	(4,483)	—
Other expense, net	(815)	(958)	(7,056)	(3,020)
Net loss and comprehensive loss	(12,133)	(6,418)	(38,403)	(13,933)
Convertible preferred stock cumulative and undeclared dividends	—	—	—	(196)
Net loss attributable to common stockholders	$ (12,133)	$ (6,418)	$ (38,403)	$ (14,129)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.22)	$ (0.12)	$ (0.70)	$ (0.30)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	55,429,211	52,766,150	55,190,587	46,603,487

Treace Medical Concepts, Inc.
Balance Sheets
(in thousands, except share and per share amounts)
(unaudited)

	September 30, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	$ 88,546	$ 105,833
Accounts receivable, net of allowance for doubtful accounts of $423 and $414 as of September 30, 2022 and December 31, 2021, respectively	18,548	18,568
Inventories	16,794	10,561
Prepaid expenses and other current assets	4,014	3,010
Total current assets	127,902	137,972
Property and equipment, net	14,148	2,849
Operating lease right-of-use assets	14,247	—
Other non-current assets	146	—
Total assets	$ 156,443	$ 140,821
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 7,881	$ 4,056
Accrued liabilities	5,189	4,518
Accrued commissions	4,131	5,181
Accrued compensation	5,049	4,455
Operating lease liabilities	330	—
Total current liabilities	22,580	18,210
Derivative liability on term loan	—	173
Long-term debt, net of discount of $1,364 and $635 as of September 30, 2022 and December 31, 2021, respectively	52,636	29,365
Operating lease liabilities, net of current portion	19,026	—
Total liabilities	94,242	47,748
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.001 par value, 5,000,000 shares authorized as of September 30, 2022 and December 31, 2021; 0 shares issued and outstanding as of September 30, 2022 and December 31, 2021	—	—
Common stock, $0.001 par value, 300,000,000 shares authorized; 55,499,242 issued and outstanding as of September 30, 2022; 300,000,000 shares authorized; 54,181,082 issued and outstanding as of December 31, 2021	46	45
Additional paid-in capital	142,463	134,933
Accumulated deficit	(80,308)	(41,905)
Total stockholders' equity	62,201	93,073
Total liabilities and stockholders' equity	$ 156,443	$ 140,821

Treace Medical Concepts, Inc.
Statements of Cash Flows
(in thousands)
(unaudited)

	Nine Months Ended September 30,	
	2022	**2021**
Cash flows from operating activities		
Net loss	$ (38,403)	$ (13,933)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization expense	1,216	409
Recovery for allowance for doubtful accounts	(38)	(56)
Share-based compensation expense	5,641	2,116
Non-cash lease expense	2,010	—
Amortization of debt issuance costs	169	133
(Recovery of) provision for inventory obsolescence	(206)	179
Gain on fair value adjustment to derivative liability	(173)	(72)
Debt extinguishment loss	4,483	—
Other, net	25	—
Net changes in operating assets and liabilities:		
Accounts Receivable	58	2,747
Inventory	(6,027)	(2,710)
Prepaid expenses and other assets	(1,058)	(3,168)
Other non-current assets	(146)	—
Operating lease liabilities	3,112	—
Accounts payable	3,825	177
Accrued liabilities	222	737
Net cash used in operating activities	(25,290)	(13,441)
Cash flows from investing activities		
Purchases of property and equipment	(12,506)	(1,805)
Net cash used in investing activities	(12,506)	(1,805)
Cash flows from financing activities		
Repayment of PPP loan	—	(1,788)
Proceeds from interest bearing term debt	49,651	—
Proceeds from interest bearing revolving debt	3,850	—
Debt issuance costs paid to third parties	(989)	—
Repayment of term loan	(33,893)	—
Proceeds from issuance of common stock upon initial public offering, net of issuance costs and underwriting fees of $10.6 million	—	107,610
Proceeds from exercise of employee stock options	1,890	804
Net cash provided by financing activities	20,509	106,626
Net (decrease) increase in cash and cash equivalents	(17,287)	91,380
Cash and cash equivalents at beginning of period	105,833	18,079
Cash and cash equivalents at end of period	$ 88,546	$ 109,459
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 3,087	$ 2,917
Operating lease right-of-use assets obtained in exchange for new lease liabilities	$ 15,300	$ —
Supplemental disclosure of noncash financing activities:		
Issuance of common stock upon exercise of warrants	$ —	$ 1
Conversion of convertible preferred stock and accrued dividends on convertible preferred stock into common stock	$ —	$ 7,935

Treace Medical Concepts, Inc.
Reconciliation of GAAP Net Loss to Adjusted Net Loss
(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**

Net loss	$ (12,133)	$ (6,418)	$ (38,403)	$ (13,933)
Adjustment:				
Debt extinguishment loss	—	—	4,483	—
Adjusted net loss	$ (12,133)	$ (6,418)	$ (33,920)	$ (13,933)
Per share				
Net loss	(0.22)	(0.12)	(0.70)	(0.30)
Adjustment:				
Debt extinguishment loss	—	—	0.08	—
Adjusted net loss	$ (0.22)	$ (0.12)	$ (0.62)	$ (0.30)
Weighted average common shares outstanding per share attributable to common stockholders, basic and diluted	55,429,211	52,766,150	55,190,587	46,603,487

Treace Medical Concepts, Inc.
Reconciliation of GAAP Net Loss to EBITDA & Adjusted EBITDA
(in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Net loss	$ (12,133)	$ (6,418)	$ (38,403)	$ (13,933)
Adjustments:				
Interest Expense	1,190	963	3,087	3,032
Taxes	—	—	—	—
Depreciation & Amortization	459	189	1,216	409
EBITDA	$ (10,484)	$ (5,266)	$ (34,100)	$ (10,492)
Share-based compensation expense	2,269	839	5,641	2,116
Debt extinguishment loss	—	—	4,483	—
Adjusted EBITDA	$ (8,215)	$ (4,427)	$ (23,976)	$ (8,376)