Treace Medical Concepts Reports Fourth Quarter and Full Year 2021 Financial Results

March 3, 2022

PONTE VEDRA, Fla., March 03, 2022 (GLOBE NEWSWIRE) -- Treace Medical Concepts, Inc. (“Treace” or the “Company”) (NasdaqGS: TMCI), a medical technology company driving a paradigm shift in the surgical treatment of hallux valgus (commonly known as bunions), today reported financial results for the fourth quarter and full year ended December 31, 2021.

Recent Highlights:

- Revenue of $33.4 million in the fourth quarter 2021, a 39% increase over the same period last year and a 55% increase sequentially. Full year 2021 revenue of $94.4 million, a 65% increase over 2020.
- Gross margin of 81.1% in the fourth quarter 2021, an increase of 220 basis points from the same period last year. Full year 2021 gross margin of 81.1%, an increase of 285 basis points over 2020.
- Increased strategic investments in our sales and marketing programs, including expanded direct sales channel and direct-to-consumer (DTC) campaigns, as well as R&D programs for product innovations.
- Fourth quarter revenue contribution from bunion-focused direct sales channel was 58% of sales, an increase from an average of 39% in the fourth quarter 2020.
- New interim data from ALIGN3D™ clinical study presented at the 2022 American College of Foot and Ankle Surgeons (ACFAS) Annual Scientific Conference demonstrating continued positive radiographic and patient-reported outcomes at 12- and 24- months following the Lapiplasty® procedure. Low recurrence rate also maintained, with 0.9% (1 out of 116 patients) and 0.0% (0 out of 54 patients) observed at 12- and 24- months post surgery, respectively.
- Granted 3 additional U.S. patents in the fourth quarter on instrumented bunion correction techniques. Patent portfolio expands to 32 granted US patents and over 30 pending US patent applications as of the end of the year.

“We are pleased with this strong performance driven by our bunion-focused direct sales channel, expanding direct-to-consumer programs, and focused R&D initiatives, paving the way for a 55% sequential increase in revenue during the fourth quarter,” said John T. Treace, CEO, Founder and Board Member of Treace. “With continued confidence in our commercial strategies and investments, complemented by our growing body of clinical evidence, we believe we remain well positioned for strong growth ahead.”

Fourth Quarter 2021 Financial Results
Revenue for the fourth quarter of 2021 was $33.4 million, representing an increase of 38.7% compared to $24.1 million in the fourth quarter of 2020. The increase was driven by an increased number of Lapiplasty® procedure kits sold and an expanded customer base.

Gross profit for the fourth quarter of 2021 was $27.1 million, compared to a gross profit of $19.0 million in the fourth quarter of 2020. Gross margin increased to 81.1% in the fourth quarter of 2021, compared to 78.9% in the fourth quarter of 2020. Gross margin expansion was due to volume increases without a corresponding increase in certain fixed costs as well as a higher blended average selling price.

Total operating expenses were $32.7 million in the fourth quarter of 2021, including sales and marketing (S&M) expenses of $22.3 million, research and development (R&D) expenses of $3.4 million, and general and administrative (G&A) expenses of $7.0 million. This compared to total operating expenses of $15.4 million, including S&M expenses of $11.4 million, R&D expenses of $1.9 million, and G&A expenses of $2.0 million in the fourth quarter of 2020. Expenses in the fourth quarter of 2021 reflect increased investments in sales and marketing as well as other G&A investments supporting our growing business.

Fourth quarter net loss attributable to common stockholders was ($6.6) million, or ($0.12) per share, compared to net income of $2.4 million, or $0.05 per share, for the same period of 2020.

Full Year 2021 Financial Results
Revenue for the year ended December 31, 2021 was $94.4 million, representing an increase of 64.6% compared to $57.4 million in 2020. The increase was driven by an increased number of Lapiplasty® procedure kits sold and an expanded customer base.

Gross profit for the year ended December 31, 2021 was $76.6 million, compared to a gross profit of $44.9 million in 2020. Gross margin increased to 81.1% in 2021, compared to 78.3% in 2020. Gross margin expansion was due to volume increases without a corresponding increase in certain fixed costs as well as a higher blended average selling price.

Total operating expenses for the year ended December 31, 2021 were $93.1 million, including S&M expenses of $64.5 million, R&D expenses of $10.2 million, and G&A expenses of $18.4 million. This compared to total operating expenses of $44.0 million, including S&M expenses of $31.7 million, R&D expenses of $5.8 million, and G&A expenses of $6.5 million in 2020. Expenses in 2021 reflect increased spending on targeted marketing initiatives, additions to our sales organization, higher commissions from increased sales, and increased public company related costs. During 2020, we delayed expenditures for surgeon education events, patient outreach campaigns and other planned sales and marketing expenses in connection with the pandemic.

Net loss attributable to common stockholders for the year ended December 31, 2021 was ($20.7) million, or ($0.43) per share, compared to net loss of ($4.3) million, or ($0.12) per share, in 2020.

Cash and cash equivalents were $105.8 million as of December 31, 2021.

Financial Outlook
Treace expects revenue for the full year 2022 to range from $125 million to $130 million, which represents approximately 32% to 38% growth over the Company's 2021 revenue.

Webcast and Conference Call Details
Treace will host a conference call today, March 3, 2022, at 4:30 p.m. ET to discuss its fourth quarter and full year 2021 financial results. The dial-in numbers are (888) 708-0264 for domestic callers or (720) 405-2122 for international callers, followed by Conference ID: 6356356. 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, stock-based compensation expense and interest income/expense. Adjusted EBITDA is presented in addition to, and not as a substitute for, or superior to, financial measures calculated in accordance with GAAP. Management uses Adjusted EBITDA to evaluate the Company's operating performance and trends, as well as for making planning decisions. The Company believes that Adjusted EBITDA helps 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. Accordingly, the Company believes Adjusted EBITDA provides 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 a key financial metric used by the Company's management in their financial and operational decision-making. The Company also presents Adjusted EBITDA because it believes investors, analysts and rating agencies consider it a useful metric 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 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 strong growth ahead; the Company's expectations regarding market share gains; 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 in the final prospectus filed with the SEC on April 26, 2021 in connection with Treace's initial public offering and its Annual Report on Form 10-K for the year ended December 31, 2021, which is expected to be filed with the SEC on or about 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 and full year ended December 31, 2021 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. Treace has pioneered and patented the Lapiplasty® 3D Bunion Correction™ system – a combination of instruments, implants, and surgical methods designed to 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 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.
Condensed Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2021	2020	2021	2020
Revenue	$ 33,439	$ 24,104	$ 94,419	$ 57,365
Cost of goods sold	6,307	5,085	17,826	12,470
Gross profit	27,132	19,019	76,593	44,895
Operating expenses				
Sales and marketing	22,325	11,424	64,467	31,654
Research and development	3,377	1,922	10,204	5,847
General and administrative	7,027	2,039	18,432	6,539
Total operating expenses	32,729	15,385	93,103	44,040
Income (loss) from operations	(5,597)	3,634	(16,510)	855
Interest and other income (expense), net	6	1	18	(1,746)
Interest expense	(1,028)	(1,070)	(4,060)	(2,777)
Other expense, net	(1,022)	(1,069)	(4,042)	(4,523)
Net income (loss) and comprehensive loss	(6,619)	2,565	(20,552)	(3,668)
Convertible preferred stock cumulative and undeclared dividends	—	(161)	(196)	(640)
Net income (loss) attributable to common stockholders	$ (6,619)	$ 2,404	$ (20,748)	$ (4,308)
Net income (loss) per share attributable to common stockholders				
Basic	$ (0.12)	$ 0.06	$ (0.43)	$ (0.12)
Diluted	$ (0.12)	$ 0.05	$ (0.43)	$ (0.12)
Weighted-average shares used in computing net loss per share attributable to common stockholders				
Basic	53,618,371	37,085,397	48,415,679	37,068,965
Diluted	53,618,371	49,596,028	48,415,679	37,068,965

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

	December 31,	
	2021	2020
Assets		
Current assets		
Cash and cash equivalents	$ 105,833	$ 18,079
Accounts receivable, net of allowance for doubtful accounts of $414 and $446 as of December 31, 2021 and 2020, respectively	18,568	14,486
Inventories	10,561	7,820
Prepaid expenses and other current assets	3,010	593
Total current assets	137,972	40,978
Property and equipment, net	2,849	829
Total assets	$ 140,821	$ 41,807
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 4,056	$ 2,265
Accrued liabilities	4,518	1,848
Accrued commissions	5,181	3,513
Accrued compensation	4,455	2,183
Short-term debt	-	1,788
Total current liabilities	18,210	11,597
Derivative liability on term loan	173	245
Long-term debt, net of discount of $635 and $811 as of December 31, 2021 and 2020, respectively	29,365	29,189
Total liabilities	47,748	41,031
Commitments and contingencies (Note 7)		
Stockholders' equity		

Series A convertible preferred stock, $0.001 par value, 0 shares authorized and 0 shares issued and outstanding as of December 31, 2021; 6,687,500 shares authorized and 6,687,475 shares issued and outstanding as of December 31, 2020, respectively; liquidation value of $0 and $8,000 as of December 31, 2021 and 2020, respectively	—	7,935
Preferred stock, $0.001 par value, 5,000,000 shares authorized; 0 shares issued and outstanding as of December 31, 2021; 0 shares authorized, issued and outstanding as of December 31, 2020	—	—
Common stock, $0.001 par value, 300,000,000 shares authorized; 54,181,082 issued and outstanding as of December 31, 2021; 66,875,000 shares authorized, 37,366,865 issued and outstanding as of December 31, 2020	45	28
Common stock Class B, $0.001 par value, 0 shares authorized, issued and outstanding as of December 31, 2021; 1,000,000 shares authorized and 0 shares issued and outstanding as of December 31, 2020	—	—
Additional paid-in capital	134,933	14,166
Accumulated deficit	(41,905)	(21,353)
Total stockholders' equity	93,073	776
Total liabilities and stockholders' equity	$ 140,821	$ 41,807

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

Year Ended December 31,	2021	2020
Cash flows from operating activities		
Net loss	$ (20,552)	$ (3,668)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization expense	685	1,210
(Recovery) Provision for allowance for doubtful accounts	(144)	216
Share-based compensation expense	3,409	919
Amortization of debt issuance costs	176	220
Impairment of capitalized surgical instruments	—	144
Gain on fair value adjustment to derivative liability	(72)	—
Provision for inventory obsolescence	347	1,144
Loss on early settlement of debt	—	639
Net changes in operating assets and liabilities:		
Accounts Receivable	(4,226)	(4,290)
Inventory	(3,088)	(3,402)
Prepaid expenses and other assets	(2,417)	(103)
Accounts payable	1,791	1,334
Accrued liabilities	6,610	1,143
Net cash used in operating activities	(17,193)	(4,494)
Cash flows from investing activities		
Purchases of property and equipment	(2,705)	(1,069)
Net cash used in investing activities	(2,705)	(1,069)
Cash flows from financing activities		
Proceeds from interest bearing debt	—	29,530
Payments on interest bearing debt	—	(20,000)
Proceeds from SBA Loan	—	1,788
Repayments on SBA Loan	(1,788)	—
Proceeds from issuance of common stock upon initial public offering, net of issuance costs and underwriting fees of $10.6 million	107,610	—
Debt issuance costs	—	(179)
Proceeds from exercise of employee stock options	1,830	364
Net cash provided by financing activities	107,652	11,503
Net increase in cash and cash equivalents	87,754	5,940
Cash and cash equivalents at beginning of period	18,079	12,139
Cash and cash equivalents at end of period	$ 105,833	$ 18,079
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 3,900	$ 1,146
NONCASH FINANCING ACTIVITIES:		
Issuance of warrants for Class A common stock in connection with the Company's Credit Facility	$ —	$ —

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	$ —
Initial fair value of derivative liability	$ —	$ 245

Treace Medical Concepts, Inc.
Reconciliation of GAAP Net Loss to Adjusted EBITDA

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2021	**2020**	**2021**	**2020**
Net income (loss)	$ (6,619)	$ 2,565	$ (20,552)	$ (3,668)
Adjustments:				
Interest	1,022	1,068	4,042	4,523
Taxes	-	-	-	-
Depreciation & Amortization	276	208	685	1,210
Non-cash compensation expense	1,293	337	3,409	919
Adjusted EBITDA	$ (4,028)	$ 4,178	$ (12,416)	$ 2,984