



Establishment Labs Reports Fourth Quarter and Full Year 2020 Financial Results; Record Fourth Quarter Revenue of \$27.0 Million

March 10, 2021

SANTA BARBARA, Calif.--(BUSINESS WIRE)--Mar. 10, 2021-- Establishment Labs Holdings Inc. (NASDAQ: ESTA), a medical technology company focused on women's health, initially in the breast aesthetics and reconstruction market, today announced its financial results for the fourth quarter and full year ended December 31, 2020 and provided initial 2021 guidance.

Fourth Quarter Highlights and Outlook

- Fourth quarter worldwide sales of \$27.0 million, an increase of 11% year-over-year and a new quarterly record; consistent with preannouncement on January 11, 2021
- 2021 guidance of \$110 million to \$112 million, an increase of 30% to 32% over 2020
- Fourth quarter operating expenses of \$22.7 million, an increase of 9% compared to the fourth quarter of 2019
- Strong cash balance of \$84.5 million as of December 31, 2020
- Updated 10-year Motiva post-market surveillance data on October 21, 2020 showing less than 1% complication rates in the key safety endpoints of capsular contracture and implant rupture in nearly 1.3 million implants placed worldwide outside of the United States
- Received CE mark for next generation Motiva Ergonomix2 silicone breast implant platform in December 2020; CE mark also includes the Motiva Ergonomix2 Diamond breast implant, a key component of the Motiva Mia system for minimally invasive breast enhancement
- Hosted virtual meeting on February 9, 2021 highlighting results from early patient case series with Motiva Mia, including procedure times as low as 13 minutes, fast recovery, low pain, and high patient satisfaction; also provided Establishment Labs' initial market size estimate for Motiva Mia of 1.9 million procedures per year, translating to a total addressable market of \$4-5 billion

"We delivered record fourth quarter revenue of \$27.0 million, which was up 11% from the fourth quarter of 2019 and 18% from the third quarter of 2020," said Juan José Chacón-Quirós, Chief Executive Officer. "With a strong recovery from the pandemic well underway and with continued momentum in our business in the first quarter, we are issuing full year 2021 revenue guidance of \$110 million to \$112 million, which is an annual growth rate of 30% to 32%."

"Our singular focus on women's health and the superior outcomes with our implants in the more than 80 countries in which we sell is resonating—and we continue to grow our total global market share." Mr. Chacón-Quirós continued. "As we look to 2021 and beyond, our regulatory and commercial timelines to begin selling Motiva implants in the U.S. and Chinese markets are progressing as planned. We have also made significant progress in advancing our portfolio of differentiated technologies and offerings, including Ergonomix2, Motiva Mia, and Flora, our novel tissue expander. We believe we are on track not only to become the leader in breast aesthetics and reconstruction, but to expand these markets as we offer safe, differentiated and accessible solutions to women."

Fourth Quarter 2020 Financial Results

Total revenue for the quarter ended December 31, 2020 was \$27.0 million compared to \$24.2 million for the same period in 2019. Direct sales comprised approximately 49% of total sales while distributor sales made up the balance.

Gross profit for the fourth quarter was \$14.6 million, or 54.3% of revenue, compared to \$16.4 million, or 67.5% of revenue, for the same period in 2019. The year over year decrease was due in part to timing of certain one-time expenses. Average selling prices in the fourth quarter were consistent with the year ago period.

Total operating expenses for the fourth quarter were \$22.7 million, an increase of \$1.9 million compared to \$20.8 million in the fourth quarter of 2019.

SG&A expenses for the fourth quarter increased \$1.1 million to \$18.2 million compared to \$17.1 million in the fourth quarter of 2019. The majority of this increase resulted from insurance costs and investment in digital transformation systems.

R&D expenses increased \$0.9 million to \$4.5 million in the fourth quarter compared to \$3.6 million for the same quarter a year ago. This increase was due to the timing of clinical trial expenses and increased investment in several development projects.

Net loss from operations for the fourth quarter was \$8.0 million compared to a net loss of \$4.4 million in the year ago period.

The Company's cash balance at December 31, 2020 was \$84.5 million. Cash increased \$3.1 million over the third quarter of 2020, primarily the result of strong working capital management.

Conference Call and Webcast Information

Establishment Labs will host a conference call and webcast today at 8:30 a.m. Eastern Time to discuss its financial results. The conference call can be accessed by dialing (877) 376-9925 (U.S. and Canada) or (629) 228-0732 (international) and using conference ID number 5664669. In addition, the live and archived webcast will be available on the Investor Relations section of the Company's website at www.establishmentlabs.com.

About Establishment Labs

Establishment Labs Holdings Inc. (NASDAQ: ESTA) is a global medical technology company focused on women's health, initially in the breast aesthetics and reconstruction market, by designing, developing, manufacturing and marketing an innovative portfolio of silicone gel-filled breast implants, branded as Motiva Implants®, the centerpiece of the Motivamagine® platform. Motiva Implants® are produced at our two manufacturing sites that are compliant with ISO13485:2016, FDA 21 CFR 820 under the MDSAP program, and are currently commercially available in more than 80 countries through exclusive distributors or the Company's direct salesforce. In March 2018, Establishment Labs received approval for an investigational device exemption (IDE) from the FDA and initiated the Motiva Implant® clinical trial in the United States in April 2018. In addition to Motiva Implants®, Establishment Labs' product and technologies portfolio includes the Divina® 3D Simulation System and other products and services. Please visit our website for additional information at www.establishmentlabs.com.

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 (the "Exchange Act"). You can find many (but not all) of these statements by looking for words such as "approximates," "believes," "expects," "anticipates," "estimates," "intends," "plans," "would," "may" or other similar expressions in this press release. Any statements that refer to projections of our future financial or operating performance, anticipated trends in our business, our goals, strategies, focus and plans, and other characterizations of future events or circumstances, including statements expressing general optimism about future operating results, related to the Company's performance, including fourth quarter and fiscal year 2020 revenue, Motiva Mia, Motiva Flora, and Motiva U.S. pivotal clinical trial and China regulatory approval, are forward-looking statements. We claim the protection of the safe harbor contained in the Private Securities Litigation Reform Act of 1995. We caution investors that any forward-looking statements presented in this report, or that we may make orally or in writing from time to time, are expressions of our beliefs and expectations based on currently available information at the time such statements are made. Such statements are based on assumptions, and the actual outcome will be affected by known and unknown risks, trends, uncertainties and factors that are beyond our control. Although we believe that our assumptions are reasonable, we cannot guarantee future performance, and some will inevitably prove to be incorrect. As a result, our actual future results may differ from our expectations, and those differences may be material. Factors that could cause or contribute to these differences include, among others, those risks and uncertainties discussed in the Company's annual report on Form 10-K filed on March 16, 2020, quarterly reports on Form 10-Q, and other filings made by the Company with the Securities and Exchange Commission. The risks included in those documents are not exhaustive, and additional factors could adversely affect our business and financial performance. We operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time, and it is not possible for us to predict all such risk factors, nor can we assess the impact of all such risk factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. We are not undertaking any obligation to update any forward-looking statements. Accordingly, investors should use caution in relying on past forward-looking statements, which are based on known results and trends at the time they are made, to anticipate future results or trends.

ESTABLISHMENT LABS HOLDINGS INC.

Consolidated Statements of Operations

(In thousands, except share and per share data)

| | Year Ended December 31, | |
|---------------------|-------------------------|-----------|
| | 2020 | 2019 |
| Revenue | \$ 84,676 | \$ 89,565 |
| Cost of revenue | 32,174 | 34,704 |
| Gross profit | 52,502 | 54,861 |
| Operating expenses: | | |

| | | |
|---|--------------|--------------|
| Sales, general and administrative | 66,625 | 70,811 |
| Research and development | 13,793 | 14,991 |
| Total operating expenses | 80,418 | 85,802 |
| Loss from operations | (27,916) | (30,941) |
| Interest income | 15 | 4 |
| Interest expense | (9,373) | (8,696) |
| Change in fair value of derivative instruments | 1,632 | 3,052 |
| Change in fair value of contingent consideration | 304 | 276 |
| Other income (expense), net | (2,679) | (1,205) |
| Loss before income taxes | (38,017) | (37,510) |
| Provision for income taxes | (104) | (640) |
| Net loss | \$ (38,121) | \$ (38,150) |
| Basic and diluted loss per share | \$ (1.63) | \$ (1.86) |
| Weighted average outstanding shares used for basic and diluted net loss per share | 23,316,102 | 20,541,528 |

ESTABLISHMENT LABS HOLDINGS INC.

Consolidated Balance Sheets

(In thousands)

| | December 31, | |
|--|---------------------|-------------|
| | 2020 | 2019 |
| Assets | | |
| Current assets: | | |
| Cash | \$ 84,523 | \$ 37,655 |
| Accounts receivable, net of allowance for doubtful accounts of \$1,143 and \$1,026 | 19,127 | 22,767 |
| Inventory, net | 23,210 | 28,660 |
| Prepaid expenses and other current assets | 5,439 | 6,757 |

| | | |
|---|------------|------------|
| Total current assets | 132,299 | 95,839 |
| Long-term assets: | | |
| Property and equipment, net of accumulated depreciation | 16,202 | 16,418 |
| Goodwill | 465 | 465 |
| Intangible assets, net of accumulated amortization | 4,148 | 3,441 |
| Right-of-use operating lease assets, net | 2,610 | — |
| Other non-current assets | 664 | 368 |
| Total assets | \$ 156,388 | \$ 116,531 |
| Liabilities and shareholders' equity | | |
| Current liabilities: | | |
| Accounts payable | \$ 9,722 | \$ 10,366 |
| Accrued liabilities | 14,532 | 10,677 |
| Other liabilities, short-term | 1,646 | 2,199 |
| Total current liabilities | 25,900 | 23,242 |
| Long-term liabilities: | | |
| Note payable, Madryn, net of debt discount and issuance costs | 49,832 | 48,142 |
| Madryn put option | 1,440 | 3,072 |
| Operating lease liabilities, non-current | 1,923 | — |
| Other liabilities, long-term | 2,332 | 2,461 |
| Total liabilities | 81,427 | 76,917 |
| Shareholders' equity: | | |
| Total shareholders' equity | 74,961 | 39,614 |
| Total liabilities and shareholders' equity | \$ 156,388 | \$ 116,531 |

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