
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

March 10, 2021

Date of Report (date of earliest event reported)

**Establishment Labs Holdings Inc.
(Exact name of registrant as specified in its charter)**

**British Virgin Islands
(State or other jurisdiction of
incorporation or organization)**

**001-38593
(Commission File No.)**

**Not applicable
(I.R.S. Employer
Identification Number)**

**Buiding B15 and 25
Coyol Free Zone
Alajuela
Costa Rica**

(Address of principal executive offices) (Zip Code)

+506 2434 2400

(Registrant's telephone number, including area code)

N/A

(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:

- 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))
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Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol	Name of each exchange on which registered
Common Shares, No Par Value	ESTA	The NASDAQ Capital Market

Indicate by check mark whether the registrant is an emerging growth company 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 10, 2021, Establishment Labs Holdings Inc. (the “Company”) issued a press release announcing the Company’s financial results for the three and twelve months ended December 31, 2020 and recent corporate highlights. A copy of the press release is furnished herewith as Exhibit 99.1.*

* The information in Item 2.02 of this Form 8-K shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Establishment Labs Holdings Inc. dated March 10, 2021.

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.

ESTABLISHMENT LABS HOLDINGS INC.

Dated: March 10, 2021

By: /s/ Renee M. Gaeta

Name: Renee M. Gaeta

Title: Chief Financial Officer

PRESS RELEASE

Investor/Media Contact:
Raj Denhoy
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Establishment Labs Reports Fourth Quarter and Full Year 2020 Financial Results; Record Fourth Quarter Revenue of \$27.0 Million

SANTA BARBARA, Calif., March 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 MotivaImagine® 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