
**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**

May 5, 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))

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 May 5, 2021, Establishment Labs Holdings Inc. (the “Company”) issued a press release announcing the Company’s financial results for the three months ended March 31, 2021 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 May 5, 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: May 5, 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 Record First Quarter 2021 Financial Results and Raises Full Year Guidance

SANTA BARBARA, Calif., May 5, 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 first quarter ended March 31, 2021 and provided updated 2021 guidance.

First Quarter Highlights and Outlook

- First quarter worldwide sales of \$30.3 million, an increase of 24% year-over-year and a new quarterly record.
- 2021 guidance increased to a new range of \$118 million to \$122 million, an increase of 39% to 44% over 2020; previous 2021 guidance range was \$110 million to \$112 million.
- First quarter operating expenses of \$22.2 million, a decrease of 4% compared to the first quarter of 2020.
- Strong cash balance of \$78.0 million as of March 31, 2021.
- Completed enrollment of one hundred patient Motiva Mia IRB approved study; filed Motiva Mia tools for CE mark.
- Commercial launch of Motiva Flora tissue expander in Europe on track.
- Timelines for US and China market entry remain unchanged.

"We delivered record first quarter revenue of \$30.3 million, which was up 24% from the first quarter of 2020 and 13% sequentially from the fourth quarter of 2020," said Juan José Chacón-Quirós, Chief Executive Officer. "With our strong first quarter results and continued momentum, we are raising full year 2021 revenue guidance to a new range of \$118 million to \$122 million, which is an annual growth rate of 39% to 44%."

"Our singular focus on women's health and the superior clinical and aesthetic outcomes with Motiva are resonating," Mr. Chacón-Quirós continued. "We are preparing for the commercial launch of our Motiva Flora tissue expander in Europe this summer, and our regulatory and commercial timelines to begin selling Motiva implants in the U.S. and Chinese markets are progressing as planned. In addition, our initial excitement around Motiva Mia is proving to be justified. We recently completed enrollment of our one hundred patient IRB study in Costa Rica, and feedback from surgeons and women who participated in the case series has been very positive. 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."

First Quarter 2021 Financial Results

Total revenue for the quarter ended March 31, 2021 was \$30.3 million compared to \$24.5 million for the same period in 2020. Direct sales comprised approximately 42% of total sales, while distributor sales made up the balance.

Gross profit for the first quarter was \$20.1 million, or 66.2% of revenue, compared to \$15.5 million, or 63.2% of revenue, for the same period in 2020. The year over year increase was due to higher revenue in the quarter. Average selling prices in the first quarter were also up slightly from the same period a year ago.

Total operating expenses for the first quarter were \$22.2 million, a decrease of \$1.0 million compared to \$23.2 million in the first quarter of 2020.

SG&A expenses for the first quarter decreased \$0.8 million to \$18.1 million compared to \$19.0 million in the first quarter of 2020. The majority of the decrease resulted from consulting and personnel related costs.

R&D expenses decreased \$0.2 million to \$4.0 million in the first quarter compared to \$4.2 million for the same quarter a year ago. This decrease was due to the timing of clinical trial and other planned expenses.

Net loss from operations for the first quarter was \$2.1 million compared to a net loss of \$7.7 million in the year ago period.

The Company's cash balance on March 31, 2021 was \$78.0 million. Cash decreased \$6.6 million from December 31, 2020, primarily as the result of the operating loss in the quarter and changes in working capital.

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) 407-8037 (U.S. and Canada) or (201) 689-8037 (international) and using conference ID number 13718169. 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, and includes statements related to Motiva Flora launch, U.S. and China regulatory timelines, and our ability to commercialize the Motiva Mia® system for minimally invasive augmentation. 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 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 15, 2021, 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)
(Unaudited)

	Three Months Ended March 31,	
	2021	2020
Revenue	\$ 30,336	\$ 24,481
Cost of revenue	10,246	9,003
Gross profit	20,090	15,478
Operating expenses:		
Sales, general and administrative	18,138	18,984
Research and development	4,048	4,199
Total operating expenses	22,186	23,183
Loss from operations	(2,096)	(7,705)
Interest income	4	8
Interest expense	(2,195)	(2,146)
Change in fair value of derivative instruments	230	(1,929)
Change in fair value of contingent consideration	—	440
Other expense, net	(2,726)	(6,190)
Loss before income taxes	(6,783)	(17,522)
Provision for income taxes	(165)	(231)
Net loss	\$ (6,948)	\$ (17,753)
Basic and diluted net loss per share	\$ (0.29)	\$ (0.79)
Weighted average outstanding shares used for basic and diluted net loss per share	23,827,137	22,456,365

ESTABLISHMENT LABS HOLDINGS INC.
Consolidated Balance Sheets
(In thousands)

	March 31, 2021 (Unaudited)	December 31, 2020
Assets		
Current assets:		
Cash	\$ 77,950	\$ 84,523
Accounts receivable, net of allowance for doubtful accounts of \$1,121 and \$1,143	23,777	19,127
Inventory, net	22,377	23,210
Prepaid expenses and other current assets	4,194	5,439
Total current assets	128,298	132,299
Long-term assets:		
Property and equipment, net of accumulated depreciation	16,321	16,202
Goodwill	465	465
Intangible assets, net of accumulated amortization	4,126	4,148
Right-of-use operating lease assets, net	2,511	2,610
Other non-current assets	628	664
Total assets	\$ 152,349	\$ 156,388
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	\$ 8,994	\$ 9,722
Accrued liabilities	14,408	14,532
Other liabilities, short-term	1,431	1,646
Total current liabilities	24,833	25,900
Long-term liabilities:		
Note payable, Madryn, net of debt discount and issuance costs	50,305	49,832
Madryn put option	1,210	1,440
Operating lease liabilities, non-current	1,630	1,923
Other liabilities, long-term	1,820	2,332
Total liabilities	79,798	81,427
Shareholders' equity:		
Total shareholders' equity	72,551	74,961
Total liabilities and shareholders' equity	\$ 152,349	\$ 156,388