
**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**

November 9, 2020

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 November 9, 2020, Establishment Labs Holdings Inc. (the “Company”) issued a press release announcing the Company’s financial results for the three and nine months ended September 30, 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 November 9, 2020.

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: November 9, 2020

By: /s/ Renee M. Gaeta

Name: Renee M. Gaeta

Title: Chief Financial Officer

Establishment Labs Reports Third Quarter 2020 Financial Results

SANTA BARBARA, Calif., November 9, 2020 -- 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 third quarter ended September 30, 2020.

Third Quarter Highlights and Outlook

- Worldwide sales of \$22.8 million, in line with preannounced range
- Full year 2020 revenue expected to be \$80 to \$82 million
- Reduced operating expenses by 23% compared to the third quarter of 2019
- Strong cash balance of \$81.4 million at September 30
- Encouraging feedback from early patient experience with Motiva Flora tissue expander
- CE mark for Motiva Ergonomix2 expected in fourth quarter
- Motiva Mia patient series in Thailand IRB approved; additional series in Latin America planned to begin by year-end

As we guided to in our October pre-announcement, total revenue in the third quarter was \$22.8 million, which is comparable to the \$22.9 million reported in the third quarter of 2019, and more than double the sales reported for the second quarter this year," said Juan José Chacón-Quirós, Chief Executive Officer. "With a strong recovery from the pandemic well underway, we are comfortable issuing full year 2020 revenue guidance of \$80 million to \$82 million.

"In addition to strong top line sales this quarter, our focus on lowering expenses and driving efficiencies led to a continued decrease in our operating cash burn," Mr. Chacón-Quirós continued. "As we look to 2021, we have truly differentiated technologies coming that will expand our comprehensive portfolio. We expect continued market share gains, both from expanding our presence in breast reconstruction, and developing new product categories like minimally invasive augmentation. These will help support our growth next year and for many years to come while we continue to plan our entry into the U.S. and China."

Third Quarter 2020 Financial Results

Total revenue for the quarter ended September 30, 2020 was \$22.8 million compared to \$22.9 million for the same period in 2019. Direct sales comprised approximately 40% of total sales while distributor sales made up the balance.

Gross profit for the third quarter was \$15.1 million, or 66.6% of revenue, compared to \$14.2 million, or 62.3% of revenue, for the same period in 2019. The year over year increase was due to the benefit of geographic mix, greater operating efficiencies, and enhanced manufacturing planning capabilities.

Total operating expenses for the third quarter were \$17.7 million, a decrease of \$5.3 million or 22.9%, compared to \$23.0 million in the third quarter of 2019.

SG&A expenses for the third quarter declined \$4.2 million, or 21.9%, to \$15.0 million compared to \$19.2 million in the third quarter of 2019. The majority of this decrease resulted from the Company's commitment to preserve cash by controlling expenses, including lower consulting fees, lower sales and marketing expenses, and reductions in other discretionary expense categories.

R&D expenses decreased \$1.1 million to \$2.7 million in the third quarter compared to \$3.8 million for the same quarter a year ago. Most of the reduction was due to the timing of clinical trial expenses and the reprioritization of certain projects. Strengthening its product portfolio to drive future growth remains a top priority, and the Company will continue to invest in research and development with discipline and focus.

Net loss from operations for the third quarter was \$2.6 million compared to a net loss of \$8.8 million in the year ago period.

The Company's cash balance at September 30, 2020 was \$81.4 million. Cash used in operations was \$3.0 million in the third quarter compared to \$6.1 million for the second quarter of 2020, and \$10.9 million for the third quarter of 2019.

Other Developments

The Company is continuing to collect early patient experience with its Motiva Flora® tissue expander in advance of a broad commercial launch in Europe early next year. Early feedback has been very encouraging, with surgeons commenting on its ease of use, and patients reporting overall satisfaction and comfort. The Company believes the market will be receptive to the advancements offered by Flora including a proprietary integrated RFID port and its SmoothSilk® bioengineered surface. Although its Motiva implants are already used in breast reconstruction procedures in Europe, the ability to pair them with one of the most advanced tissue expanders available means Establishment Labs will be able to fully access this important market segment.

The Company continues to expect receipt of a CE mark in Europe for its Motiva Ergonomix2® platform in the fourth quarter of 2020. Ergonomix2 builds upon its successful Ergonomix implant, which has become the Company's best-selling and most premium offering in many markets including Europe and Asia Pacific. The features of this innovative new product, including enhanced mechanical properties, advanced chemistry and improved ergonomics, should result in even greater patient satisfaction.

The Company's Motiva Mia® minimally invasive breast augmentation program continues to make good progress and is being expanded to include an IRB approved patient series in Thailand. Commencement of an additional patient series in Latin America is planned for the end of the year. Establishment Labs is excited by the opportunity to expand the addressable market for breast aesthetics by creating a new product category with its unique, proprietary technology. The Company continues to believe there are a large number of women who would be interested in a less invasive breast procedure, which if successful, would contribute meaningfully to its growth and further differentiate it in the market.

Submission timelines to gain regulatory clearance and begin selling Motiva Implants® in the U.S. and Chinese markets remain on track. These two geographies would significantly expand the addressable market for the company's Motiva® product portfolio.

Outlook

Mr. Chacón-Quirós concluded, "I would like to express my gratitude to our plastic surgeons and business partners for their ongoing commitment to Establishment Labs. I also want to acknowledge and thank the employees of Establishment Labs for their tremendous effort and resilience, which has enabled us to successfully navigate a challenging year while meeting our operating and financial commitments. Establishment Labs has a very bright future, and we are excited about our ability to grow and create value for our shareholders."

Conference Call and Webcast Information

Establishment Labs will host a conference call and webcast today at 5:00 p.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 9187774. 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)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenue	\$ 22,758	\$ 22,854	\$ 57,713	\$ 65,316
Cost of revenue	7,612	8,616	19,855	26,814
Gross profit	15,146	14,238	37,858	38,502
Operating expenses:				
Sales, general and administrative	15,008	19,227	48,430	53,677
Research and development	2,729	3,776	9,327	11,361
Total operating expenses	17,737	23,003	57,757	65,038
Loss from operations	(2,591)	(8,765)	(19,899)	(26,536)
Interest income	2	3	12	13
Interest expense	(2,886)	(1,805)	(7,162)	(6,568)
Change in fair value of derivative instruments	879	235	442	2,843
Change in fair value of contingent consideration	5	205	304	567
Other income (expense), net	525	(2,340)	(5,568)	(2,526)
Loss before income taxes	(4,066)	(12,467)	(31,871)	(32,207)
Provision for income taxes	(181)	(308)	(606)	(387)
Net loss	\$ (4,247)	\$ (12,775)	\$ (32,477)	\$ (32,594)
Basic and diluted net loss per share	\$ (0.18)	\$ (0.62)	\$ (1.40)	\$ (1.59)
Weighted average outstanding shares used for basic and diluted net loss per share	23,611,925	20,620,828	23,184,322	20,478,603

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

	September 30, 2020 (Unaudited)	December 31, 2019
Assets		
Current assets:		
Cash	\$ 81,431	\$ 37,655
Accounts receivable, net of allowance for doubtful accounts of \$1,665 and \$1,026	18,756	22,767
Inventory, net	28,400	28,660
Prepaid expenses and other current assets	5,431	6,757
Total current assets	134,018	95,839
Long-term assets:		
Property and equipment, net of accumulated depreciation	16,263	16,418
Goodwill	465	465
Intangible assets, net of accumulated amortization	3,537	3,441
Other non-current assets	401	368
Total assets	\$ 154,684	\$ 116,531
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	\$ 6,954	\$ 10,366
Accrued liabilities	12,092	10,677
Other liabilities, short term	1,095	2,199
Total current liabilities	20,141	23,242
Long-term liabilities:		
Note payable, Madryn, net of debt discount and issuance costs	49,374	48,142
Madryn put option	2,630	3,072
Other liabilities, long term	2,582	2,461
Total liabilities	74,727	76,917
Shareholders' equity:		
Total shareholders' equity	79,957	39,614
Total liabilities and shareholders' equity	\$ 154,684	\$ 116,531

Investor/Media Contact:

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