

---

---

**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, 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 November 9, 2021, 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, 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	<a href="#">Press Release of Establishment Labs Holdings Inc. dated November 9, 2021.</a>

---

## 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, 2021

By: /s/ Rajbir S. Denhoy

Name: Rajbir S. Denhoy

Title: Interim Chief Financial Officer

---

# PRESS RELEASE

**Investor/Media Contact:**  
Raj Denhoy  
415 828-1044  
rdenhoy@establishmentlabs.com

## **Establishment Labs Reports Third Quarter 2021 Financial Results and Raises Full Year Guidance**

**SANTA BARBARA, Calif., Nov 9, 2021** -- Establishment Labs Holdings Inc. (NASDAQ: ESTA), a global medical technology company dedicated to improving women's health and wellness, principally in breast aesthetics and reconstruction, today announced its financial results for the third quarter ended September 30, 2021 and provided updated 2021 guidance.

### **Third Quarter Highlights and Outlook**

- Third quarter worldwide sales of \$29.0 million, an increase of 27.6% year-over-year.
- 2021 guidance increased to a new range of \$124 million to \$128 million, an increase of 46% to 51% over 2020; previous 2021 guidance range was \$122 million to \$126 million.
- Gross profit for the third quarter was 67.6% of revenue, compared to 66.6% of revenue for the same period in 2020.
- Third quarter operating expenses of \$28.7 million, an increase of 61.6% compared to the third quarter of 2020 as spending returned to more normalized levels following the global disruption in 2020.
- Cash balance of \$64.6 million as of September 30, 2021.
- Launched Motiva Flora<sup>®</sup> tissue expander in Europe and CE mark countries at London Breast Meeting.
- Motiva JOY<sup>®</sup> and Motiva MIA<sup>®</sup> development and commercialization plans progressing as planned.
- Timelines for US and China market entry remain unchanged.

"The momentum we have seen across all areas of our business in 2021 continued in the third quarter," said Juan José Chacón-Quirós, Chief Executive Officer. "Third quarter revenue of \$29.0 million was up 27.6% from the third quarter of 2020 and we are raising full year 2021 revenue guidance to a new range of \$124 million to \$128 million."

"Our strong financial results are being matched by the significant progress we are making across a number of programs and initiatives," Mr. Chacón-Quirós continued. "We launched our Motiva Flora tissue expander at the London Breast Meeting during the third quarter. This is an important step in our Aesthetic BreastRecon<sup>®</sup> program, where we are working to expand awareness and access of post-mastectomy reconstruction while offering the tools and techniques that allow women to receive reconstructive surgeries that achieve the aesthetic ideals to which they aspire."

"In addition, our JOY and MIA programs are progressing. These advances are not only opening up significant new markets, they are also allowing us to have a more direct relationship with women on their journey with Motiva. Our regulatory and commercial timelines to begin selling Motiva implants in the U.S. and Chinese markets are also progressing as planned. We remain on a clear path to becoming the leader in breast aesthetics and reconstruction, and to expand these markets as we offer safe, differentiated, and accessible solutions to women."

### **Third Quarter 2021 Financial Results**

Total revenue for the quarter ended September 30, 2021 was \$29.0 million compared to \$22.8 million for the same period in 2020. Direct sales comprised approximately 41% of total sales, while distributor sales made up the balance.

Gross profit for the third quarter was \$19.6 million, or 67.6% of revenue, compared to \$15.1 million, or 66.6% of revenue, for the same period in 2020. The change in gross margin was the result of regional mix returning to more normalized levels as well as increased production volumes.

Total operating expenses for the third quarter were \$28.7 million, an increase of \$10.9 million compared to \$17.7 million in the third quarter of 2020.

SG&A expenses for the third quarter increased approximately \$9.8 million to \$24.8 million compared to \$15.0 million in the third quarter of 2020. The increase resulted from more normalized business practices following disruption from the global pandemic in the year ago period.

R&D expenses increased approximately \$1.2 million to \$3.9 million in the third quarter compared to \$2.7 million for the same quarter a year ago. The majority of the increase was due to a normalization of spending levels and the timing of clinical trial and other expenses.

Net loss from operations for the third quarter was \$9.0 million compared to a net loss of \$2.6 million in the year ago period.

The Company's cash balance on September 30, 2021 was \$64.6 million. Cash decreased \$19.9 million from December 31, 2020 and \$12.2 million from the prior quarter, primarily as the result of operating losses 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 13723217. In addition, the live and archived webcast will be available on the Investor Relations section of the Company's website at [www.establishmentlabs.com](http://www.establishmentlabs.com).

### **About Establishment Labs**

Establishment Labs Holdings Inc. is a global medical technology company dedicated to improving women's health and wellness. The company's initial focus is breast health, principally breast aesthetics and reconstruction. Establishment Labs offers a portfolio of advanced silicone gel-filled breast implants, branded as Motiva Implants<sup>®</sup> that include a number of innovative and patented features designed to deliver improved aesthetic and clinical outcomes. Since commercial launch in 2010, more than 1.8 million Motiva Implants<sup>®</sup> have been delivered to plastic surgeons in over 80 countries. The company also offers or has under development a number of related products and technologies, including the Motiva Flora<sup>®</sup> tissue expander and Motiva MIA<sup>®</sup>, the company's minimally invasive breast enhancement procedure. In 2018, Establishment Labs received an investigational device exemption (IDE) from the FDA for the Motiva Implant<sup>®</sup> and began a clinical trial to support regulatory approval in the United States. Motiva Implants<sup>®</sup> are manufactured at the company's two facilities in Costa Rica, which are compliant with all applicable regulatory standards under ISO13485:2016 and FDA 21 CFR 820 under the MDSAP program. Please visit our website for additional information at [www.establishmentlabs.com](http://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," "intends to," "would," "will," "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, including related product development and

commercialization and regulatory approvals, 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 and the timing of events may differ from our expectations, and those differences may be material. Factors, among others, that could cause actual results and events to differ materially from those described in any forward-looking statements include risks and uncertainties relating to: our ability to successfully, timely and cost-effectively develop, seek and obtain regulatory clearance for and commercialize our product offerings; the rate of adoption of our products by healthcare providers or other customers; the success of our marketing initiatives; the safe and effective use of our products; our ability to protect our intellectual property; our future expansion plans and capital allocation; our ability to expand upon and/or secure sources of credit or capital; our ability to develop and maintain relationships with qualified suppliers to avoid a significant interruption in our supply chains; our ability to attract and retain key personnel; our ability to scale our operations to meet market demands; the effect on our business of existing and new regulatory requirements; and other economic and competitive factors. These and other factors that could cause or contribute to actual results differing materially from our expectations include, among others, those risks and uncertainties discussed in the company's quarterly report on Form 10-Q filed on July 30, 2021, 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,	
	2021	2020	2021	2020
Revenue	\$ 29,039	\$ 22,758	\$ 91,369	\$ 57,713
Cost of revenue	9,419	7,612	30,191	19,855
Gross profit	19,620	15,146	61,178	37,858
Operating expenses:				
Sales, general and administrative	24,780	15,008	64,671	48,430
Research and development	3,884	2,729	12,281	9,327
Total operating expenses	28,664	17,737	76,952	57,757
Loss from operations	(9,044)	(2,591)	(15,774)	(19,899)
Interest income	7	2	15	12
Interest expense	(2,293)	(2,886)	(6,736)	(7,162)
Change in fair value of derivative instruments	57	879	546	442
Change in fair value of contingent consideration	—	5	—	304
Other income (expense), net	(3,339)	527	(4,360)	(5,561)
Loss before income taxes	(14,612)	(4,064)	(26,309)	(31,864)
Provision for income taxes	(66)	(181)	(639)	(606)
Net loss	\$ (14,678)	\$ (4,245)	\$ (26,948)	\$ (32,470)
Basic and diluted net loss per share	\$ (0.61)	\$ (0.18)	\$ (1.13)	\$ (1.40)
Weighted average outstanding shares used for basic and diluted net loss per share	24,091,546	23,611,925	23,885,412	23,184,322

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

	September 30, 2021 (Unaudited)	December 31, 2020
<b>Assets</b>		
Current assets:		
Cash	\$ 64,623	\$ 84,523
Accounts receivable, net of allowance for doubtful accounts of \$1,542 and \$1,143	24,704	19,127
Inventory, net	26,652	23,210
Prepaid expenses and other current assets	8,726	5,439
Total current assets	124,705	132,299
Long-term assets:		
Property and equipment, net of accumulated depreciation	16,781	16,202
Goodwill	465	465
Intangible assets, net of accumulated amortization	3,654	4,148
Right-of-use operating lease assets, net	2,307	2,610
Other non-current assets	447	664
Total assets	\$ 148,359	\$ 156,388
<b>Liabilities and shareholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 10,257	\$ 9,722
Accrued liabilities	19,178	14,532
Other liabilities, short-term	1,015	1,646
Total current liabilities	30,450	25,900
Long-term liabilities:		
Note payable, Madryn, net of debt discount and issuance costs	51,343	49,832
Madryn put option	894	1,440
Operating lease liabilities, non-current	1,967	1,923
Other liabilities, long-term	2,145	2,332
Total liabilities	86,799	81,427
Shareholders' equity:		
Total shareholders' equity	61,560	74,961
Total liabilities and shareholders' equity	\$ 148,359	\$ 156,388