

**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**

**July 29, 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 July 29, 2021, Establishment Labs Holdings Inc. (the “Company”) issued a press release announcing the Company’s financial results for the three and six months ended June 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 July 29, 2021.</a>

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## 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: July 29, 2021

By: /s/ Renee M. Gaeta

Name: Renee M. Gaeta

Title: Chief Financial Officer

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# PRESS RELEASE

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

## Establishment Labs Reports Record Second Quarter 2021 Financial Results and Raises Full Year Guidance

**SANTA BARBARA, Calif., July 29, 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 second quarter ended June 30, 2021 and provided updated 2021 guidance.

### Second Quarter Highlights and Outlook

- Second quarter worldwide sales of \$32.0 million, an increase of 205% year-over-year and a new quarterly record; results are in line with preannounced range of \$31 million to \$32 million provided on July 12, 2021.
- 2021 guidance increased to a new range of \$122 million to \$126 million, an increase of 44% to 49% over 2020; previous 2021 guidance range was \$118 million to \$122 million.
- Second quarter operating expenses of \$26.1 million, an increase of 55% compared to the second quarter of 2020 as spending returned to more normalized levels following the global disruption in 2020.
- Total net cash burn of \$1.1 million in the second quarter. Cash balance of \$76.8 million as of June 30, 2021.
- Publication of landmark study in *Nature Biomedical Engineering* showing superior biocompatibility of Motiva<sup>®</sup> SmoothSilk<sup>®</sup> implant technology.
- Marketing and commercial activities with Motiva Ergonomix2<sup>®</sup> expanding.
- Commercial launch of Motiva Flora<sup>®</sup> tissue expander in Europe continuing.
- Motiva MIA<sup>®</sup> development and commercialization plans progressing as planned.
- Timelines for US and China market entry remain unchanged.
- Held groundbreaking on Sulaym Innovation Campus, which will expand manufacturing capacity to approximately 1.9 million implants per year when complete and add new capabilities in R&D, media, and medical education.

“We delivered record second quarter revenue of \$32.0 million, which was up 205% from the second quarter of 2020 and 5% sequentially from the first quarter of 2021,” said Juan José Chacón-Quirós, Chief Executive Officer. “Our strong second quarter and first half financial results show that our business is in very good shape. With this momentum, we are raising full year 2021 revenue guidance to a new range of \$122 million to \$126 million.”

“The second quarter was a productive period for Establishment Labs,” Mr. Chacón-Quirós continued. “The publication in late June of the paper “The surface topography of silicone breast implants mediates the foreign body response in mice, rabbits and humans” in *Nature Biomedical Engineering* was a watershed event for women's health. The paper showed that our bioengineered SmoothSilk surface reduces inflammation and produces the most biocompatible immune response compared to other implants. The findings add to a foundation of clinical and scientific data built over the last decade in the market and explains one of the key reasons our implants perform so well.”

“As our core implant business continues to take share globally, we are expanding availability of our Ergonomix2 implant line and launching into reconstruction with our Motiva Flora tissue expander. In addition, market

development work on Motiva MIA is continuing and our expectations for commercialization in 2022 remain unchanged. Our regulatory and commercial timelines to begin selling Motiva implants in the U.S. and Chinese markets are also progressing as planned. Despite the ongoing challenges from the pandemic, we remain on a clearly defined path to become the leader in breast aesthetics and reconstruction, and to expand these markets as we offer safe, differentiated and accessible solutions to women.”

### **Second Quarter 2021 Financial Results**

Total revenue for the quarter ended June 30, 2021 was \$32.0 million compared to \$10.5 million for the same period in 2020. Direct sales comprised approximately 44% of total sales, while distributor sales made up the balance.

Gross profit for the second quarter was \$21.5 million, or 67.1% of revenue, compared to \$7.2 million, or 69.1% 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. Average selling prices in the second quarter were up slightly from the first quarter of 2021.

Total operating expenses for the second quarter were \$26.1 million, an increase of \$9.3 million compared to \$16.8 million in the second quarter of 2020.

SG&A expenses for the second quarter increased approximately \$7.3 million to \$21.8 million compared to \$14.4 million in the second 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 \$2.0 million to \$4.3 million in the second quarter compared to \$2.4 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 second quarter was \$5.3 million compared to a net loss of \$10.5 million in the year ago period.

The Company’s cash balance on June 30, 2021 was \$76.8 million. Cash decreased \$7.7 million from December 31, 2020 and \$1.1 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 13721659. 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 1.6 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. 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. 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 and the timing of events 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.

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**ESTABLISHMENT LABS HOLDINGS INC.**  
**Consolidated Statements of Operations**  
(In thousands, except share and per share data)  
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenue	\$ 31,994	\$ 10,474	\$ 62,330	\$ 34,955
Cost of revenue	10,526	3,240	20,772	12,243
Gross profit	21,468	7,234	41,558	22,712
Operating expenses:				
Sales, general and administrative	21,753	14,438	39,891	33,422
Research and development	4,349	2,399	8,397	6,598
Total operating expenses	26,102	16,837	48,288	40,020
Loss from operations	(4,634)	(9,603)	(6,730)	(17,308)
Interest income	4	2	8	10
Interest expense	(2,248)	(2,130)	(4,443)	(4,276)
Change in fair value of derivative instruments	259	1,492	489	(437)
Change in fair value of contingent consideration	—	(141)	—	299
Other income (expense), net	1,705	102	(1,021)	(6,088)
Loss before income taxes	(4,914)	(10,278)	(11,697)	(27,800)
Provision for income taxes	(408)	(194)	(573)	(425)
Net loss	<u>\$ (5,322)</u>	<u>\$ (10,472)</u>	<u>\$ (12,270)</u>	<u>\$ (28,225)</u>
Basic and diluted net loss per share	<u>\$ (0.22)</u>	<u>\$ (0.45)</u>	<u>\$ (0.51)</u>	<u>\$ (1.23)</u>
Weighted average outstanding shares used for basic and diluted net loss per share	<u>23,949,006</u>	<u>23,482,031</u>	<u>23,883,366</u>	<u>22,969,162</u>

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

	June 30, 2021 (Unaudited)	December 31, 2020
<b>Assets</b>		
Current assets:		
Cash	\$ 76,806	\$ 84,523
Accounts receivable, net of allowance for doubtful accounts of \$1,232 and \$1,143	23,093	19,127
Inventory, net	23,946	23,210
Prepaid expenses and other current assets	4,336	5,439
Total current assets	128,181	132,299
Long-term assets:		
Property and equipment, net of accumulated depreciation	16,590	16,202
Goodwill	465	465
Intangible assets, net of accumulated amortization	3,859	4,148
Right-of-use operating lease assets, net	2,408	2,610
Other non-current assets	617	664
Total assets	\$ 152,120	\$ 156,388
<b>Liabilities and shareholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 10,020	\$ 9,722
Accrued liabilities	16,180	14,532
Other liabilities, short-term	1,070	1,646
Total current liabilities	27,270	25,900
Long-term liabilities:		
Note payable, Madryn, net of debt discount and issuance costs	50,810	49,832
Madryn put option	951	1,440
Operating lease liabilities, non-current	2,041	1,923
Other liabilities, long-term	2,219	2,332
Total liabilities	83,291	81,427
Shareholders' equity:		
Total shareholders' equity	68,829	74,961
Total liabilities and shareholders' equity	\$ 152,120	\$ 156,388