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

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FORM 8-K

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

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August 8, 2022

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**Date of Report (date of earliest event reported)**

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

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**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)**

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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.

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**Item 2.02. Results of Operations and Financial Condition.**

On August 8, 2022, 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, 2022 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 August 8, 2022.</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: August 8, 2022

By: /s/ Rajbir S. Denhoy

Name: Rajbir S. Denhoy

Title: Chief Financial Officer

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# PRESS RELEASE

**Investor/Media Contact:**  
Raj Denhoy  
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rdenhoy@establishmentlabs.com

## Establishment Labs Reports Record Second Quarter 2022 Financial Results

**SANTA BARBARA, Calif., August 8, 2022** -- 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, 2022.

### Second Quarter Highlights and Outlook

- Strong momentum with second quarter worldwide sales of \$41.2 million, an increase of 28.7% year-over-year and a new quarterly record; excluding the impact of foreign currency changes, revenue growth in the second quarter would have been 33.3%.
- Gross profit for the second quarter was 66.7% of revenue, compared to 67.1% of revenue for the same period in 2021.
- Second quarter operating expenses of \$37.9 million, an increase of 45.0% compared to the second quarter of 2021.
- Cash balance of \$91.3 million as of June 30, 2022; reflecting initial \$150 million tranche of new \$225 million credit facility entered into on April 26, 2022.
- Motiva Flora<sup>®</sup> tissue expander launch ongoing.
- Motiva JOY<sup>™</sup> rollout expanding globally.
- Mía<sup>®</sup> development and commercialization programs progressing.
- Modular PMA submission for U.S. FDA approval progressing with the third module submitted to the FDA last week; completed enrollment in all cohorts of U.S. IDE trial.

"The strong momentum in our business continued in the second quarter of 2022," said Juan José Chacón-Quirós, Chief Executive Officer. "Second quarter revenue of \$41.2 million was up 28.7% from the second quarter of 2021; excluding the impact of the stronger U.S. dollar, which reduced reported revenue by approximately \$1.5 million, growth in the second quarter would have been 33.3%. We are maintaining our 2022 revenue guidance of \$155 million to \$165 million, which is reported annual growth of 22% to 30%. The strength of our technology and the underlying trends in our business are allowing us to maintain this outlook despite foreign currency changes."

"The second quarter saw a number of notable events," Mr. Chacón-Quirós continued. "In April, data from our U.S. IDE trial was presented at The Aesthetic Meeting by Dr. Caroline Glicksman. This was followed by our new \$225 million credit facility, providing us with sufficient capital under current forecasts to fund our business to cash flow profitability. Last week we submitted the third module of our modular PMA to the FDA, and we expect to submit the fourth and final module before the end of the year."

"We are transforming our markets through our commitment to innovation in women's health," Mr. Chacón-Quirós concluded. "We are creating new categories for growth and more importantly, creating new options for women. We believe we are on track to become the leading global company in breast aesthetics and reconstruction and to grow these markets through clinically superior and patient-centric offerings."

## **Second Quarter 2022 Financial Results**

Total revenue for the quarter ended June 30, 2022 was \$41.2 million compared to \$32.0 million for the same period in 2021. Direct sales comprised approximately 41% of total sales, while distributor sales made up the balance.

Gross profit for the second quarter was \$27.5 million, or 66.7% of revenue, compared to \$21.5 million, or 67.1% of revenue, for the same period in 2021.

Total operating expenses for the second quarter were \$37.9 million, an increase of \$11.8 million compared to \$26.1 million in the second quarter of 2021.

SG&A expenses for the second quarter increased approximately \$11.2 million to \$33.0 million compared to \$21.8 million in the second quarter of 2021. The increase in SG&A was primarily due to an increase in personnel and related costs due to increased headcount, an increase in sales and marketing expenses, as well as an increase in consulting fees.

R&D expenses increased approximately \$0.6 million to \$4.9 million in the second quarter compared to \$4.3 million for the same quarter a year ago. The increase was primarily due to an increase in regulatory affair costs and expenditures related to our U.S. IDE clinical study.

Net loss from operations for the second quarter was \$10.4 million compared to a net loss of \$4.6 million in the year ago period.

The Company's cash balance on June 30, 2022 was \$91.3 million. Cash increased \$37.8 million from December 31, 2021, primarily as a result of borrowings under the new credit facility, partially offset by repayment of the Madryn debt agreement, operating losses and investments in facility expansion.

## **Conference Call and Webcast Information**

Establishment Labs will host a conference call and webcast today at 4:30 p.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 13731615. 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, over 2.0 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 Mía<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).

## **Non-GAAP Financial Measures**

To supplement the consolidated financial results prepared in accordance with Generally Accepted Accounting Principles ("GAAP"), we have disclosed in this press release constant currency sales (or revenue) information, which is a non-GAAP measure that excludes the impact of foreign exchange currency fluctuations. Fluctuations in

currency exchange rates impact the sales growth rates of our underlying business. Management believes that excluding the impact of currency exchange rate fluctuations from its sales growth provides investors a more useful comparison to historical financial results. In order to remove the impact of fluctuations in foreign currency exchange rates, we calculate constant currency revenue, which represents the outcome that would have resulted had exchange rates in the current period been the same as those in effect in the comparable prior period. Management believes that providing investors with this non-GAAP measure gives them additional information to enable them to assess, in the same way management assesses, the Company's current and future continuing operations. This non-GAAP measure is not in accordance with, or an alternative for, GAAP, and may be different from non-GAAP measures used by other companies.

### **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, our liquidity and anticipated cash plans; 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 press release, 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 cash requirements and ability to generate positive cash flow from operations; 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; the effect on our business of the current Russia-Ukraine conflict; the impact of foreign currency exchange rates; the impact on our business of an economic downturn or deterioration of general macroeconomic conditions, including slower growth or recession, inflation or decreases in consumer spending power or confidence; other economic and competitive factors; and the other risks and uncertainties discussed in Item 1A, Risk Factors, in the company's annual report on Form 10-K filed on March 1, 2022, as such risks and uncertainties will be updated in the company's quarterly report on Form 10-Q for the three months ended June 30, 2022, which is expected to be filed with the SEC on August 9, 2022. These and other factors that could cause or contribute to actual results differing materially from our expectations may also be amended, updated or superseded from time to time in the future in 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,	
	2022	2021	2022	2021
Revenue	\$ 41,190	\$ 31,994	\$ 79,642	\$ 62,330
Cost of revenue	13,736	10,526	27,252	20,772
Gross profit	27,454	21,468	52,390	41,558
Operating expenses:				
Sales, general and administrative	32,957	21,753	59,870	39,891
Research and development	4,903	4,349	8,501	8,397
Total operating expenses	37,860	26,102	68,371	48,288
Loss from operations	(10,406)	(4,634)	(15,981)	(6,730)
Interest income	32	4	52	8
Interest expense	(3,388)	(2,248)	(5,680)	(4,443)
Change in fair value of derivative instruments	1,099	259	703	489
Other income (expense), net	(4,860)	1,705	(2,151)	(1,021)
Loss on extinguishment of debt	(19,019)	—	(19,019)	—
Loss before income taxes	(36,542)	(4,914)	(42,076)	(11,697)
Provision for income taxes	(564)	(408)	(963)	(573)
Net loss	\$ (37,106)	\$ (5,322)	\$ (43,039)	\$ (12,270)
Basic and diluted net loss per share	\$ (1.52)	\$ (0.22)	\$ (1.77)	\$ (0.51)
Weighted average outstanding shares used for basic and diluted net loss per share	24,396,847	23,949,006	24,354,005	23,883,366

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

	<u>June 30, 2022</u>	<u>December 31, 2021</u>
	<u>(Unaudited)</u>	
<b>Assets</b>		
Current assets:		
Cash	\$ 91,259	\$ 53,415
Accounts receivable, net of allowance for doubtful accounts of \$791 and \$1,221	32,003	24,437
Inventory, net	26,532	28,407
Prepaid expenses and other current assets	6,634	7,012
Total current assets	<u>156,428</u>	<u>113,271</u>
Long-term assets:		
Property and equipment, net of accumulated depreciation	35,359	18,658
Goodwill	465	465
Intangible assets, net of accumulated amortization	4,414	4,371
Right-of-use operating lease assets, net	2,023	2,206
Other non-current assets	1,194	558
Total assets	<u>\$ 199,883</u>	<u>\$ 139,529</u>
<b>Liabilities and shareholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 15,986	\$ 14,475
Accrued liabilities	17,600	16,236
Other liabilities, short-term	1,166	1,178
Total current liabilities	<u>34,752</u>	<u>31,889</u>
Long-term liabilities:		
Note payable, Oaktree, net of debt discount and issuance costs	145,482	—
Note payable, Madryn, net of debt discount and issuance costs	—	51,906
Madryn put option	—	703
Operating lease liabilities, non-current	1,726	1,900
Other liabilities, long-term	2,056	2,392
Total liabilities	<u>184,016</u>	<u>88,790</u>
Shareholders' equity:		
Total shareholders' equity	<u>15,867</u>	<u>50,739</u>
Total liabilities and shareholders' equity	<u>\$ 199,883</u>	<u>\$ 139,529</u>