



## Establishment Labs Reports Third Quarter 2022 Financial Results

November 7, 2022

SANTA BARBARA, Calif.--(BUSINESS WIRE)--Nov. 7, 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 third quarter ended September 30, 2022.

### Third Quarter Highlights and Outlook

- Third quarter worldwide sales of \$38.2 million, an increase of 31.7% year-over-year; excluding the impact of foreign currency changes, revenue growth in the third quarter would have been 37.7%.
- Revenue guidance for 2022 tightened to a range of \$158 million to \$162 million, an increase of 25% to 28% over 2021; previous 2022 guidance range was \$155 million to \$165 million.
- Foreign exchange expected to negatively impact 2022 revenue by approximately \$6.5 million; constant currency revenue guidance of \$164.5 million to \$168.5 million represents growth of 30% to 33% over 2021.
- Gross profit for the third quarter was 68.1% of revenue, compared to 67.6% of revenue for the same period in 2021.
- Third quarter operating expenses of \$36.6 million, an increase of 27.5% compared to the third quarter of 2021.
- Cash balance of \$65.3 million as of September 30, 2022.
- Mia Femtech™ commercialization expected in 1H 2023.
- China approval and launch expected in 1H 2023.
- Expect to submit Motiva Implants for U.S. FDA approval in Q4 2022; all cohorts of U.S. IDE trial enrolled.

"The significant momentum in our business continued in the third quarter of 2022 and we expect our strong financial results will continue into the fourth quarter and into 2023," said Juan José Chacón-Quirós, Founder and Chief Executive Officer. "We are preparing for a number of significant new opportunities, including launches of Motiva into the U.S. and China and the commercial introduction of Mia Femtech. In October, we hosted a webcast highlighting the progress we have made in bringing Mia to market and we remain on track for commercialization in the first half of 2023. We have also completed all surgeries in our U.S. IDE clinical trial, and we expect to submit the fourth and final module for our first PMA approval before the end of the year."

"We are creating new categories for growth and more importantly, creating new options for women," Mr. Chacón-Quirós continued. "We believe we are on a clear path to becoming the leading global company in breast aesthetics and reconstruction and that we can grow these markets through safe, differentiated, and accessible solutions."

### Third Quarter 2022 Financial Results

Total revenue for the quarter ended September 30, 2022 was \$38.2 million compared to \$29.0 million for the same period in 2021. Direct sales comprised approximately 38% of total sales, while distributor sales made up the balance.

Gross profit for the third quarter was \$26.0 million, or 68.1% of revenue, compared to \$19.6 million, or 67.6% of revenue, for the same period in 2021.

Total operating expenses for the third quarter were \$36.6 million, an increase of \$7.9 million compared to \$28.7 million in the third quarter of 2021.

SG&A expenses for the third quarter increased approximately \$6.5 million to \$31.3 million compared to \$24.8 million in the third 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 freight charges.

R&D expenses increased approximately \$1.4 million to \$5.3 million in the third quarter compared to \$3.9 million for the same quarter a year ago. The increase was primarily due to an increase in personnel costs and expenditures related to our U.S. IDE clinical study.

Net loss from operations for the third quarter was \$10.5 million compared to a net loss of \$9.0 million in the year ago period.

The Company's cash balance on September 30, 2022 was \$65.3 million. Cash increased \$11.9 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 13733889. 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, approximately 2.5 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 Mia Femtech<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 September 30, 2022, which is expected to be filed with the SEC on November 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.

## **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,	
	2022	2021	2022	2021
Revenue	\$ 38,245	\$ 29,039	\$ 117,887	\$ 91,369
Cost of revenue	12,205	9,419	39,457	30,191
Gross profit	26,040	19,620	78,430	61,178
Operating expenses:				
Sales, general and administrative	31,268	24,780	91,138	64,671
Research and development	5,289	3,884	13,790	12,281
Total operating expenses	36,557	28,664	104,928	76,952
Loss from operations	(10,517 )	(9,044 )	(26,498 )	(15,774 )
Interest income	10	7	62	15
Interest expense	(3,880 )	(2,293 )	(9,560 )	(6,736 )
Change in fair value of derivative instruments	—	57	703	546
Other expense, net	(3,618 )	(3,339 )	(5,769 )	(4,360 )
Loss on extinguishment of debt	—	—	(19,019 )	—
Loss before income taxes	(18,005 )	(14,612 )	(60,081 )	(26,309 )
Provision for income taxes	(603 )	(66 )	(1,566 )	(639 )
Net loss	\$ (18,608 )	\$ (14,678 )	\$ (61,647 )	\$ (26,948 )
Basic and diluted net loss per share	\$ (0.76 )	\$ (0.61 )	\$ (2.53 )	\$ (1.13 )
Weighted average outstanding shares used for basic and diluted net loss per share	24,511,495	24,091,546	24,406,389	23,885,412

**ESTABLISHMENT LABS HOLDINGS INC.**

**Consolidated Balance Sheets**

**(In thousands)**

September 30, December 31,  
2022 2021

(Unaudited)

**Assets**

Current assets:

Cash	\$ 65,349	\$ 53,415
Accounts receivable, net of allowance for doubtful accounts of \$989 and \$1,221	31,246	24,437
Inventory, net	31,557	28,407
Prepaid expenses and other current assets	10,013	7,012
Total current assets	138,165	113,271

Long-term assets:

Property and equipment, net of accumulated depreciation	39,214	18,658
Goodwill	465	465
Intangible assets, net of accumulated amortization	4,632	4,371
Right-of-use operating lease assets, net	3,730	2,206
Other non-current assets	1,447	558
Total assets	\$ 187,653	\$ 139,529

**Liabilities and shareholders' equity**

Current liabilities:

Accounts payable	\$ 14,878	\$ 14,475
Accrued liabilities	16,705	16,236
Other liabilities, short-term	793	1,178
Total current liabilities	32,376	31,889

Long-term liabilities:

Note payable, Oaktree, net of debt discount and issuance costs	148,192	—
Note payable, Madryn, net of debt discount and issuance costs	—	51,906

Madryn put option	—	703
Operating lease liabilities, non-current	3,323	1,900
Other liabilities, long-term	2,243	2,392
Total liabilities	186,134	88,790
Shareholders' equity:		
Total shareholders' equity	1,519	50,739
Total liabilities and shareholders' equity	\$ 187,653	\$ 139,529

View source version on [businesswire.com](https://www.businesswire.com/news/home/20221107005400/en/): <https://www.businesswire.com/news/home/20221107005400/en/>

**Investor/Media Contact:**

Raj Denhoy

415 828-1044

[rdenhoy@establishmentlabs.com](mailto:rdenhoy@establishmentlabs.com)

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