



Establishment Labs Reports Second Quarter 2020 Financial Results

August 6, 2020

NEW YORK, Aug. 06, 2020 (GLOBE NEWSWIRE) -- 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 second quarter ended June 30, 2020.

Second Quarter Highlights and Outlook

- Worldwide sales of \$10.5 million; steady monthly increases recorded during the quarter
- Q3 2020 revenue expected to be \$18 to \$21 million
- Reduced operating expenses by 27% compared to Q1 2020
- Strong cash balance of \$86.4 million at June 30
- Follow-up phase for Motiva U.S. IDE trial aesthetic cohorts continuing; enrollment completed in revision reconstruction sub-cohort
- Regulatory progress in China with Motiva product testing; approval delayed to first half of 2022
- Motiva Mia clinical cases recently resumed in Asia; application to initiate patient series in Thailand submitted
- Long-term fundamentals of business remain strong

"As expected, this was a challenging quarter as our global business was impacted by COVID-19. Encouragingly, we saw improvement throughout the quarter as countries began to reopen and elective procedures resumed in various regions around the world," said Juan José Chacón-Quirós, Chief Executive Officer of Establishment Labs. "Our business is recovering with the strength and resilience that we had hoped for, and we estimate that third quarter revenue this year will be between \$18 and \$21 million.

"We have taken this time to address budgets and headcount in a very meaningful way and the result is that we are doing more with less. At the same time, we are investing in our future by continuing to develop innovative, market expanding products, and enhancing our digital platforms to broaden the reach of the Motiva brand and forge stronger and more cost-effective connections with our plastic surgeon customers and their patients. These actions are making Establishment Labs an even stronger company that will come out of this pandemic well positioned for continued growth and success," Mr. Chacón-Quirós continued.

Second Quarter 2020 Financial Results

Total revenues for the quarter ended June 30, 2020 were \$10.5 million compared to \$21.7 million for the same period in 2019. Direct sales comprised nearly two-thirds of the sales this quarter with distributor sales making up the balance.

Gross profit for the second quarter was \$7.2 million, or 69.1% of revenue, compared to \$13.0 million, or 60.0% 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 second quarter this year were \$16.8 million, a decrease of \$5.6 million or 24.8%, compared to \$22.4 million in the second quarter of 2019. Compared to the first quarter of 2020, operating expenses in the second quarter were 27% lower.

SG&A expenses this quarter declined \$4.0 million, or 21.5%, to \$14.4 million compared to \$18.4 million in the second quarter of 2019. Over half of the decrease resulted from the Company's actions to control expenses including a decrease in the number of in-person marketing events, lowered compensation expense through headcount reductions and reduced or eliminated other discretionary expenses.

R&D expenses decreased \$1.6 million to \$2.4 million in the second quarter compared to \$4.0 million for the same quarter a year ago. While the Company continues to invest in research and development to strengthen its product portfolio and drive future growth, it has narrowed the scope of its efforts. In addition, a portion of the decline was due to the timing of clinical trial expenses and a COVID-19 related reduction in U.S. IDE costs.

Net loss from operations for the second quarter was \$9.6 million compared to a net loss of \$9.4 million in the year ago period.

The Company's cash balance at June 30, 2020 was \$86.4 million. Cash used in operations was \$6.1 million in the second quarter compared to \$6.8 million for the first quarter of 2020, and \$7.1 million for the second quarter of 2019.

Other Developments

This month marks the halfway point in the two-year endpoint of the protocol for the aesthetic cohorts in the Company's Motiva U.S. IDE trial, and patient follow-ups are continuing as part of the monitoring phase. While COVID-19 has impacted the pace of enrollment in the reconstruction cohorts, the Company has continued to activate new trial sites and during the quarter successfully completed enrollment in the revision reconstruction sub-cohort.

The Company is making progress with its Motiva regulatory submission in China and recently passed the latest round of product testing. The regulatory backlog caused by COVID-19 impacted the approval timeline and the Company now expects to receive approval during the first half of 2022. The Company remains committed introducing its Motiva product line to plastic surgeons and patients in China, one of the largest and most dynamic markets in the world for breast aesthetics.

Clinical cases have recently resumed in Asia in the Company's Motiva Mia minimally invasive breast augmentation procedure, and it expects a Motiva Mia patient series to be initiated in Thailand next month. The introduction of a less invasive augmentation procedure that would provide a safety profile similar to the Company's current Motiva Implants, has the potential to grow the total addressable market for breast aesthetics and contribute meaningfully to the Company's longer-term growth strategy.

Outlook

Mr. Chacón-Quirós concluded, "Plastic surgeons all over the world are reporting strong interest in aesthetic procedures from new patients, which reinforces our confidence in the long-term fundamentals of our business. Our innovation and commitment to women's health resonate very strongly with plastic surgeons and their patients, which is why we have been able to gain market share over the years, and why we believe we can continue to do so even during these times. I'm confident that Establishment Labs is in a solid financial position, that we have a strong and adaptable team, and that our best days are still ahead."

Conference Call and Webcast Information

Establishment Labs will host a conference call and webcast today at 5:30 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 2649347. 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 Motiva Mia, and the impact of the COVID-19 pandemic on our operations 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.

	<u>June 30, 2020</u>	<u>December 31, 2019</u>
	(Unaudited)	
Assets		
Current assets:		
Cash	\$ 86,382	\$ 37,655
Accounts receivable, net of allowance for doubtful accounts of \$1,954 and \$1,026	17,142	22,767
Inventory, net	29,057	28,660
Prepaid expenses and other current assets	3,841	6,757
Total current assets	<u>136,422</u>	<u>95,839</u>
Long-term assets:		
Property and equipment, net of accumulated depreciation	16,085	16,418
Goodwill	465	465
Intangible assets, net of accumulated amortization	3,480	3,441
Other non-current assets	360	368
Total assets	<u>\$ 156,812</u>	<u>\$ 116,531</u>
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	\$ 8,293	\$ 10,366
Accrued liabilities	10,517	10,677
Other liabilities, short term	1,742	2,199
Total current liabilities	<u>20,552</u>	<u>23,242</u>
Long-term liabilities:		
Note payable, Madryn, net of debt discount and issuance costs	48,939	48,142
Madryn put option	3,509	3,072
Other liabilities, long term	2,026	2,461
Total liabilities	<u>75,026</u>	<u>76,917</u>
Shareholders' equity:		
Total shareholders' equity	<u>81,786</u>	<u>39,614</u>
Total liabilities and shareholders' equity	<u>\$ 156,812</u>	<u>\$ 116,531</u>

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

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
Revenue	\$ 10,474	\$ 21,684	\$ 34,955	\$ 42,462
Cost of revenue	3,240	8,672	12,243	18,198
Gross profit	<u>7,234</u>	<u>13,012</u>	<u>22,712</u>	<u>24,264</u>
Operating expenses:				
Sales, general and administrative	14,438	18,394	33,422	34,450
Research and development	2,399	4,001	6,598	7,585
Total operating expenses	<u>16,837</u>	<u>22,395</u>	<u>40,020</u>	<u>42,035</u>
Loss from operations	(9,603)	(9,383)	(17,308)	(17,771)
Interest income	2	4	10	10
Interest expense	(2,130)	(2,521)	(4,276)	(4,763)
Change in fair value of derivative instruments	1,492	2,640	(437)	2,608
Change in fair value of contingent consideration	(141)	137	299	362
Other expense, net	103	118	(6,093)	(186)
Loss before income taxes	<u>(10,277)</u>	<u>(9,005)</u>	<u>(27,805)</u>	<u>(19,740)</u>
Provision for income taxes	(194)	(35)	(425)	(79)
Net loss	<u>\$ (10,471)</u>	<u>\$ (9,040)</u>	<u>\$ (28,230)</u>	<u>\$ (19,819)</u>

Basic and diluted net loss per share	<u>\$ (0.45)</u>	<u>\$ (0.44)</u>	<u>\$ (1.23)</u>	<u>\$ (0.97)</u>
Weighted average outstanding shares used for basic and diluted net loss per share	<u>23,482,031</u>	<u>20,448,643</u>	<u>22,969,162</u>	<u>20,407,912</u>

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