

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

FORM 10-K/A
(Amendment No. 1)

(Mark One)

- ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2019
or
 TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission file number: 001-38593

Establishment Labs Holdings Inc.

(Exact name of registrant as specified in its charter)

British Virgin Islands State or Other Jurisdiction of Incorporation or Organization	Not applicable I.R.S. Employer Identification No.
Building B15 and 25 Coyol Free Zone Alajuela Costa Rica Address of Principal Executive Offices	Not applicable Zip Code

Registrant's telephone number, including area code: +506 2434 2400

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Shares, No Par Value	ESTA	The NASDAQ Capital Market

Securities registered pursuant to Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act. Yes No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes No

The aggregate market value of the common stock held by non-affiliates of the registrant on June 28, 2019 was approximately \$299,678,686. Shares of the registrant's common stock held by each executive officer, director and holder of 5% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This calculation does not reflect a determination that certain persons are affiliates of the registrant for any other purpose. The registrant has no non-voting equity.
As of March 13, 2020, the number of the registrant's common shares outstanding was 23,326,060.

DOCUMENTS INCORPORATED BY REFERENCE

None.

EXPLANATORY NOTE

This Form 10-K/A (Amendment No. 1) is being filed by Establishment Labs Holdings Inc. (the “Company”) to amend the Company’s Form 10-K (“Initial 10-K”) for the year ended December 31, 2019 filed with the Securities and Exchange Commission (the “SEC”) on March 16, 2020 (the “Original Filing”) as a result of comments received from the SEC in connection with its review of the Company’s periodic reports. This Form 10-K/A (Amendment No. 1) is being filed to amend the Original Filing by supplementing certain disclosures in Item 9A “Controls and Procedures – Disclosure Controls and Procedures.”

Other than as set forth in amended Item 9A, this Form 10-K/A (Amendment No. 1) does not reflect events occurring after the filing of the Original Filing, and no other information in the Original Filings is amended hereby. Other events or circumstances occurring after the date of the Original Filing or other disclosures necessary to reflect subsequent events have not been updated subsequent to the date of the Original Filing. Accordingly, this Form 10-K/A (Amendment No. 1) should be read in conjunction with the Original Filing and our filings with the SEC subsequent to the Original Filing.

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PART III

Item 9A. Controls and Procedures

Evaluation of disclosure controls and procedures

As of December 31, 2019, the end of the period covered by this Annual Report on Form 10-K, our management, with the participation of our Chief Executive Officer and Chief Financial Officer, have evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this annual report. Disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (ii) accumulated and communicated to the company's management, including its principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Based on the evaluation of our disclosure controls and procedures, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were not effective as of the end of the period covered by this annual report at the reasonable assurance level.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) of the Exchange Act. Our management has assessed the effectiveness of our internal control over financial reporting as of December 31, 2019 using the criteria established in "Internal Control—Integrated Framework" (2013), issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. Based on that assessment, our management has concluded that the Company did not maintain effective internal control over financial reporting as of December 31, 2019 because the material weakness in internal control over financial reporting discussed below continues to exist as of December 31, 2019.

Material Weakness in Internal Control over Financial Reporting

We disclosed in our Annual Report on Form 10-K for the year ended December 31, 2018, that the following material weakness in our internal control over financial reporting existed as of December 31, 2018: a lack of adequate review over the manual consolidation process, resulting in an audit adjustment, or the Material Weakness.

Changes in Internal Control over Financial Reporting

Other than with respect to the remediation efforts discussed below, there was no change in our internal control over financial reporting that occurred during the fourth quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Remediation of Previous Material Weaknesses

We have implemented and are continuing to implement a number of measures to address the Material Weakness identified as of December 31, 2018. We improved policies and procedures and designed and documented more effective controls that addressed the relevant risks in order to remediate the previously identified Material Weakness in addition to hiring additional personnel in our accounting department and engaging consultants with technical expertise to assist in accounting for complex transactions. We also engaged a third-party consulting firm to assist us with the implementation of SAP, which is a global information technology solution designed to address, among other items, the elements which gave rise to the Material Weakness. However, despite the progress made to our internal control environment, management determined that the Material Weakness identified as of December 31, 2018 has not been remediated as of December 31, 2019, in part due to the implementation of SAP at one of our subsidiaries. We will continue to implement additional measures to address the Material Weakness identified as of December 31, 2019.

Limitations on Effectiveness of Controls and Procedures

Our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving the desired control objectives. Our management recognizes that any control system, no matter how well designed and operated, is based upon certain judgments and assumptions and cannot provide absolute assurance that its objectives will be met. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs. Similarly, an evaluation of controls cannot provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(3) Exhibits

Exhibit Number	Description	Incorporated by Reference From Form
31.3	<u>Certification of Principal Executive Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>	Filed herewith
31.4	<u>Certification of Principal Financial Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>	Filed herewith
104	The cover page from this Amendment No. 1 on Form 10-K/A, formatted in Inline XBRL.	Filed herewith

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Amendment No. 1 to its Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: September 25, 2020

ESTABLISHMENT LABS HOLDINGS INC.

By: _____ /s/ Juan José Chacón Quirós

Juan José Chacón Quirós
Chief Executive Officer and Director

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Juan José Chacón Quirós</u> Juan José Chacón Quirós	Chief Executive Officer (Principal Executive Officer); Director	September 25, 2020
<u>/s/ Renee M. Gaeta</u> Renee M. Gaeta	Chief Financial Officer (Principal Financial and Accounting Officer)	September 25, 2020
<u>/s/ Nicholas Lewin</u> Nicholas Lewin	Chairman of the Board of Directors	September 25, 2020
<u>/s/ Lisa N. Colleran</u> Lisa N. Colleran	Director	September 25, 2020
<u>/s/ Dennis Condon</u> Dennis Condon	Director	September 25, 2020
<u>/s/ Lisa Gersh</u> Lisa Gersh	Director	September 25, 2020
<u>/s/ David Hung, M.D.</u> David Hung, M.D.	Director	September 25, 2020
<u>/s/ Edward Schutter</u> Edward Schutter	Director	September 25, 2020

INDEX TO EXHIBITS

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104	The cover page from this Amendment No. 1 on Form 10-K/A, formatted in Inline XBRL.	Filed herewith

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Juan José Chacón Quirós, certify that:

1. I have reviewed this quarterly report on Form 10-K/A of Establishment Labs Holdings Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13(a)-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: September 25, 2020

/s/ Juan José Chacón Quirós

Juan José Chacón Quirós

*Chief Executive Officer and Director
(Principal Executive Officer)*

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Renee M. Gaeta, certify that:

1. I have reviewed this quarterly report on Form 10-K/A of Establishment Labs Holdings Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13(a)-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: September 25, 2020

/s/ Renee M. Gaeta

Renee M. Gaeta

Chief Financial Officer

(Principal Financial and Accounting Officer)