
**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**

September 21, 2020

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 1.01 Entry into a Material Definitive Agreement.

On September 21, 2020, Establishment Labs S.A., an affiliate of Establishment Labs Holdings Inc. (the “Company”), and Puregraft LLC (“Puregraft”), entered into a second amendment (the “Amendment”) to that Exclusive Distribution Agreement dated September 7, 2016, as amended, between the Company and Puregraft (the “Distribution Agreement”). The Amendment makes the following principal changes to the Distribution Agreement: (i) extends the term of the Distribution Agreement by an additional two years, (ii) the Company will no longer be the exclusive distributor of Puregraft line of products for autologous adipose tissue harvesting and redistribution in certain countries, (iii) the Company will no longer have any minimum purchase requirements, and (iv) Puregraft will now be able to repurchase a certain amount of inventory back from the Company.

The foregoing description of the Amendment does not purport to be complete and is qualified in its entirety by reference to the complete text of the Amendment, which is filed hereto as Exhibit 10.1 and is incorporated herein by reference.

Item 8.01 Other Events.

The Company issued a press release on September 25, 2020 announcing the Amendment. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
10.1*	Second Amendment to Exclusive Distribution Agreement by and between Establishment Labs S.A. and Puregraft LLC dated September 21, 2020.
99.1	Press Release of Establishment Labs Holdings Inc. dated September 25, 2020.

* Portions of this exhibit are redacted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

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: September 25, 2020

By: /s/ Renee M. Gaeta

Name: Renee M. Gaeta

Title: Chief Financial Officer

Certain identified confidential information contained in this document, marked by brackets, has been excluded from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

SECOND AMENDMENT TO EXCLUSIVE DISTRIBUTION AGREEMENT

This Second Amendment to the Exclusive Distribution Agreement (this “**Second Amendment**”) is made and entered into effective as of September 21, 2020 (the “**Second Amendment Effective Date**”), and is by and between **Puregraft LLC**, a Delaware Limited Liability Company having its primary office and place of business at 420 Steven Avenue, Suite 220, Solana Beach, CA 92075, its parent company Bimini Technologies, LLC, and any affiliate and/or subsidiaries thereto (together, “**Puregraft**”) and **Establishment Labs S.A.**, a company organized under the laws of Costa Rica, having its primary office and place of business at Coyol Free Zone Building 25, Alajuela, Costa Rica (“**Distributor**”) (each a “**Party**” and collectively the “**Parties**”).

RECITALS:

WHEREAS, Puregraft and Establishment Labs Holdings Inc. (“**ELHI**”), an affiliate of Distributor, entered into that certain Exclusive Distribution Agreement dated September 7, 2016 (the “**Original Agreement**”);

WHEREAS, Puregraft, ELHI and Distributor entered into that certain First Amendment to Exclusive Distribution Agreement dated August 9, 2019 (the “**First Amendment**”) and together with the Original Agreement, the “**Agreement**”), pursuant to which (a) ELHI transferred and assigned to Distributor all of ELHI’s right, title and interest in and to the Agreement, (b) Distributor assumed and agreed to perform all of ELHI’s obligations, responsibilities, and duties under the Agreement, and (c) certain other terms of the Agreement were amended;

WHEREAS, Puregraft and Distributor have been in a dispute regarding each Party’s performance obligations under the Agreement for the supply and purchase of Products, and whether Puregraft properly terminated the Agreement (the “**Disputed Performance Obligations**”);

WHEREAS, the Parties have agreed to amicably resolve and settle their dispute by reinstating and further amending the Agreement and releasing any claims either of them may have against the other in connection with the Disputed Performance Obligations, all pursuant to the terms and conditions of this Second Amendment;

NOW, THEREFORE, in consideration of the mutual promises, covenants and agreements hereinafter set forth, and for other good and valuable consideration, the receipt, adequacy, and sufficiency of which is hereby acknowledged, the parties agree as follows:

SECTION 1: DEFINITIONS

Capitalized terms herein used which are not herein defined shall have the respective meanings ascribed to them in the Agreement. All references to the term “Agreement” in the Agreement and this Second Amendment shall be deemed to include the Agreement as amended by this Second Amendment.

SECTION 2: AMENDMENTS TO AGREEMENT

- A. **Term**. Notwithstanding Puregraft’s letter to Distributor dated April 28, 2020 indicating that the Agreement would automatically terminate as of 5:00 pm PT on May 4, 2020, and anything set forth in the Agreement to the contrary, including without limitation, Section 14 thereof, the Parties hereby agree to reinstate the Agreement and all of its terms and conditions except to the extent modified by this Second Amendment and that the Term shall expire on December 31, 2022 and may not be renewed or extended without the mutual written agreement of both Parties, which may be granted or withheld in each Party’s sole discretion. Upon the expiration or early termination of the term of the Agreement, Distributor shall have no rights to market, sell or distribute Products.
- B. **Non-Exclusive Basis**. Notwithstanding anything set forth in the Agreement to the contrary, including without limitation, Section 2 thereof, Distributor’s rights under the Agreement shall, as of the Second Amendment Effective Date be non-exclusive, except for the Exempted Countries (as defined below) in which Distributor’s exclusivity shall continue to apply subject to the terms of the Agreement (as modified by this Second Amendment).

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- C. **Motiva Hybrid Bundle.** Notwithstanding anything set forth in the Agreement to the contrary, except as expressly set forth below, Distributor may not sell or otherwise distribute Products on a stand-alone basis. Instead, all sales and/or distribution of Products by Distributor (and its sub-distributors) under the Agreement shall be limited to Products being bundled and used solely with Motiva® breast implants on a [COMMERCIAL SENSITIVE INFORMATION REDACTED] basis (“**Motiva Hybrid Bundle**”); provided, however, the following exceptions shall apply: [COMMERCIAL SENSITIVE INFORMATION REDACTED]
- D. **No Further Minimum Purchase Requirements.** Notwithstanding anything set forth in the Agreement to the contrary, including without limitation Section 3.2 and the Schedules thereof, there shall be no minimum Product purchase requirements on Distributor for the remainder of the Term and any and all prior unfulfilled minimum purchase requirements under the Agreement (including orders not placed by Distributor, orders that have not been fully delivered to Distributor, or amounts payable to Puregraft for orders, or portions thereof, not accepted by Distributor prior to the Second Amendment Effective Date) are hereby excused and forgiven and no further action shall be taken by either Party in relation thereto. The Parties do not intend for Distributor to purchase any additional Products during the remainder of the term of the Agreement; provided, however, in the event Distributor desires to purchase additional Products from Puregraft during the remainder of the term of the Agreement, the Parties will work in good faith for the purchase/supply of such additional Products pursuant to the terms of the Agreement.
- E. **Puregraft Repurchase of Inventory.** Puregraft agrees to repurchase from Distributor [COMMERCIAL SENSITIVE INFORMATION REDACTED] of Puregraft 250 Products and [COMMERCIAL SENSITIVE INFORMATION REDACTED] of Puregraft 850 Products (collectively the “**Repurchased Products**”), subject to the following:
1. **Pricing:** The re-purchase pricing for Puregraft 250 Products shall be [COMMERCIAL SENSITIVE INFORMATION REDACTED]. The re-purchase pricing for Puregraft 850 Products shall be [COMMERCIAL SENSITIVE INFORMATION REDACTED]. The foregoing prices shall be all-in and inclusive of taxes, tariffs, shipping, or other reasonable amounts.
 2. **Delivery:** The Repurchased Products must be in their original, unopened and non-damaged packaging, and will be delivered, at Distributor’s sole cost and expense (DDP, Incoterms 2020), from Distributor’s Belgium-based warehouse to Puregraft’s distribution center in Germany (“**Delivery**”). Distributor will ship the Repurchased Products no later than ten (10) business days after the Second Amendment Effective Date.
 3. **Shelf-Life:** Each Repurchased Product shall, upon Delivery to Puregraft, have at least twenty-four (24) months of remaining shelf-life.
 4. **Inspection:** Puregraft may inspect any or all shipments of Repurchased Products within ten (10) business days of Puregraft’s receipt of each shipment (the “**Inspection Period**”) to confirm compliance with this Section 2.E., and Puregraft has the right to reject, via notification to Distributor within the Inspection Period, any or all of a shipment of Repurchased Products that fails to satisfy such requirements. In the event Puregraft does not provide notification of rejection prior to the expiration of the Inspection Period, then the applicable Repurchased Products delivered to Puregraft shall be deemed accepted by Puregraft. In the event Puregraft timely rejects any Repurchased Products pursuant to this Section 2.E.iv. (“**Rejected Repurchased Products**”), Distributor may, in its sole discretion, promptly replace the Rejected Repurchased Products with other Repurchased Products (which shall continue to be subject to the terms of the Section 2.E.).
 5. **Invoicing and Payment:** Distributor will invoice Puregraft for the total repurchase price of the Repurchased Products pursuant to this Section 2.E in [COMMERCIAL SENSITIVE INFORMATION REDACTED] equal installments. Distributor will issue the first invoice upon

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Delivery and the remaining [COMMERCIALY SENSITIVE INFORMATION REDACTED] invoices will be issued over the [COMMERCIALY SENSITIVE INFORMATION REDACTED] consecutive calendar quarters following the Second Amendment Effective Date. Puregraft will pay each invoice for accepted Repurchased Products within thirty (30) calendar days of receipt of such invoice.

The Parties acknowledge and agree that, commencing six (6) months after the Second Amendment Effective Date, Puregraft shall, at Distributor's sole discretion, buy back up to an additional [COMMERCIALY SENSITIVE INFORMATION REDACTED] units of Puregraft 250 Products and [COMMERCIALY SENSITIVE INFORMATION REDACTED] units of Puregraft 850 Products from Distributor during the remainder of the Term in accordance with the applicable terms of this Section 2.E. Such additional repurchased Products shall be deemed Repurchased Products hereunder.

- F. Reports and Audit Rights. Within fifteen (15) business days following the end of each calendar quarter during the remaining Term, Distributor will provide to Puregraft, a report detailing its sales and other distribution activities under this Second Amendment. Each such report shall solely (i) identify the Products sold/distributed during such calendar quarter, (ii) minimal, de-identified, general information about the Customer(s), and (iii) shall include the information Distributor reasonably believes necessary to verify Distributor's compliance with the Motiva Hybrid Bundle requirements under Section 2.C. above. The Parties acknowledge and agree that any and all such reports are the Confidential Information of Distributor. Without limiting the foregoing, during the remaining Term, and for a period of one (1) year thereafter ("**Audit Period**"), Distributor will keep and maintain accurate and detailed books and records reasonably necessary for a neutral, mutually agreed upon third party (the "**Report Auditor**") to verify Distributor's compliance with the requirements under this Second Amendment. Puregraft will have the right, no more than once during any twelve (12) month period during the Audit Period, upon fifteen (15) business days' prior written notice to Distributor, to use the Report Auditor to inspect and audit Distributor's books and records during normal business hours and on agreed upon dates for the sole purpose of verifying Distributor's compliance with the requirements under this Second Amendment. The Report Auditor shall enter into confidentiality agreements with Distributor in a form reasonably suitable to Distributor. Each audit engaged by Puregraft will be conducted at Puregraft's expense; provided, however, if any audit reveals that Distributor has failed to comply with the requirements under this Second Amendment, in any material respect, Distributor will reimburse Puregraft for all reasonable costs and expenses incurred by Puregraft in connection with such audit(s). Without limiting any of Puregraft's rights or remedies under the Agreement or otherwise, Distributor shall promptly take all commercially reasonable actions to remedy any non-conformance or non-compliance revealed during an audit.

SECTION 3: RELEASE OF CLAIMS

- A. Release of Claims. Each Party, on behalf of itself and its affiliates, and its and its affiliates' respective officers, directors, stockholders, members, employees, representatives, attorneys, agents, successors, heirs, and assigns (collectively, the "**Releasors**"), hereby fully and forever releases and discharges the other Party and its affiliates, and its and its affiliates' respective officers, directors, stockholders, members, employees, representatives, attorneys, agents, successors, heirs, and assigns (collectively, the "**Releasees**"), from any and all claims, demands, actions, agreements, suits, causes of action, obligations, controversies, debts, costs, attorneys' fees, expenses, damages, judgments, orders and liabilities of whatever kind or nature in law, equity or otherwise, past, present or future, known or unknown, suspected or unsuspected, concerning the Disputed Performance Obligations from the beginning of time until the Second Amendment Effective Date, arising out of or in connection with the Agreement (collectively, the "**Claims**"), except for any claims that cannot be waived by law or claims for enforcement of this release.
- B. Waiver of Other Claims. The Parties acknowledge that there is a possibility that subsequent to the execution of this Second Amendment, a Party may discover facts or incur or suffer claims concerning the Disputed Performance Obligations that were unknown or unsuspected at the time this Second Amendment was executed, and which if known by such Party at that time may have materially affected such Party's decision to agree to the

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release of Claims in this Second Amendment. The Parties acknowledge and agree that by reason of this Second Amendment, and the releases contained in this Section 3, each Party (for itself and on behalf of the applicable Releasers) is assuming any risk of such unknown facts and such unknown and unsuspected claims. Without limiting the generality of the foregoing, in giving the release under this Section 3, which includes claims which may be unknown to a Party at present, each Party acknowledges that it has read and understands Section 1542 of the California Civil Code which reads as follows: “*A general release does not extend to claims that the creditor or releasing party does not know or suspect to exist in his or her favor at the time of executing the release and that, if known by him or her, would have materially affected his or her settlement with the debtor or released party.*” Each Party (for itself and on behalf of the applicable Releasers) hereby expressly waives and relinquishes all rights and benefits under that section and any law of any jurisdiction of similar effect with respect to the release of any unknown or unsuspected claims concerning the Disputed Performance Obligations a Party may have against the other Party and such Party’s Releasees.

- C. **Forbearance of Suit.** Each Party, on behalf of itself and the Releasers, agrees that each Party and its applicable Releasers will forever refrain and forbear from commencing, instituting or prosecuting any lawsuit, action or other proceeding of any kind whatsoever, by way of action, defense, set-off, cross-complaint or counterclaim, against such other Party and its applicable Releasees based on, arising out of, or in connection with any Claim which is released and discharged pursuant to this Section 3.
- D. **No Assignment.** Each Party expressly warrants that the Claims or other rights which are released pursuant to this Section 3 have not been assigned, conveyed or in any manner whatsoever transferred, and will not in the future be transferred, conveyed, or transferred to any other person or entity. If a Party breaches the foregoing warranty, such Party agrees to hold harmless and to indemnify the other Party and such other Party’s Releasees for any damages caused by such breach (including any attorneys’ fees and costs incurred as a result of the breach).
- E. **No Admission of Liability.** The release under this Section 3 is not, and shall not in any way be construed to be, an admission by either Party, or any of their former or current parent companies, successors, assigns, affiliates, subsidiaries, directors, officers, employees and agents, that any one of them has acted wrongfully in any manner and the settlement set forth herein shall not be construed by any person or in any court, agency or tribunal whatsoever as a present or past admission of liability.
- F. **Confidentiality.** The provisions of this Section 3 shall be held in strictest confidence by each Party and shall not be publicized or disclosed in any manner whatsoever; provided, however, that each Party may disclose the provisions of this Section 3 in confidence to its officers, directors, stockholders, members and employees having a need to know, attorneys, accountants, tax preparers, financial advisors, and investors (actual or potential), and each Party may also disclose the provisions of this Section 3 insofar as such disclosure may be necessary to enforce its terms or as otherwise required by law or regulation, including the rules or regulations of any tax authority, the United States Securities and Exchange Commission, or any other similar regulatory agencies in a country other than the United States or of any stock exchange or other securities trading institution.
- G. **No Present Knowledge of Additional Claims.** Each Party represents and warrants to the other that, as of the Second Amendment Effective Date, to the best of such Party’s knowledge, it is not aware of any pending, suspected, or threatened claim against the other Party other than the released Claims.

SECTION 4: MISCELLANEOUS

- A. **Governing Law.** This Second Amendment will be governed by and interpreted in accordance with the laws of the State of California, USA, without reference to its choice of laws rules.
- B. **Unenforceable Terms.** If any provision of this Second Amendment is held by a court of competent jurisdiction to be unenforceable, such provision will be deemed modified and will be interpreted to accomplish the

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objectives of such provision to the greatest extent possible under applicable law and the remaining provisions of this Second Amendment will continue in full force and effect.

- C. Entire Agreement. This Second Amendment and the terms hereof shall constitute the entire agreement between the parties hereto with respect to all of the matters herein and its execution has not been induced by, nor do any of the parties hereto rely upon or regard as material, any representations or writings whatsoever not incorporated herein and made a part hereof.
- D. No Other Amendments. Except as herein set forth, the Agreement has not been modified and, as amended by this Second Amendment, remains of full force and effect. To the extent there are any inconsistencies or ambiguities between the specific subject matter of this Second Amendment and the Agreement, the terms of this Second Amendment shall supersede the Agreement.
- E. Headings. Descriptive headings used herein are used for convenience only and shall not be deemed to affect the meaning or construction of any provisions hereof.
- F. Waiver of Terms. A waiver of any term or condition of this Second Amendment will not be deemed to be, and may not be construed as, a waiver of any other term or condition hereof.
- G. Neutral Construction. This Second Amendment will be construed neutrally, and will not be applied more strictly against one party than another.
- H. Counterparts. This Second Amendment may be executed in two (2) or more counterparts, each of which shall be deemed an original but all of which taken together shall constitute one and the same instrument. Signatures to this Second Amendment transmitted by facsimile, email, portable document format (.pdf) or by any other electronic means intended to preserve the original graphic and pictorial appearance of this Second Amendment shall have the same effect as the physical delivery of the paper document bearing original signatures.

IN WITNESS WHEREOF, the parties hereto have caused this Second Amendment to be executed by their duly authorized representatives as of the Second Amendment Effective Date.

PUREGRAFT LLC

/s/ Bradford A. Conlan

Signature

Bradford A. Conlan

Name

CEO

Title

ESTABLISHMENT LABS S.A.

/s/ Juan José Chacón-Quirós

Signature

Juan José Chacón-Quirós

Name

CEO

Title

Establishment Labs Finalizes Distribution Agreement with Puregraft LLC

SANTA BARBARA, Calif., September 25, 2020 – 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 it has finalized an amendment to its distribution agreement with Puregraft LLC for Puregraft’s line of products for autologous adipose tissue harvesting and redistribution. This amended agreement, which now will continue through the end of 2022, modifies the terms of the original distribution agreement that had terminated earlier this year.

“We are pleased to have reached this modified understanding with Puregraft that will enable us to continue offering the most advanced solution for fat grafting as part of our MotivaHybrid® procedure, giving women the option of a natural breast augmentation utilizing their own adipose tissue and our innovative Motiva Implants®,” said chief executive officer Juan José Chacón-Quirós.

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, and includes statements related our ability to commercialize Motiva Implants and Puregraft. 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 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.

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