

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

Date of Report (Date of Earliest Event Reported): September 1, 2022

**Statera Biopharma, Inc.**  
(Exact Name of Registrant as Specified in Charter)

DELAWARE  
(State or Other Jurisdiction of Incorporation)

001-32954  
(Commission File Number)

20-0077155  
(I.R.S. Employer Identification Number)

2537 Research Boulevard, Suite 201  
Fort Collins, CO 80526  
(Address of Principal Executive Offices and zip code)

(888) 613-8802  
(Registrant's Telephone Number, Including Area Code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.005	STAB	NASDAQ Capital Market

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))

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 2, 2022, Statera Biopharma, Inc. (the “Company”) entered a Binding Letter of Intent (“LOI”) with Lay Sciences, Inc. (“Lay”), pursuant to which the Company will manufacture, and test IgY polyclonal antibody products created by Lay. The LOI provides for an exclusivity period of ninety (90) days (the “Exclusivity Period”) for negotiating and finalizing a definitive agreement (the “Definitive Agreement”). During the Exclusivity Period, which begins from the date of the LOI, Lay will not engage in activities with any third party in relation to the acquisition of the Company.

Pursuant to the LOI, (i) Lay shall complete technology transfer to the Company; and (ii) the Company shall (A) assist Lay in testing its current and future products for activity and purity, In consideration of the manufacturing right granted to the Company by Lay, the Company shall (i) issue 500,000 shares of preferred stock of the Company to Lay and (ii) pay up to \$500,000 to Lay within 30 days of the execution of the LOI.

The foregoing description of the LOI does not purport to be complete and is qualified in its entirety by reference to the full text of the LOI, a copy of which is filed as Ex. 10.1 to this report and is incorporated by reference herein.

### **Item 3.01 Notice of Delisting or Failure to Satisfy a Continued Listing Rule or Standard; Transfer of Listing.**

On September 1, 2022, the Company was notified by the Listing Qualifications Staff (the “Staff”) of The Nasdaq Stock Market LLC (“Nasdaq”) that the Company’s common stock would be subject to delisting due to the Company’s non-compliance with the filing requirement set forth in Nasdaq Listing Rule 5250(c)(1) unless the Company timely requested a hearing before the Nasdaq Hearings Panel (the “Panel”). The Company has not yet filed the Form 10-K for the fiscal year ended December 31, 2021 (“Form 10-K”), or the Forms 10-Q for the quarterly periods ended March 31, 2022 and June 30, 2022 (collectively, “Form 10-Qs”) with the Securities and Exchange Commission. The Company intends to timely request a hearing before the Panel, which request will stay any further action by Nasdaq at least pending the issuance of a decision by the Panel and the expiration of any extension the Panel may grant to the Company following the hearing.

The Company is diligently working to evidence compliance with the filing requirement; however, there can be no assurance that the Panel will determine to continue the Company’s listing or that the Company will be able to evidence compliance with the applicable listing criteria within the period of time that may be granted by the Panel.

The Company expects and intends to submit the Form 10-K and the Form 10-Qs and intends to file the Form 10-K and Form 10-Qs as soon as practicable.

### **Item 3.02 Unregistered Sales of Equity Securities.**

The information contained above in Item 1.01 is hereby incorporated by reference into this Item 3.02 in its entirety. The Company intends to issue shares of preferred stock to Lay pursuant to the exemption from the registration requirements of the Securities Act of 1933, as amended (the “Securities Act”), available under Section 4(a)(2) and/or Rule 506(b) of Regulation D promulgated thereunder.

### **Item 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.**

On September 2, 2022, the Board of Directors of the Company appointed John Kallassy as a director of the Company, effective September 2, 2022, to fill the vacancy created by Randy Saluck’s resignation. Mr. Kallassy will serve in such position until his successor is elected and qualified or until his earlier death, resignation, or removal. Mr. Kallassy will serve as a member of the Board’s audit committee, compensation committee, and nominating and corporate governance committee. The Board has affirmatively determined that Mr. Kallassy is “independent” within the meaning of the listing standards of The Nasdaq Stock Market (“Nasdaq”). In addition, Mr. Kallassy is independent under Nasdaq’s heightened independence standards applicable to audit committee and compensation committee members. The Board also appointed Mr. Kallassy as an “audit committee financial expert” as defined in Item 407(d)(5) of Regulation S-K and Chairperson of the Audit Committee of the Board.

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Mr. Kallassy currently serves as Chief Executive Officer and Board Chairman of biotech company Bactana Corp and Chief Financial Officer of animal health biologics company Torigen Pharmaceuticals, Inc. Mr. Kallassy has more than 25 years' experience in finance and biotech innovation, including roles as CEO of Siemens spinoff Zargis Medical Corp and chief financial officer of Jaguar Health, which he supported through its Nasdaq IPO in 2015. Mr. Kallassy received his bachelor's degree in biology from the State University of New York at Brockport, studied pharmacology at the University of Leeds, and received his MBA from Cornell's Johnson Graduate School of Management.

The Company confirms that (1) there is no family relationship between Mr. Kallassy and any director or executive officer of the Company, (2) there was no arrangement or understanding between Mr. Kallassy and any other person pursuant to which he was elected to his position with the Company, and (3) there is no transaction between Mr. Kallassy and the Company that would require disclosure under Item 404(a) of Regulation S-K.

### Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements that are based on management's beliefs and assumptions and on information currently available to the Company's management. Forward-looking statements include statements regarding the Company's intention to enter into a Definitive Agreement, the Company's intention to request a hearing before the Panel, the Company's ability to file the Form 10-K and the Form 10-Qs with the SEC. Forward-looking statements include statements that are not historical facts and can be identified by terms such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "seek," "should," "will," "would" or similar expressions and the negatives of those terms. The Company's actual results and the timing of events could materially differ from those anticipated in such forward-looking statements as a result of certain risks and uncertainties including those described in more detail in the Company's most recent Annual Report on Form 10-K and other documents on file with the SEC, each of which can be found on the SEC's website, [www.sec.gov](http://www.sec.gov), or the investor relations portion of the Company's website, <https://ir.staterabiopharma.com/financial-information/sec-filings>. Except as required by law, the Company assumes no obligation to update these forward-looking statements, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<b>Exhibit No.</b>	<b>Description</b>
10.1	<a href="#">Binding Letter of Intent, dated September 2, 2022, by and between Statera Biopharma, Inc. and Lay Sciences, Inc.</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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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.

**Statera Biopharma, Inc.**

Date: September 6, 2022

By: /s/ Michael K. Handley

Name: Michael K. Handley

Title: Chief Executive Officer

**CONFIDENTIAL BINDING LETTER OF INTENT**

September 2, 2022

Dr. Satish Chandran  
President & CEO  
Lay Sciences

SUBJECT: BINDING LETTER OF INTENT

Dear Dr. Chandran:

Lay Sciences in (“LAY”) and Statera Biopharma, Inc. (“STAB”) have been discussing a possible collaboration between the two companies to create a program to develop IgY polyclonal antibodies for a multitude of diseases.

Both parties are interested in entering into a definitive collaboration agreement (the “Agreement”) to manufacture and test multiple IgY products for LAY.

In order to expedite the development and execution of the Agreement, we propose that on signing of this LOI, we enter into an exclusive period of negotiation for ninety (90) days to complete the definitive Agreement. Accordingly, on behalf of LAY, I am pleased to provide you with this binding Letter of Intent (“LOI”).

**Proposed Transaction:** STAB and LAY will work on a definitive agreement that will outline a relationship to cooperate to manufacture and test current and future LAY products.

**Collaboration.** The goal of this collaboration is to leverage LAY ’s expertise in IgY drug development, and STAB’s expertise in manufacturing and testing.

2. **Consideration.** For consideration for LAY ’s assistance and finance product development programs, STAB and LAY agree to the following:

- 2.1 LAY will complete an assessment of the GI disease market and provide the assessment to STAB on which indication the Company intends to commercialize.
- a. **Testing:** Through STAB’s subsidiary, ImQuest, STAB will assist LAY in testing their current and future IgY and hyperimmune egg products for activity and purity.
  - b. **Non-Exclusive Manufacturing Rights:** STATERA agrees to provide product to LAY at a cost of no more than LAY’s current manufacturing cost. The manufacturing rights shall be structured as follows:
    - i. **Payments:** Five hundred thousand (500,000) shares in Statera Biopharma preferred stock and \$500,000 in cash within thirty (30) days of the execution of this binding LOI (“Execution Date”) This will be the only preferred class of stock issued by STAB. LAY will work with STAB to transfer the technology for manufacturing the products to STAB and their facilities. Additionally, payments will be made as described in the term sheet from June 9<sup>th</sup> 2022.
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3. **Definitive Manufacturing & Testing Agreement**. STAB will draft the Definitive Agreement (the “Agreement”) between LAY and STAB, and the parties will continue to negotiate, in good faith, the terms thereof.
4. **Public Announcements**. Subject to applicable law, neither party hereto shall make any additional public announcement relating to this transaction until the signing of the collaboration agreement, and any announcements made thereafter will be mutually agreed upon and jointly made by the parties.
5. **Filings and Applications**. Each party shall continue to cooperate fully with the other party in furnishing any necessary information required in connection with (i) the preparation, distribution and filing with the Securities and Exchange Commission (“SEC”), in each case, if necessary, of a proxy statement, an information statement, and any other filing or document required by the SEC, and (ii) the preparation, distribution and filing of any filings, applications and notices which may be required by other federal, state and local governmental or regulatory agencies or stock exchanges in any jurisdiction, including the United States and Canada.
6. **Brokers**. Neither LAY, STAB, nor any of their officers, directors, employees, or stockholders has retained or used, and none of them will retain or use, the services of any broker, finder, or investment banker which would result in the imposition of a fee or any other compensation of any kind to any third-parties in connection with this LOI or the collaboration agreement.
7. **Responsibility and Costs**. Each party will be responsible for their own costs and expenses associated with the transactions contemplated hereby, including, but not limited to, legal fees and costs, and the costs associated with obtaining shareholder, governmental and other third party approvals. Also, STAB will be responsible the funding of the developmental work, including but not limited to GMP manufacturing and product testing.
8. **Exclusivity**. In consideration of STAB’s undertaking the effort of , LAY agrees that for a period of ninety (90) days after the date hereof, it shall not consider, seek or solicit, negotiate with, or engage anyone to seek, solicit, or negotiate on behalf of STAB or its stockholders, or provide or cause to be provided information to, any third party in connection with any proposal or offer with respect to the acquisition of STAB, or all or substantially all of its assets.
9. **Governing Law/Jurisdiction**. This Letter of Intent shall be governed by, and construed in accordance with, the laws of the State of Delaware, without regard to such State’s principles of conflicts of law. The parties’ consent to the jurisdiction of the courts of the United States and Delaware located in such state for the resolution of any dispute relating to this Letter of Intent.
10. **Confidentiality**. LAY and STAB have strict respect for the significant value of each other’s confidential information. LAY and STAB are parties to a Confidential Nondisclosure Agreement dated February 9th, 2022 (“CDA”). By the execution hereof, LAY and STAB agree that the CDA are and remain in effect in accordance with the respective terms, and they reaffirm their respective rights and duties thereunder. If both parties enter into the Agreement, the Agreement will supersede the CDA.
11. **Third Parties**. This Letter of Intent is intended for the sole and exclusive benefit of the parties hereto and their respective successors and controlling persons, and no other person, firm or corporation shall have any third-party beneficiary or other rights hereunder.
12. **Approval and Authority**. The individuals signing this LOI on behalf of the parties have all authority needed to execute this document on their respective behalf.
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13. **Binding Provisions.** Notwithstanding the non-binding nature of this LOI, Sections 8 “Exclusivity” and 10 “Confidentiality” hereof are binding upon the parties and shall be enforceable by them.

14. **Next Steps.** Negotiation Period will begin upon execution of this document. STAB will prepare a first draft of the Agreement. Following the signing of this LOI, the Agreement will be negotiated (the Negotiation Period). The Negotiation Period will begin at the signing of the LOI and will end when the Agreement is fully signed. It is foreseen that the Negotiation Period will last for ninety (90) days, however it is noted that this period may be longer than ninety (90) days, depending on the efficiency of both parties in the activities to be conducted during the Negotiation Period. If the Parties haven't executed the Agreement by the end of the Negotiation Period, the Parties may mutually agree to extend the Negotiation Period upon the payment of appropriate consideration. Both parties agree to negotiate the Agreement in good faith, as expeditiously as reasonable

**This letter is intended to constitute an offer that is binding with respect to Section 8 and Section 10 upon acceptance. Except as specified above, neither party is under any obligation with respect to the subject matter hereof until such time that both parties have executed the Agreement and related agreements, if any, and all conditions set forth therein have been satisfied.**

Statera Biopharma, Inc.

By: /s/ Michael K. Handley  
Name: Michael K. Handley  
Title: President & CEO

Accepted and Agreed as of the date first set forth above.

Lay Sciences, Inc.

DocuSigned by:  
By: Satish Chandran  
Name: Satish Chandran, Ph.D.  
Title: CEO & President