# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**WASHINGTON, DC 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): March 15, 2022**

# Shattuck Labs, Inc.
**(Exact name of registrant as specified in its charter)**

| **Delaware** | **001-39593** | **81-2575858** |
|---|---|---|
| **(State or other jurisdiction of incorporation or organization)** | **(Commission File Number)** | **(I.R.S. Employer Identification Number)** |

**500 W. 5th Street, Suite 1200**
**Austin, TX 78701**
**(Address of principal executive offices including zip code)**

**(512) 900-4690**
**(Registrant's telephone number, including area code)**

**Not Applicable**

**(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 pursuance 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 $0.0001 per share | STTK | The Nasdaq Global Select 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 2.02 Results of Operations and Financial Condition**

On March 15, 2022, Shattuck Labs, Inc. issued a press release announcing its financial results for the three months and year ended December 31, 2021. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

*As provided in General Instruction B.2 of Form 8-K, the information in this Item 2.02 and Exhibit 99.1 incorporated herein shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall such information or Exhibit 99.1 be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.*

**Item 9.01 Financial Statements and Exhibits**

Exhibits

| Exhibit Number | Description of Exhibit |
|---|---|
| 99.1 | Press release issued by Shattuck Labs, Inc. regarding its financial results for the three months and year ended December 31, 2021, dated March 15, 2022. |
| 104 | The cover page from the Company's Current Report on Form 8-K formatted in Inline XBRL. |

**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 thereunto duly authorized.

**Shattuck Labs, Inc.**

Date: March 15, 2022

By: /s/ Dr. Taylor Schreiber

Dr. Taylor Schreiber
*Chief Executive Officer*
*(principal executive officer)*

**Exhibit 99.1**

**Shattuck Labs Reports Fourth Quarter and Full Year 2021 Financial Results and Recent Business Highlights**

*– Presented positive initial dose-escalation clinical data for SL-172154, including high target occupancy, dose-dependent immune activation, and unique safety profile in heavily pretreated cancer patients –*

*– Presented positive initial dose-escalation clinical data for SL-279252, including anti-tumor activity, high target occupancy, and dose-dependent immune activation in heavily pretreated cancer patients –*

**AUSTIN, TX and DURHAM, NC, March 15, 2022** – Shattuck Labs, Inc. (Shattuck) (NASDAQ: STTK), a clinical-stage biotechnology company pioneering the development of bi-functional fusion proteins as a new class of biologic medicine for the treatment of patients with cancer and autoimmune disease, today reported financial results for the fourth quarter and full year ended December 31, 2021 and provided recent business highlights.

"We took a very important step in 2021 toward validating the Agonist Redirected Checkpoint (ARC) platform as a new class of biologic medicine, through sharing initial clinical data from our SL-172154 and SL-279252 programs at the 36th annual meeting of the Society for the Immunotherapy of Cancer. The observation of initial anti-tumor activity and dose-dependent activation of CD40 and OX40 are differentiating features of ARCs that bode well for the next stage of clinical development," said Taylor Schreiber, M.D., Ph.D., and Chief Executive Officer of Shattuck. "With SL-172154, we are pleased with the safety profile, evidence of target saturation, and potent dose-dependent CD40 activation, which prompted our combination strategy aimed to demonstrate significant anti-tumor activity. Based on the clinical data to date and evolving development landscape, we believe SL-172154 could emerge as both a first-in-class and best-in-class CD47 inhibitor and CD40 agonist."

**Fourth Quarter 2021 Recent Business Highlights and Other Recent Developments**

***ARC Clinical-Stage and Preclinical Pipeline***

**SL-172154 (SIRPα-Fc-CD40L)**

- **Announced Initial Data from SL-172154 Phase 1 Dose-Escalation Clinical Trial in Platinum- Resistant Ovarian Cancer Demonstrating Favorable Safety Profile, High Target Occupancy, and Unique Pharmacodynamic Activity at the 36th Annual SITC Meeting:** The Phase 1 trial is an open-label, multi-center, dose-escalation trial to evaluate the safety, tolerability, pharmacokinetics, anti-tumor activity, and pharmacodynamic effects of SL-172154 administered intravenously in patients with platinum- resistant ovarian cancer. Data reported at the 36th Annual SITC Meeting was in 15 evaluable patients, across four dose levels on two schedules: schedule 1 (day 1, 8, 15, 29, then every two weeks) at 0.1 and 0.3 mg/kg and schedule 2 (weekly) at 0.3, 1.0, and 3.0 mg/kg. SL-172154 was well tolerated through 3.0 mg/kg, and no dose-limiting toxicities were observed. Preferential binding to CD47 on leukocytes, compared to red blood cells, was observed and exceeded 80% of CD47 expressing leukocytes in most patients at doses of 1.0 and 3.0 mg/kg. Dose-dependent CD40 receptor occupancy was also observed, which approached 100% of CD40 expressing cells at the 3.0 mg/kg dose level and correlated with multiple signs of CD40 activation. Specifically, dose-dependent margination of CD40 expressing B cells and monocytes was observed following each infusion, and large increases in multiple serum cytokines, including IL-12, were also reported. Shattuck is continuing dose escalation to 10.0 mg/kg.
- **Combination Trial with SL-172154 with Liposomal Doxorubicin Expected to Begin in 2022:** A Phase 1B trial of SL-172154 in combination with liposomal doxorubicin to evaluate safety, tolerability, pharmacokinetics, anti-tumor activity, and pharmacodynamics in patients with advanced, platinum-resistant ovarian cancer is expected to begin enrollment in 2022. Initial combination data from the trial are expected in the first half of 2023. Additional combination trials with SL-172154 in ovarian cancer and novel agents are currently being planned.

- **Initiated Phase 1A/B Clinical Trial in AML and HR-MDS with SL-172154:** Shattuck is conducting a Phase 1A/B clinical trial evaluating the safety, tolerability, pharmacokinetics, anti-tumor activity, and pharmacodynamic effects of SL-172154, as both monotherapy and in combination. In acute myeloid leukemia (AML), Shattuck plans to evaluate SL-172154 in combination with both azacitidine and venetoclax. In both HR-MDS and TP53 mutant AML, Shattuck plans to evaluate SL-172154 in combination with azacitidine. Initial data from the trial are expected in the first half of 2023.
- **Closed Enrollment of Intratumorally Administered SL-172154 Phase 1 Clinical Trial in Squamous Cell Carcinoma of the Head and Neck or Skin to Focus on Intravenous Administration Strategy:** Based on the totality of the safety and biomarker data collected to date in our ongoing Phase 1A clinical trial in ovarian cancer patients, we have decided to focus development of SL-172154 as an intravenously administered product candidate. As of February 24, 2022, Shattuck has closed enrollment of the Phase 1 clinical trial for SL-172154 in patients with squamous cell carcinoma of the head and neck (HNSCC) or skin (CSCC) to further focus all development of SL-172154 as an intravenously administered product candidate. Shattuck did not observe dose-limiting toxicities and did not reach a maximum tolerated dose in this trial. Data from the trial are expected in the first half of 2022. Shattuck may continue further development of HNSCC and/or CSCC in an intravenous administration trial of SL-172154 following selection of a recommended Phase 2 dose in Shattuck's ovarian cancer trial.

**SL-279252 (PD1-Fc-OX40L)**

- **Announced Initial Data from Ongoing SL-279252 Phase 1 Dose-Escalation Clinical Trial in Advanced Solid Tumors Demonstrating Evidence of Anti-Tumor Activity and Dose-Dependent Pharmacodynamic Activity at the 36th Annual SITC Meeting:** The Phase 1 trial is an open-label, multi-center, dose-escalation study to evaluate the safety, tolerability, pharmacokinetics, anti-tumor activity and pharmacodynamic effects of SL-279252 in patients with advanced solid tumors and lymphoma. SL-279252 was well tolerated across a dose-range of 0.0001 mg/kg through 6.0 mg/kg, and dose-dependent margination of CD4+OX40+ T cells was the primary pharmacodynamic effect observed and had not plateaued through the 6.0 mg/kg dose level. Monotherapy anti-tumor activity was observed at doses of 1.0 mg/kg and higher, including a confirmed partial response in a PD-1 and CTLA-4 inhibitor experienced ocular melanoma patient who remained on therapy for over 12 months. Shattuck continues to dose patients, primarily selecting for patients with PD-L1 expressing tumors, at 12.0 mg/kg and plans to continue dose escalation to 24.0 mg/kg, to fully characterize pharmacokinetic, pharmacodynamic, and anti-tumor activity. Additional dose-escalation data from the trial are expected in the second half of 2022.

**Preclinical**

- **Presented Continued Preclinical Development of SL-9258 at the TIGIT Therapies Digital Summit in December 2021:** Preclinical data for SL-9258 (TIGIT-Fc-LIGHT), a dual TIGIT inhibitor and HVEM/LTβR agonist, were presented at the TIGIT Therapies Summit in December 2021. These data, from studies in a mouse model, provided preclinical evidence for anti-tumor activity of the murine equivalent of SL-9258 in PD-1 acquired resistant tumors and increased tumor rejection in comparison to TIGIT blocking antibodies.

**Upcoming Events**

- American Association for Cancer Research Annual Meeting (AACR), April 8-13
    - Poster presentation on the preclinical development of SL-9258
    - Poster presentation on the preclinical development of GADLEN compounds
- Shattuck plans to attend the following investor conferences. Details of the presentations and webcasts will be announced prior to the events.
    - 21st Annual Needham Healthcare Conference, April 11-14
    - 8th Annual Berenberg Conference USA 2022, May 23-25

**Fourth Quarter 2021 Financial Results**

- **Cash Position:** As of December 31, 2021, cash, cash equivalents and short-term investments were $268.8 million, as compared to $335.4 million as of December 31, 2020.
- **Collaboration Revenue:** Revenue for the fourth quarter of 2021, was $30.1 million, as compared to $1.3 million for the fourth quarter of 2020. Revenue for the year ended December 31, 2021 was $30.0 million, as compared to $9.9 million for the year ended December 31, 2020. The increase in revenue was due to the recognition of all remaining deferred revenue related to the Collaboration Agreement with Takeda Pharmaceuticals in the fourth quarter of 2021.
- **Research and Development (R&D) Expenses:** R&D expenses were $16.2 million for the fourth quarter of 2021, as compared to $9.8 million for the fourth quarter of 2020. R&D expenses for the year ended December 31, 2021 were $56.6 million, as compared to $37.5 million for the year ended December 31, 2020. This increase was primarily due to clinical development, personnel-related costs, and laboratory capabilities.
- **General and Administrative (G&A) Expenses:** G&A expenses were $4.6 million for the fourth quarter of 2021, as compared to $3.6 million for the fourth quarter of 2020. General and administrative expenses for the year ended December 31, 2021 were $18.7 million, as compared to $9.4 million for the year ended December 31, 2020. This increase was primarily due to personnel-related costs to support the operational expansion and costs associated with being a public company.
- **Net Income/Loss:** Net income was $7.8 million for the fourth quarter of 2021, or $0.19 per basic share and $0.18 per diluted share, as compared to a net loss of $12.0 million for the fourth quarter of 2020, or $0.31 per basic and diluted share. Net loss for the year ended December 31, 2021 was $45.0 million, or $1.07 per basic and diluted share, as compared to $36.6 million, or $2.36 per basic and diluted share, for the year ended December 31, 2020.

**2022 Financial Guidance**

Shattuck believes its cash, cash equivalents and short-term investments will be sufficient to fund its operations into the second half of 2024, which is beyond results from its Phase 1 clinical trials of SL-172154 and SL-279252. This cash runway guidance is based on the Company's current operational plans and excludes any additional funding that may be received or business development or additional clinical development activities that may be undertaken.

**About SL-172154**
SL-172154 (SIRPα-Fc-CD40L) is an investigational ARC® fusion protein designed to simultaneously inhibit the CD47/SIRPα checkpoint interaction and activate the CD40 costimulatory receptor to bolster an anti-tumor immune response in patients with advanced cancer. Two Phase 1 clinical trials are ongoing, the first for patients with advanced and platinum-resistant ovarian cancer (NCT04406623) and the second for patients with AML and HR-MDS (NCT05275439).

**About SL-279252**

SL-279252 (PD1-Fc-OX40L) is an investigational ARC® fusion protein designed to simultaneously inhibit the PD-1/PD-L1 interaction and activate the OX40 receptor in patients with advanced cancers. A Phase 1 trial in patients with solid tumors and lymphoma is ongoing (NCT03894618).

**About Shattuck Labs, Inc.**

Shattuck Labs, Inc. (NASDAQ: STTK) is a clinical-stage biotechnology company pioneering the development of bi-functional fusion proteins as a new class of biologic medicine for the treatment of patients with cancer and autoimmune disease, with multiple ongoing Phase 1 clinical trials. Compounds derived from Shattuck's proprietary Agonist Redirected Checkpoint, ARC®, platform simultaneously inhibit checkpoint molecules and activate costimulatory molecules within a single therapeutic. The company's SL-172154 (SIRPα-Fc-CD40L) program, which is designed to block the CD47 immune checkpoint and simultaneously agonize the CD40 pathway, is being evaluated in two Phase 1 trials. A second product candidate, SL-279252 (PD1-Fc-OX40L), is being evaluated in a Phase 1 trial in solid tumors or lymphomas. Additionally, the company is advancing a proprietary Gamma Delta T Cell Engager, GADLEN™, platform, which is designed to bridge gamma delta T cells to tumor antigens for the

treatment of patients with cancer. Shattuck has offices in both Austin, Texas and Durham, North Carolina. For more information, please visit: www.ShattuckLabs.com.

**Forward-Looking Statements**
Certain statements in this press release may constitute “forward-looking statements” within the meaning of the federal securities laws, including, but not limited to, our expectations regarding plans for our preclinical studies, clinical trials and research and development programs, the anticipated timing of enrollment of those trials, the anticipated timing of the results from those studies and trials, anticipated timing for preclinical development updates, the potential for additional studies based on current trials and studies, the efficacy and safety of our product candidates, the potential clinical benefit of our product candidates, and expectations regarding the time period over which our capital resources will be sufficient to fund our anticipated operations. Words such as “may,” “might,” “will,” “objective,” “intend,” “should,” “could,” “can,” “would,” “expect,” “believe,” “design,” “estimate,” “predict,” “potential,” “develop,” “plan” or the negative of these terms, and similar expressions, or statements regarding intent, belief, or current expectations, are forward-looking statements. While we believe these forward-looking statements are reasonable, undue reliance should not be placed on any such forward-looking statements, which are based on information available to us on the date of this release. These forward-looking statements are based upon current estimates and assumptions and are subject to various risks and uncertainties (including, without limitation, those set forth in our filings with the U.S. Securities and Exchange Commission (the “SEC”)), many of which are beyond our control and subject to change. Actual results could be materially different. Risks and uncertainties include: the recent and ongoing COVID-19 pandemic; expectations regarding the initiation, progress, and expected results of our preclinical studies, clinical trials and research and development programs; expectations regarding the timing, completion and outcome of our ongoing clinical trials; the unpredictable relationship between preclinical study results and clinical study results; the timing or likelihood of regulatory filings and approvals; liquidity and capital resources; and other risks and uncertainties identified in our Annual Report on Form 10-K for the year ended December 31, 2021, to be filed on March 15, 2022 with the SEC. We claim the protection of the Safe Harbor contained in the Private Securities Litigation Reform Act of 1995 for forward-looking statements. We expressly disclaim any obligation to update or alter any statements whether as a result of new information, future events or otherwise, except as required by law.

The Company intends to use the investor relations portion of its website as a means of disclosing material non-public information and for complying with disclosure obligations under Regulation FD.

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**FINANCIAL INFORMATION**

**SHATTUCK LABS, INC.**
**BALANCE SHEETS**
**(In thousands)**

| | December 31, | |
|---|---|---|
| | **2021** | **2020** |
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 92,268 | $ 157,898 |
| Short-term investments | 176,536 | 177,551 |
| Prepaid expenses and other current assets | 19,462 | 10,190 |
| Total current assets | 288,266 | 345,639 |
| Property and equipment, net | 9,938 | 3,000 |
| Other assets | 381 | 349 |
| Total assets | $ 298,585 | $ 348,988 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 10,012 | $ 1,754 |
| Accrued expenses | 14,574 | 7,352 |
| Deferred revenue - related party | — | 7,728 |
| Total current liabilities | 24,586 | 16,834 |
| Deferred rent | 2,213 | 987 |
| Deferred revenue - related party, net of current portion | — | 21,306 |
| Total liabilities | 26,799 | 39,127 |
| Stockholders' equity: | | |
| Common stock | 5 | 5 |
| Additional paid-in capital | 389,408 | 382,012 |
| Accumulated other comprehensive loss | (560) | (63) |
| Accumulated deficit | (117,067) | (72,093) |
| Total stockholders' equity | 271,786 | 309,861 |
| Total liabilities and stockholders' equity | $ 298,585 | $ 348,988 |

**SHATTUCK LABS, INC.**
**STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**
**(In thousands, except share and per share amounts)**

| | Three Months Ended December 31, (Unaudited) | | Year Ended December 31, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| Collaboration revenue - related party | $ 30,078 | $ 1,342 | $ 30,017 | $ 9,934 |
| Operating expenses: | | | | |
| Research and development | 16,207 | 9,786 | 56,563 | 37,483 |
| General and administrative | 4,624 | 3,567 | 18,723 | 9,382 |
| Expense from operations | 20,831 | 13,353 | 75,286 | 46,865 |
| Gain (loss) from operations | 9,247 | (12,011) | (45,269) | (36,931) |
| | | | | |
| Other income (expense): | | | | |
| Interest income (expense) | (1,321) | 75 | 625 | 549 |
| Other | (79) | (77) | (330) | (221) |
| Total other income (expense) | (1,400) | (2) | 295 | 328 |
| Net income (loss) | $ 7,847 | $ (12,013) | $ (44,974) | $ (36,603) |
| Unrealized gain (loss) on investments | 1,267 | (52) | (497) | (117) |
| Comprehensive gain (loss) | $ 9,114 | $ (12,065) | $ (45,471) | $ (36,720) |
| | | | | |
| Basic and Diluted Per Common Share Data: | | | | |
| Net earnings (loss) per share - basic | $ 0.19 | $ (0.31) | $ (1.07) | $ (2.36) |
| Weighted-average shares outstanding - basic | 42,286,190 | 38,800,057 | 42,032,384 | 15,506,067 |
| Net earnings (loss) per share - diluted | $ 0.18 | $ (0.31) | $ (1.07) | $ (2.36) |
| Weighted-average shares outstanding - diluted | 44,734,866 | 38,800,057 | 42,032,384 | 15,506,067 |