



# Shattuck Labs Reports Third Quarter 2022 Financial Results and Recent Business Highlights

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- Completed enrollment in Phase 1 dose-escalation clinical trial of SL-172154 as monotherapy in platinum-resistant ovarian cancer; complete data expected midyear 2023 -*
- Dosed first patient in ongoing Phase 1B clinical trial of SL-172154 in combination with liposomal doxorubicin in platinum-resistant ovarian cancer; initial combination data expected midyear 2023 -*
- Announced plans to present updated preclinical data from Gamma Delta T Cell Engager (GADLEN) platform preclinical product candidates at the Society for Immunotherapy of Cancer (SITC) Annual Meeting in November -*

AUSTIN, TX and DURHAM, NC, Nov. 08, 2022 (GLOBE NEWSWIRE) -- 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 quarter ended September 30, 2022 and provided recent business highlights.

"We are pleased to have completed the monotherapy dose-escalation trial with SL-172154 in platinum-resistant ovarian cancer and to have advanced to the combination phase of clinical development for SL-172154 in both platinum-resistant ovarian cancer and AML and HR-MDS," said Taylor Schreiber, M.D., Ph.D., and Chief Executive Officer of Shattuck. "This year we have significantly expanded our clinical trial footprint to enable steady execution of our clinical studies and are looking forward to the opportunity for SL-172154 to differentiate from other CD47 inhibitors over the course of a data-rich 2023. Beyond our clinical-stage product candidates, we have progressed our gamma delta T cell engager (GADLEN) platform and published key preclinical data which will guide our clinical strategy. We expect to provide additional updates later this month at the SITC annual meeting."

## **Third Quarter 2022 Recent Business Highlights and Other Recent Developments**

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

## SL-172154 (SIRP $\alpha$ -Fc-CD40L) Program Update

- **Completed Enrollment and Study Objectives in Phase 1 Monotherapy Dose-Escalation Clinical Trial of SL-172154 in Platinum-Resistant Ovarian Cancer:** This open-label, multi-center, dose-escalation clinical trial evaluated the safety, tolerability, pharmacokinetics, anti-tumor activity, and pharmacodynamic effects of SL-172154 administered intravenously in patients with advanced platinum-resistant ovarian cancer. We reached a maximum administered dose of 10.0 mg/kg and completed enrollment of additional patients at 3.0 mg/kg with an extended infusion time. We expect to present complete dose-escalation data from the trial midyear 2023.
- **First Patient Dosed in Combination Trial of SL-172154 with Liposomal Doxorubicin in Advanced Platinum-Resistant Ovarian Cancer:** Enrollment is continuing in this trial, which is evaluating the safety, tolerability, pharmacokinetics, anti-tumor activity, and pharmacodynamic effects of SL-172154, starting at 3.0 mg/kg, in combination with liposomal doxorubicin in patients with advanced platinum-resistant ovarian cancer. We expect to present initial data from the trial midyear 2023.
- **Enrollment Progressing in Phase 1A/B Clinical Trial of in SL-172154 in AML and HR-MDS:** This trial is evaluating the safety, tolerability, pharmacokinetics, anti-tumor activity, and pharmacodynamic effects of SL-172154 as both monotherapy and in combination with azacitidine in a parallel staggered dose escalation. Patients have been dosed in the initial monotherapy cohorts of this trial and enrollment in the azacitidine combination cohorts is expected to begin in the fourth quarter of 2022. Initial dose-escalation data from both monotherapy and azacitidine combination cohorts are expected in the first half of 2023.

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

- **Continued Enrollment of SL-279252 Phase 1 Dose-Escalation Clinical Trial in Advanced Solid Tumors:** Enrollment of patients with primarily PD-L1 selected tumors continues in the Phase 1 open-label, multi-center, dose-escalation clinical trial to evaluate the safety, tolerability, pharmacokinetics, anti-tumor activity and pharmacodynamic effects of SL-279252 in patients with advanced solid tumors and lymphoma. Top-line data from the Phase 1 trial are anticipated in the first quarter of 2023.

## GADLEN

- **Preclinical Candidates from GADLEN Platform Continue to Advance:** We have developed both CD20-directed and B7H3-directed GADLEN product candidates. Additional preclinical data on both programs will be presented at the annual SITC conference in November. We plan to provide additional clinical development detail and further program guidance in 2023.

## Upcoming Events

- **37<sup>th</sup> Annual SITC Annual Meeting:** Updated preclinical data on Gamma Delta T Cell Engager (GADLEN) platform candidates to be presented at Society for Immunotherapy of Cancer (SITC) Annual Meeting taking place in Boston on November 8-12, 2022.
- **Cowen's 6th Annual IO Next Summit:** Management will participate in a fireside chat with covering analyst Marc Frahm at Cowen's Annual IO Next Conference taking place virtually on November 11, 2022.
- **5<sup>th</sup> Annual Evercore ISI HealthCONx Conference:** Management will participate in investor one-on-one meetings and a fireside chat with covering analyst Jonathan Miller at the Evercore ISI HealthCONx Conference taking place virtually on November 30 - December 1, 2022.

- **34th Annual Piper Sandler Healthcare Conference:** Management will participate in investor one-on-one meetings and present a corporate update at the Annual Piper Sandler Healthcare Conference taking place in New York City on November 29 - December 1, 2022.
- Live and archived audio webcasts of the fireside chats and presentation will be available on the Events & Presentations section of the Company's website.

### Third Quarter 2022 Financial Results

- **Cash Position:** As of September 30, 2022, cash and cash equivalents and investments were \$185.1 million, as compared to \$268.8 million as of December 31, 2021.
- **Research and Development (R&D) Expenses:** R&D expenses for the quarter ended September 30, 2022 were \$18.9 million, as compared to \$15.1 million for the quarter ended September 30, 2021. This increase was primarily driven by increases in clinical costs, including clinical site and contract research organization costs, to support clinical development of SL-172154, lab supplies, and personnel-related costs.
- **General and Administrative (G&A) Expenses:** G&A expenses for the quarter ended September 30, 2022 were \$6.6 million, as compared to \$4.3 million for the quarter ended September 30, 2021. This increase was primarily driven by a litigation settlement of \$1.4 million and increases in personnel-related and other operating costs.
- **Net Loss:** Net loss was \$24.6 million for the quarter ended September 30, 2022, or \$0.58 per basic and diluted share, as compared to a net loss of \$17.4 million for the quarter ended September 30, 2021, or \$0.41 per basic and diluted share.

### 2022 Financial Guidance

Shattuck believes its cash and cash equivalents and investments will be sufficient to fund its operations into the second half of 2024, 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, proceeds from business development transactions, or additional costs associated with clinical development activities that may be undertaken.

#### About SL-172154

SL-172154 (SIRP $\alpha$ -Fc-CD40L) is an investigational ARC® fusion protein designed to simultaneously inhibit the CD47/SIRP $\alpha$  checkpoint interaction and activate the CD40 costimulatory receptor to bolster an anti-tumor immune response in patients with advanced cancer. Phase 1 clinical trials are ongoing for patients with advanced platinum-resistant ovarian cancer (NCT05483933) and 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. Compounds derived from Shattuck's proprietary

Agonist Redirected Checkpoint, ARC®, platform simultaneously inhibit checkpoint molecules and activate costimulatory molecules with 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 multiple 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](http://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 for enrollment of our clinical trials, the anticipated timing of the results from our preclinical studies and clinical trials, anticipated timing for preclinical development updates, 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 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, and subsequent disclosure documents filed 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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## PART I - FINANCIAL INFORMATION

## Item 1. Financial Statements

### SHATTUCK LABS, INC. BALANCE SHEETS

(In thousands)

	<b>September 30, 2022 (unaudited)</b>	<b>December 31, 2021</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 39,758	\$ 92,268
Investments	145,356	176,536
Prepaid expenses and other current assets	16,402	19,462
Total current assets	<u>201,516</u>	<u>288,266</u>
Property and equipment, net	18,242	9,938
Other assets	3,185	381
Total assets	<u>\$ 222,943</u>	<u>\$ 298,585</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 3,036	\$ 10,012
Accrued expenses and other current liabilities	16,103	14,574
Total current liabilities	<u>19,139</u>	<u>24,586</u>
Non-current operating lease liabilities	4,386	—
Deferred rent	—	2,213
Total liabilities	<u>23,525</u>	<u>26,799</u>
Stockholders' equity:		
Common stock	5	5
Additional paid-in capital	394,348	389,408
Accumulated other comprehensive loss	(1,334)	(560)
Accumulated deficit	<u>(193,601)</u>	<u>(117,067)</u>
Total stockholders' equity	<u>199,418</u>	<u>271,786</u>
Total liabilities and stockholders' equity	<u>\$ 222,943</u>	<u>\$ 298,585</u>

### SHATTUCK LABS, INC. STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (Unaudited)

(In thousands, except share and per share amounts)

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2022</b>	<b>2021</b>	<b>2022</b>	<b>2021</b>
Collaboration revenue	\$ 212	\$ 1,900	\$ 262	\$ (61)
Operating expenses:				
Research and development	<u>18,862</u>	<u>15,137</u>	<u>61,012</u>	<u>40,356</u>

General and administrative	<u>6,579</u>	<u>4,343</u>	<u>16,303</u>	<u>14,098</u>
Expense from operations	<u>25,441</u>	<u>19,480</u>	<u>77,315</u>	<u>54,454</u>
Loss from operations	<u>(25,229)</u>	<u>(17,580)</u>	<u>(77,053)</u>	<u>(54,515)</u>
Other income	<u>594</u>	<u>170</u>	<u>519</u>	<u>1,694</u>
Net loss	<u>\$ (24,635)</u>	<u>\$ (17,410)</u>	<u>\$ (76,534)</u>	<u>\$ (52,821)</u>
Unrealized loss on investments	<u>(226)</u>	<u>(207)</u>	<u>(774)</u>	<u>(1,764)</u>
Comprehensive loss	<u>\$ (24,861)</u>	<u>\$ (17,617)</u>	<u>\$ (77,308)</u>	<u>\$ (54,585)</u>
Net loss per share – basic and diluted	<u>\$ (0.58)</u>	<u>\$ (0.41)</u>	<u>\$ (1.81)</u>	<u>\$ (1.26)</u>
Weighted-average shares outstanding – basic and diluted	42,386,470	42,155,981	42,374,955	41,946,852

Source: Shattuck Labs, Inc.