Surrozen Reports Third Quarter 2022 Financial Results and Provides Corporate Update

November 14, 2022

SOUTH SAN FRANCISCO, Calif., Nov. 14, 2022 (GLOBE NEWSWIRE) -- Surrozen, Inc. ("Surrozen" or the "Company") (Nasdaq: SRZN), a company pioneering targeted therapeutics that selectively activate the Wnt pathway for tissue repair and regeneration, today reported financial results for the third quarter of 2022 and provided a corporate update.

SZN-1326 Update
Surrozen announced today that it voluntarily paused enrollment in the single ascending dose (SAD) portion of the Company's Phase 1 clinical trial evaluating SZN-1326 in healthy volunteers following the observation of treatment-related adverse events. Several subjects experienced asymptomatic liver transaminase elevations, including three subjects with grade 3 ALT and AST elevations. There were no corresponding increases in total bilirubin nor any changes in liver function markers such as coagulation markers or albumin. No other clinically significant laboratory abnormalities were observed, and the transaminase elevations resolved spontaneously in all subjects. No serious adverse events were observed during the study. SZN-1326 is a Wnt mimetic bi-specific antibody that selectively activates the Wnt pathway and is in development for treatment of patients with ulcerative colitis

Surrozen intends to further analyze available clinical data with the study investigator and conduct additional pre-clinical experiments to identify the potential mechanism of the transaminase elevations, which had not been observed in the GLP-toxicology studies, and determine next steps in the development program.

SZN-043 Update
The Phase 1 SAD portion of the SZN-043 trial in healthy volunteers is ongoing. Grade 1 and 2 treatment-related asymptomatic liver transaminase elevations were present in several subjects dosed with SZN-043. There were no corresponding increases in total bilirubin or GGT nor any changes in liver function markers such as coagulation markers or albumin in these subjects. No other clinically significant laboratory abnormalities were observed, and the transaminase increases for these subjects resolved spontaneously. No serious adverse events were observed during the study. Surrozen will be re-evaluating the overall clinical development timeline for this program and will provide an update at the appropriate time.

"We are grateful to the participants and study investigators for their involvement in our clinical studies," said Craig Parker, President and Chief Executive Officer of Surrozen. "We will continue to analyze the data from the initial portion of our Phase 1 studies, expand our pre-clinical research into the potential mechanisms of the observed adverse events and plot a course that reflects our commitment to patient safety and the potential for our technologies to address significant unmet medical need. Accordingly, we will be conducting a review of our financial resources and prioritization of our research pipeline."

SZN-413 for Vascular-associated Retinopathies, including Diabetic Retinopathy and Diabetic Macular Edema, recently partnered to Boehringer Ingelheim
SZN-413, a Fzd4-targeted bi-specific antibody, also using Surrozen's SWAP™ technology, has the potential to treat retinal vascular associated diseases including diabetic retinopathy and diabetic macular edema. Surrozen recently entered into a strategic partnership with Boehringer Ingelheim for the research and development of SZN-413 for the treatment of retinal diseases. Under the terms of the agreement, Boehringer Ingelheim will receive an exclusive, worldwide license to develop SZN-413 and other Fzd4-specific Wnt-modulating molecules for all purposes, including as a treatment for retinal diseases, in exchange for an upfront payment to Surrozen of $12.5 million. Surrozen will also be eligible to receive up to $586.5 million in success-based development, regulatory, and commercial milestone payments, in addition to mid-single digit to low-double digit royalties on sales. After an initial period of joint research, Boehringer Ingelheim will assume all development and commercial responsibilities.

Financial Results for the Third Quarter Ended September 30, 2022

Cash Position: Cash, cash equivalents and marketable securities for the third quarter ended September 30, 2022 were $78.4 million, compared to $92.7 million as of June 30, 2022. In connection with the Collaboration and License Agreement executed in October 2022, we will receive non-refundable gross proceeds of $12.5 million, before deducting the related fees of $1.3 million to be paid to academic institutions.

Research and Development Expenses: Research and development expenses for the third quarter ended September 30, 2022 were $8.6 million, as compared to $10.4 million for the same period in 2021. The decrease was primarily due to the completion of manufacturing drug substance for SZN-1326 and SZN-043 in 2021. Research and development expenses include non-cash stock-based compensation expenses of $0.4 million for the third quarter ended September 30, 2022, as compared to $0.2 million for the same period in 2021.

General and Administrative Expenses: General and administrative expenses for the third quarter ended September 30, 2022 were $5.0 million, as compared to $3.3 million for the same period in 2021. The increase was primarily related to employee-related expenses, including stock-based compensation expenses, insurance costs and professional service fees, supporting the growth in our operations and costs associated with being a public company. General and administrative expenses include non-cash stock-based compensation expenses of $0.7 million for the third quarter ended September 30, 2022, as compared to $0.4 million for the same period in 2021.

Interest Income: Interest income for the third quarter ended September 30, 2022 was $0.2 million, as compared to $14,000 for the same period in 2021. The increase was primarily related to the increase in interest rates on our money market funds and marketable securities.

Other Income (Expense), Net: Other income (expense), net for the third quarter ended September 30, 2022 was a net other income of $50,000, as compared to a net other expense of $0.3 million for the same period in 2021. The variance was primarily related to the warrant liabilities transaction costs incurred during the three months ended September 30, 2021 in connection with the business combination consummated in August 2021.

Net Loss: Net loss for the third quarter ended September 30, 2022 was $13.4 million, as compared to $14.0 million for the same period in 2021.

About SZN-1326 for Ulcerative Colitis
SZN-1326 is the first development candidate designed using Surrozen's SWAP™ technology and targets the Wnt-signaling pathway in the intestinal epithelium. Surrozen is initially developing SZN-1326 for moderate to severe ulcerative colitis. Dosing of healthy volunteers in a three-part Phase 1 clinical trial began in May 2022 and was paused in the fourth quarter of 2022 to further understand the observed transaminase elevations. Surrozen published in *Cellular and Molecular Gastroenterology* in 2022, findings demonstrating that SZN-1326 showed the most rapid and robust repair of the injured colon epithelium of evaluated molecules, without affecting normal epithelium and without causing hyperplasia.

About SZN-043 for Severe Alcoholic Hepatitis
SZN-043 is the first development candidate using Surrozen's SWEETS™ technology. Surrozen is developing SZN-043 for severe liver diseases, initially focusing on severe alcoholic hepatitis. Dosing of healthy volunteers in a Phase 1 clinical trial began in June 2022.

About Wnt Signaling
Wnt signaling plays key roles in the control of development, homeostasis, and regeneration of many essential organs and tissues, including liver, intestine, lung, kidney, retina, central nervous system, cochlea, bone and others. Modulation of Wnt signaling pathways has potential for treatment of degenerative diseases and tissue injuries. Surrozen's platform and proprietary technologies have the potential to overcome the limitations in pursuing the Wnt pathway as a therapeutic strategy.

About Surrozen
Surrozen is a clinical stage biotechnology company discovering and developing drug candidates to selectively modulate the Wnt pathway. Surrozen is developing tissue-specific antibodies designed to engage the body's existing biological repair mechanisms with potential application across multiple disease areas, including inflammatory bowel disease, hepatitis, eye diseases, hearing loss, lung and airway diseases, and certain neurological disorders. For more information, please visit surrozen.com.

Forward Looking Statements
This press release contains certain forward-looking statements within the meaning of the federal securities laws. Forward-looking statements generally are accompanied by words such as "will," "plan," "intend," "potential," "expect," "could," or the negative of these words and similar expressions that predict or indicate future events or trends or that are not statements of historical matters. These forward-looking statements include, but are not limited to, statements regarding Surrozen's discovery, research and development activities, in particular its development plans for its product candidates SZN-1326, SZN-043, and SZN-413, including anticipated clinical development timelines, and the potential for such product candidates to be used to treat human disease. These statements are based on various assumptions, whether or not identified in this press release, and on the current expectations of the management of Surrozen and are not predictions of actual performance. These forward-looking statements are provided for illustrative purposes only and are not intended to serve as, and must not be relied on as, a guarantee, an assurance, a prediction, or a definitive statement of fact or probability. Actual events and circumstances are difficult or impossible to predict and will differ from assumptions. Many actual events and circumstances are beyond the control of Surrozen. These forward-looking statements are subject to a number of risks and uncertainties, including the initiation, cost, timing, progress and results of research and development activities, preclinical or and clinical trials with respect to SZN-1326, SZN-043, SZN-413 and potential future drug candidates, including our ability to resume clinical trials for SZN-1326; our ability to fund our clinical trials and development efforts, whether with existing funds or through additional fundraising; Surrozen's ability to identify, develop and commercialize drug candidates; Surrozen's ability to successfully complete preclinical and clinical studies for SZN-1326, SZN-043, SZN-413, or other future product candidates; the effects that arise from volatility in global economic, political, regulatory and market conditions, which may be adversely affected by the conflict between Russia and Ukraine; the ongoing coronavirus (COVID-19) pandemic; and all other factors discussed in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2022 under the heading "Risk Factors," our Annual Report on Form 10-K for the year ended December 31, 2021 and other documents Surrozen has filed, or will file, with the Securities and Exchange Commission. If any of these risks materialize or our assumptions prove incorrect, actual results could differ materially from the results implied by these forward-looking statements. There may be additional risks that Surrozen presently does not know, or that Surrozen currently believes are immaterial, that could also cause actual results to differ from those contained in the forward-looking statements. In addition, forward-looking statements reflect Surrozen's expectations, plans, or forecasts of future events and views as of the date of this press release. Surrozen anticipates that subsequent events and developments will cause its assessments to change. However, while Surrozen may elect to update these forward-looking statements at some point in the future, Surrozen specifically disclaims any obligation to do so, except as required by law. These forward-looking statements should not be relied upon as representing Surrozen's assessments of any date subsequent to the date of this press release. Accordingly, undue reliance should not be placed upon the forward-looking statements.

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SURROZEN, INC.
Condensed Consolidated Statements of Operations
(In thousands, except per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Operating expenses:				

Research and development	$ 8,624	$ 10,418	$ 27,576	$ 29,284
General and administrative	4,981	3,287	14,594	10,112
Total operating expenses	13,605	13,705	42,170	39,396
Loss from operations	(13,605)	(13,705)	(42,170)	(39,396)
Interest income	198	14	307	30
Other income (expense), net	50	(328)	6,634	(328)
Net loss	$ (13,357)	$ (14,019)	$ (35,229)	$ (39,694)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.38)	$ (0.51)	$ (1.01)	$ (1.86)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	34,968	27,402	34,926	21,291

SURROZEN, INC.
Condensed Consolidated Balance Sheets
(In thousands)

	September 30, 2022	December 31, 2021[1]
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 25,531	$ 33,091
Short-term marketable securities	52,864	68,760
Prepaid expenses and other current assets	4,324	3,338
Total current assets	82,719	105,189
Property and equipment, net	3,906	4,794
Operating lease right-of-use assets	3,558	4,582
Long-term marketable securities	—	21,655
Restricted cash	405	405
Other assets	846	549
Total assets	$ 91,434	$ 137,174
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 362	$ 2,718
Accrued and other liabilities	6,133	8,662
Lease liabilities, current portion	2,159	2,193
Total current liabilities	8,654	13,573
Lease liabilities, noncurrent portion	3,957	5,600
Warrant liabilities	1,332	8,301
Total liabilities	13,943	27,474
Stockholders' equity:		
Preferred stock	—	—
Common stock	4	4
Additional paid-in capital	255,789	252,464
Accumulated other comprehensive loss	(424)	(119)
Accumulated deficit	(177,878)	(142,649)
Total stockholders' equity	77,491	109,700
Total liabilities and stockholders' equity	$ 91,434	$ 137,174

[1] Derived from the audited financial statements, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2021.