
**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): November 06, 2024

Surrozen, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-39635
(Commission File Number)

30-1374889
(IRS Employer
Identification No.)

171 Oyster Point Blvd
Suite 400
South San Francisco, California
(Address of Principal Executive Offices)

94080
(Zip Code)

Registrant's Telephone Number, Including Area Code: +1 (650) 489-9000

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(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value per share	SRZN	The Nasdaq Capital Market
Redeemable warrants, each whole warrant exercisable for one-fifteenth of a share of Common Stock	SRZNW	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 2.02 Results of Operations and Financial Condition.

On November 6, 2024, Surrozen, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended September 30, 2024. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information set forth under this “Item 2.02. Results of Operations and Financial Condition” (including the exhibit referenced herein) shall not be deemed to be “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be incorporated by reference in any filing made by the Company pursuant to the Securities Act of 1933, as amended.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Surrozen, Inc. dated November 6, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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.

SURROZEN, INC.

Date: November 6, 2024

By: /s/ Charles Williams

Name: Charles Williams

Title: Chief Financial Officer, Chief Operating Officer and Corporate Secretary

Surrozen Provides Third Quarter 2024 Financial Results and Business Update

Substantial enrollment progress in Phase 1b trial of SZN-043 in severe alcohol-associated hepatitis patients with proof-of-concept data expected in the first half of 2025

Nominated novel portfolio of preclinical ophthalmology product candidates to R&D pipeline

Received \$10 million milestone payment from Boehringer Ingelheim strategic collaboration on SZN-413 in retinal vascular associated diseases

SOUTH SAN FRANCISCO, Calif., November 6, 2024 (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 provided third quarter 2024 financial results and business updates.

"In the third quarter, we made substantial progress on enrolling patients in the SZN-043 Phase 1b trial, received notification that Boehringer planned to further develop SZN-413 to advance the compound and prepare it for clinical testing and nominated a portfolio of novel preclinical ophthalmology candidates," said Craig Parker, President and Chief Executive Officer of Surrozen. "More recently, we also announced a research collaboration with TCGFB to utilize Surrozen's antibody development capabilities and expertise to discover antibodies targeting TGF- β . We remain focused on transforming the treatment of severe diseases of the liver and eye through leveraging our research capabilities and expertise in antibody engineering technologies."

Research and Development Pipeline Highlights

SZN-043
Surrozen is developing SZN-043 for severe liver disease with an initial focus on severe alcohol-associated hepatitis. The Phase 1b study is enrolling patients and the Company expects proof-of-concept data in the first half of 2025. The study is being conducted at nine sites in five countries.

Surrozen successfully completed dosing and 30-day follow-up for cohort 1 in its Phase 1b trial of SZN-043 in severe alcohol-associated hepatitis (sAH). No drug related serious adverse events (SAEs) were observed in the first cohort of six patients receiving 0.5mg/kg of SZN-043. There were no patient deaths at day 30 of the study, and the company observed a potential clinical benefit based on reductions in bilirubin and MELD score. A majority of patients experienced improvements in AST and ALT levels. Surrozen expects to present data from the Phase 1b study at an upcoming liver disease conference.

"Published data in the severe alcohol-associated hepatitis population indicates an expected mortality rate of approximately 15 to 20% at day 30 and absence of any improvement in

markers of liver physiology such as bilirubin”, said Craig Parker, President and Chief Executive Officer of Surrozen. “We are encouraged to see that SZN-043 is safe at the first dose level in the study and showing signs of providing a clinical benefit to patients. We’re also looking forward to data from additional higher dose cohorts of sAH patients in the study. This preliminary data appears to indicate SZN-043’s mechanism of stimulating hepatocyte specific regeneration in the liver through Wnt signaling translates to beneficial changes in liver function and potentially clinical benefit.”

Nominated Novel Portfolio of Ophthalmology Preclinical Product Candidates to R&D Pipeline

Surrozen developed multiple novel ophthalmology product candidates targeting Fzd4 leveraging the Company’s antibody research capabilities and expertise in antibody engineering technologies. Wnt signaling has been implicated in multiple diseases and tissues in the eye. These product candidates do not fall within the scope of the partnership with BI and are wholly owned by Surrozen.

Product Candidates SZN-8141 and SZN-8143

Data generated in preclinical models of retinopathy demonstrated that SZN-8141 and SZN-8143 stimulated Wnt signaling and induced normal retinal vessel regrowth while suppressing pathological vessel growth.

- SZN-8141 combines Frizzled 4 (Fzd4) agonism and Vascular Endothelial Growth Factor (VEGF) antagonism which has the potential to provide benefits over treatment with single agents for Diabetic Macular Edema (DME) and neovascular Age Related Macular Degeneration (wet AMD)
- SZN-8143: combines Fzd4 agonism, VEGF antagonism, and interleukin-6 (IL-6) antagonism which may have benefits over single agents for treatment of DME/wet AMD/uveitic macular edema (UME)

Product Candidate SZN-113

SZN-113 targets Fzd127 and is in development for Fuchs’ Endothelial Corneal Dystrophy (FECD) and Geographic Atrophy (GA).

- FECD preclinical models: SZN-113 enhanced proliferation of primary human corneal endothelial cells *in vitro*, demonstrated evidence of wound healing in acute corneal endothelial injury models, and rapidly reduced central corneal thickness along with demonstrating improved corneal clarity in a cryoinjury model in mouse and rabbit.
 - GA preclinical models: Fzd127 molecules stimulated retinal pigment epithelium cell proliferation and differentiation in culture and provided neuroprotection in acute injury and progressive degeneration models of photoreceptor degeneration.
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Corporate Updates

Corporate Partnerships

Surrozen executed a partnership with Boehringer Ingelheim (BI) in the fourth quarter of 2022 to develop a Wnt agonist, SZN-413, for the treatment of people with retinal diseases.

In September 2024, Surrozen announced that Boehringer Ingelheim will further develop SZN-413 to advance the compound and prepare it for clinical testing. The milestone achievement triggered a \$10 million payment to Surrozen as part of the agreement. This milestone payment was received in October 2024.

Research Collaboration with TCGFB

In November, Surrozen announced a strategic research collaboration with privately-held TCGFB, Inc. ("TCGFB") to discover antibody therapeutics targeting Transforming Growth Factor Beta (TGF- β) for the potential treatment of patients with idiopathic pulmonary fibrosis (IPF). TCGFB will own all TGF- β product related intellectual property. Under the terms of the agreement, Surrozen will provide antibody discovery services for a period of up to two years. In exchange for Surrozen's research services, TCGFB will pay Surrozen up to \$6 million in the aggregate, plus any third-party costs, and will issue Surrozen a warrant for up to 3,380,000 shares of TCGFB common stock at an exercise price of \$0.0001 per share based on certain vesting conditions.

Financial Results for the Second Quarter Ended September 30, 2024

Cash Position: Cash and cash equivalents were \$31.0 million as of September 30, 2024, compared to \$37.8 million as of June 30, 2024. In addition, Surrozen received a \$10 million milestone payment from BI in October 2024.

Collaboration and License Revenue: Collaboration and license revenue for the third quarter ended September 30, 2024 was \$10.0 million, as compared to zero for the same period in 2023. The increase was due to the recognition of a milestone achieved under the collaboration and license agreement with BI in September 2024.

Research and Development Expenses: Research and development expenses for the third quarter ended September 30, 2024 were \$5.2 million, as compared to \$6.1 million for the same period in 2023. The decrease was primarily due to the restructuring executed in 2023 to prioritize and focus our resources on clinical stage programs, as well as the discontinuation of the clinical development of SZN-1326. Research and development expenses include non-cash stock-based compensation expenses of \$0.3 million for the third quarter ended September 30, 2024, as compared to \$0.2 million for the same period in 2023.

General and Administrative Expenses: General and administrative expenses were \$3.6 million for both the third quarter ended September 30, 2024 and 2023. General and

administrative expenses include non-cash stock-based compensation expenses of \$0.7 million for both the third quarter ended September 30, 2024 and 2023.

Restructuring: Restructuring charges for the third quarter ended September 30, 2024 were zero, as compared to \$1.5 million for the same period in 2023. The decrease was attributable to a restructuring plan implemented in 2023.

Interest Income: Interest income for the third quarter ended September 30, 2024 was \$0.4 million, as compared to \$0.7 million for the same period in 2023. The decrease was primarily related to the decrease in our cash equivalents and marketable securities.

Other (Expense) Income, Net: Other (expense) income, net for the third quarter ended September 30, 2024 was a net other expense of \$3.1 million, as compared to a net other income of \$0.1 million for the same period in 2023. The variance was primarily related to the non-cash change in fair value of warrant liabilities.

Net Loss: Net loss for the third quarter ended September 30, 2024 was \$1.4 million, as compared to \$10.4 million for the same period in 2023.

About SZN-043 for Severe Alcohol-Associated 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 alcohol-associated hepatitis. The Company has completed the Phase 1a clinical trial in patients with chronic liver disease and healthy volunteers. SZN-043 demonstrated acceptable safety and tolerability in all subjects, with evidence of target engagement, Wnt signal activation and effects on liver function. Enrollment is ongoing in the Phase 1b clinical trial in patients with severe alcohol-associated hepatitis. Cohort 1 in the Phase 1b trial completed enrollment in 6 patients with no drug related SAEs. There were no patient deaths at day 30 of the study and the company observed a potential clinical benefit based on reductions in bilirubin and MELD score. A majority of patients experienced improvements in AST and ALT levels. Proof-of-concept data is anticipated in the first half of 2025.

About SZN-413 for Retinal Diseases

SZN-413 is a bi-specific antibody targeting Fzd4-mediated Wnt signaling designed using Surrozen's SWAP™ technology. SZN-413 is being developed for the treatment of retinal vascular-associated diseases. Data generated by Surrozen with SZN-413 in preclinical models of retinopathy demonstrated that SZN-413 could potently stimulate Wnt signaling in the eye, induce normal retinal vessel regrowth, suppress pathological vessel growth and reduce vascular leakage. This novel approach could thus potentially allow for regeneration of healthy eye tissue, not only halting retinopathy, but possibly allowing for a full reversal of the patient's disease.

In the fourth quarter of 2022, Surrozen 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 received 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 \$587.0 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.

In September 2024, Surrozen announced that Boehringer Ingelheim will further develop SZN-413 to advance the compound and prepare it for clinical testing. The milestone achievement triggered a \$10 million payment to Surrozen as part of the agreement.

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 a current focus on severe liver and eye diseases. For more information, please visit www.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 (including anticipated clinical development plans and timelines, the availability of data, the potential for such product candidates to be used to

treat human disease, as well as the potential benefits of such product candidates), the Company's partnership with Boehringer Ingelheim, including the potential for future success-based development, regulatory, and commercial milestone payments, in addition to mid-single digit to low-double digit royalties on sales, and the potential of TGF- β to be a novel, first-in-class therapeutic to treat the pathology of Idiopathic Pulmonary Fibrosis. 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 and clinical trials with respect to its product candidates; the Company's ability to fund its preclinical and 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 its product candidates; the effects that arise from volatility in global economic, political, regulatory and market conditions; and all other factors discussed in Surrozen's Annual Report on Form 10-K for the year ended December 31, 2023 and Surrozen's Quarterly Report on Form 10-Q for the quarter ended September 30, 2024 to be filed with the Securities and Exchange Commission ("SEC") under the heading "Risk Factors," and other documents Surrozen has filed, or will file, with the SEC. 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 after the date of this press release. Accordingly, undue reliance should not be placed upon the forward-looking statements.

Investor and Media Contact:

Investorinfo@surrozen.com

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Collaboration and license revenue	\$ 10,000	\$ —	\$ 10,000	\$ —
Operating expenses:				
Research and development	5,200	6,112	15,782	21,135
General and administrative	3,568	3,572	11,165	12,209
Restructuring	—	1,505	—	2,712
Total operating expenses	8,768	11,189	26,947	36,056
Income (loss) from operations	1,232	(11,189)	(16,947)	(36,056)
Interest income	431	661	1,306	1,831
Other (expense) income, net	(3,097)	83	513	96
Loss on issuance of common stock, pre-funded warrants and warrants	—	—	(20,397)	—
Net loss	\$ (1,434)	\$ (10,445)	\$ (35,525)	\$ (34,129)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.44)	\$ (5.14)	\$ (12.57)	\$ (16.96)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	3,228	2,033	2,826	2,012

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

	September 30, 2024	December 31, 2023 ⁽¹⁾
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 31,012	\$ 36,043
Accounts receivable	12,196	2,152
Prepaid expenses and other current assets	2,078	2,937
Total current assets	45,286	41,132
Property and equipment, net	856	1,969
Operating lease right-of-use assets	817	1,889
Restricted cash	688	688
Other assets	351	402
Total assets	<u>\$ 47,998</u>	<u>\$ 46,080</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 276	\$ 525
Accrued and other liabilities	4,317	4,126
Lease liabilities, current portion	1,527	2,497
Total current liabilities	6,120	7,148
Lease liabilities, noncurrent portion	—	882
Warrant liabilities	36,211	115
Total liabilities	<u>42,331</u>	<u>8,145</u>
Stockholders' equity:		
Preferred stock	—	—
Common stock	—	—
Additional paid-in-capital	262,887	259,630
Accumulated deficit	(257,220)	(221,695)
Total stockholders' equity	5,667	37,935
Total liabilities and stockholders' equity	<u>\$ 47,998</u>	<u>\$ 46,080</u>

⁽¹⁾ Derived from the audited financial statements, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2023.

